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## Original Articles

# Effectiveness of Chiropractic and Physiotherapy in the Treatment of Low Back Pain: A Critical Discussion of the British Randomized Clinical Trial

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### ABSTRACT

This article discusses the methodology of a recently published British randomized clinical trial comparing chiropractic and physiotherapy as treatments for low back pain. The authors base their main conclusions on a difference shown by the Oswestry pain questionnaire 2 yr after randomization, when data of only 26% of the patients were available. This might have led to an overestimation, because it appears that the difference in Oswestry scores is much larger for patients included early in the study. It may also be doubted whether the magnitude of the effect reported really indicates a clinically significant difference between the interventions. In addition to allocated intervention, the groups also

differ in duration of treatment, number of sessions, level of experience of the therapist, and health care setting. The results are difficult to extrapolate, because only a small portion of the eligible patients participated, and chiropractic seems to be clearly superior only in the subgroup originally presenting to a chiropractic clinic. We conclude that it is premature to draw conclusions about the long-term effectiveness of chiropractic based on the results of this study alone. (*J Manipulative Physiol Ther* 1991; 14:281-286).

Key Indexing Terms: Chiropractic, Physiotherapy, Backache/Therapy, Outpatient Clinics, Hospital, Comparative Study, Random Allocation.

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### INTRODUCTION

The recent publication of a randomized clinical trial (RCT) in the *British Medical Journal* by Meade et al. (1) comparing chiropractic and physiotherapy as treatments for low back pain has drawn considerable media attention. The authors conclude that chiropractic, especially in the long term, is more effective than hospital outpatient treatment consisting of physiotherapy. They recommend consideration of the introduction of chiropractic into the British National Health Service. Many letters to the editor following the publication of the study illustrate that this point of view is not shared by everyone (2). For the chiropractic profession this

was the first large scale RCT supporting the effectiveness of chiropractic treatment (3) and its success was rapidly heralded (4). Surprisingly, the positive effect did not appear during the first 6 wk of therapy, but only much later, reaching its maximum after 2 yr follow-up. This contradicts the results of earlier studies on the effectiveness of manipulation, which tend to indicate a more rapid recovery of the manipulated patients compared to their controls, but no difference during long-term followup (5-7).

The *British Medical Journal* trial seems to be of great importance for the discussion about the effectiveness of chiropractic (8). Because of the potential impact of this RCT (9) we think a detailed methodological discussion is indicated.

### DISCUSSION

#### Design

The British trial included 741 patients aged 18-65 yr with low back pain of mechanical origin. A patient was excluded if a nerve root was clearly affected or if a contraindication for manipulation existed. Restricted

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straight leg raising on its own was not a reason for exclusion. Patients were recruited from 11 centers, each center consisting of a chiropractic clinic and a hospital outpatient physiotherapy department. Eligible patients were randomly allocated, irrespective of the type of care initially chosen by the patient. The choice of treatment was at the discretion of the allocated therapist. The physiotherapists used Maitland manipulation or mobilization for 72% of the patients and Cyriax manipulation for 12% of the patients. As expected, the chiropractors used high velocity, low amplitude manipulation for almost all (99%) of the patients. The physiotherapy departments used modalities and exercise therapy more often than the chiropractors did. Patients in the physiotherapy group received an average of 6.3 treatments compared to 9.1 for patients in the chiropractic group. For this last group the treatment period was considerably longer. After 6 wk, 79% of the physiotherapists had completed their treatment, compared to only 29% of the chiropractors.

The Oswestry back pain questionnaire (10, 11) was used as the principal outcome measure. This instrument consists of 10 sections. Each section covers a different aspect of back pain and contains six statements. The overall scores are expressed on a scale ranging from 0–100 percent-points. Straight leg raising and lumbar flexion were chosen as the most important subsidiary measures of outcome. The questionnaires were sent by post at weekly intervals during the first 6 wk of treatment, at 6 months, at 1 yr and at 2 yr after entry. The subsidiary outcome measures were recorded at 6 wk by the coordinating nurse, who was not blinded with respect to the allocated intervention.

### Most Important Results

After the feasibility study the authors decided to direct their attention primarily to the early treatment phase (12). In contrast with the expectation raised by this decision, Meade et al. were not able to detect a clear difference in Oswestry-score between the two treatments during the first 6 wk. After 6 months a difference in favor of chiropractic appeared, and maximized after 2 yr (according to the addendum to the *British Medical Journal* article, this difference remained even after 3 yr). At the start of the study Meade et al. hoped to detect at least a 2 percent-point difference (12), but after 2 and 3 yr they even found differences of 7.2 and 9.6 percent-points, respectively. Chiropractic appeared to be especially effective for patients with relatively intensive pain (a high Oswestry score) at the start of the study and for patients with recurrent episodes of back pain. Of the most important subsidiary outcome measures, significant differences in favor of chiropractic were found only for the straight leg raising of the right leg.

### Moment of Entry in the Study

The recommendation by Meade et al., to consider introduction of chiropractic in the National Health Service, is mainly based on the results after 2 yr. According to the authors they had a 72% response at that moment. Table 1 illustrates that after 2 yr 194 of the original 741 patients (only 26%) had returned their questionnaires. The *British Medical Journal* article offers no reason for this discrepancy. Personal communication with the author made clear that a large number of patients actually entered the trial less than 2 yr ago.

**TABLE 1. Difference in average Oswestry score in percent-points between physiotherapy patients (P) and chiropractic patients (C)**

|  | 6 wk                    | 6 months                             | 1 yr                               | 2 yr                                |
|--|-------------------------|--------------------------------------|------------------------------------|-------------------------------------|
| All patients with data (I)                             | 1.69<br>P = 309 C = 357 | 3.31 <sup>a</sup><br>P = 282 C = 325 | 2.09<br>P = 207 C = 247            | 7.16 <sup>b</sup><br>P = 90 C = 104 |
| Patients with data at all follow-up moments (II)       | 2.92<br>P = 83 C = 97   | 7.89 <sup>b</sup><br>P = 83 C = 97   | 6.69 <sup>b</sup><br>P = 83 C = 97 | 7.45 <sup>b</sup><br>P = 83 C = 97  |
| Patients with data but not all follow-up moments (III) | 1.23<br>P = 226 C = 260 | 1.37<br>P = 199 C = 228              | -0.93<br>P = 124 C = 150           | 3.43<br>P = 7 C = 7                 |

<sup>a</sup>  $p < 0.05$ .

<sup>b</sup>  $p < 0.01$ .

The scores of group III are calculated with the assumption that both groups (P and C) are of equal size. The calculated differences for group III could not be statistically tested.

Formula used for calculation of values for group III in Table 1:

$$OS_{III} = \frac{[OS_x \times (P_I + C_I)] - [OS_{II} \times (P_{II} + C_{II})]}{P_{III} + C_{III}}$$

Legend for the formula used for the calculation of values for group III in Table 1:

OS = difference in Oswestry-score at the particular moment of follow-up.

I, II and III are the groups as described in the text and Table 1.

P<sub>x</sub> = number of physiotherapy patients and C<sub>x</sub> = number of chiropractic patients, with x = I, II or III.

Therefore, the majority of the patients had not yet been able to complete the entire follow-up period, and in fact an interim analysis is presented in the *British Medical Journal* article. The 6 month follow-up was completed by all patients included in the study (minus 16% nonresponse). Using the authors' response figures, about 575 patients have had a follow-up of 1 yr, and only 270 patients have completed 2 yr (this is only about one-third of all the randomized patients). The decision to publish an interim analysis might bias the Oswestry scores collected after the publicity given to the positive results of chiropractic. We do not know which proportion of follow-up measurements this concerns, but when these data are substantially different from earlier responses, there is a serious interpretation problem.

In the data published in the *British Medical Journal* article a clear time effect can already be detected. The authors discern between all patients and patients starting the trial early by presenting figures 2A (Oswestry scores for all patients) and 2B (Oswestry scores for all patients who had been followed up for 2 yr). In their results paragraph they conclude that "the general pattern was similar . . ." for all patients (2A) and early starters (2B). It would have been much more illustrative if the authors had presented a figure 2C showing changes in Oswestry scores for patients who had not been followed up for 2 yr. Since no direct comparison between early and late starters is available, we will try to estimate values for this late group indirectly. The authors present the data of the subgroup that returned their questionnaires at all recorded follow-up moments in their table V (group II in our Table 1). From this table it is clear that the group on which data after 2 yr are available, and on which Meade et al. base their main conclusions (group I), is almost identical to this group II. From the data supplied by the authors the scores of another group (group III) can be estimated. Group III consists of all patients whose data for a particular follow-up moment were available, but who did not (yet) return all four follow-up questionnaires. Comparing group II (consisting of patients starting early in the trial) with group III (consisting mostly of patients starting later) shows that group II has a more favorable score for chiropractic than group III at 6 wk, 6 months and 1 yr.

It is difficult to guess the reasons for the diminishing difference in effectiveness between chiropractic and physiotherapy. It is possible that the chiropractors, through extra effort, gave a better treatment during the first year of the trial than in the subsequent years. Another explanation could be that the physiotherapy

departments had problems giving an optimal therapy in the beginning of the trial. This latter possibility is suggested by the authors in their discussion:

"The undoubted difficulties under which some of the physiotherapy departments were working during the trial almost certainly meant that they were unable to give all the specific treatments they would have wished to all patients" (1).

When this trend perseveres it is questionable whether the significant difference reported at 2 yr will remain demonstrable when data become available from the patients who were not yet able to participate in this follow-up measurement. It is possible that at this follow-up moment the same will happen as for the 1 yr follow-up, when group III (consisting mostly of late starters) almost completely erased the favorable effect for chiropractic.

#### Drop-outs

In a RCT with a long follow-up period and frequent measurements it is almost inevitable that some patients do not participate in all follow-up measurements. Especially during the later follow-up moments, nonresponse due to drop-out can be substantial. In the Meade study the percentages of nonresponders were 10% at 6 wk, 16% at 6 months, 21% at 1 yr, and 28% at 2 yr. Conclusions on the basis of data with a considerable drop-out rate should always be drawn with some caution. Because the motives of patients lost to follow-up are not explicitly described, there is the possibility of bias due to selective drop-out. For example, the assumption that drop-outs did not improve or even deteriorated with the assigned therapy would lead to an overestimation of the effectiveness of the therapy in the group with the greatest drop-out rate.

Table IV of the original article shows the inequality in drop-out rate between the chiropractic patients compared to the physiotherapy patients at 6 wks and 6 months (7.0% vs. 13.4% after 6 wk, and 15.4% vs. 21.0% after 6 months). If our assumption about the reasons for drop-out is correct, this would mean that the real difference between physiotherapy and chiropractic would be larger. The intention-to-treat analysis presented by Meade et al. only provide a correction for possible bias introduced by patients changing ( $n = 29$ ) or not completing ( $n = 134$ ) treatment. For an assessment of the influence on the results of missing data due to drop-out, other techniques should be used [e.g., a "worst-case" analysis (13)].

### Some Inaccuracies

In the article by Meade et al. (1) we found some additional flaws which might partly be responsible for their conclusions favoring chiropractic. When Meade et al. discuss the fact that one of the 11 physiotherapy departments was more effective than its clustered chiropractic clinic, they reason:

“This centre recruited many patients, mostly through open access arrangements, and omitting its results increased the apparent effectiveness of chiropractic in the other 10 centres” (1).

This does not seem to make much sense, because the exclusion of this center from analysis seems to be motivated by its therapeutic success.

To illustrate the practical meaning of differences in Oswestry scores, a table containing some examples is presented in the original article. For readers not familiar with the use of the Oswestry scale, this is the only help they have in determination of the clinical significance of the data (4, 14). It is pointed out that, for example, an overall difference of 6 percent-points could be the consequence of a difference of one position in the three most relevant sections (“pain”, “lifting” and “sitting”). This example assumes that there are no simultaneous differences for the other seven items. The original publication (9) clearly shows that the scores on all sections are closely associated, which means that this assumption is not justified at all. It is clear that a difference of a certain amount of percent points on the three sections “pain”, “lifting” and “sitting” will be associated with a much larger actual overall difference on all 10 items. This means that for a clinical improvement such as that described in the examples in the article, a much larger change in Oswestry score would be needed than is indicated. Therefore, adapting this information to a more valid use of the Oswestry scale will yield a more realistic interpretation of the differences in percent-points found in the study. Consequently, a less favorable impression of the effectiveness of chiropractic should have been given in the article. In our view the maximum difference of 7 percent-points is not very impressive.

### Interpretation

In the Meade study the actual treatments had no particular protocol. Only the maximal number of sessions was fixed in advance. The consequence was that once the authors had found a difference, it was impos-

sible to identify the responsible component: the type of manipulation (Cyriax/Maitland vs. chiropractic), the number of treatments (chiropractors giving 44% more treatments), the length of treatment (much longer for chiropractors), levels of experience in manipulation (chiropractors having 4–5 yr of training in manipulation, while the duration of the physiotherapists’ training in manipulation varies widely), or practice characteristics (nationalized outpatient physiotherapy vs. private chiropractic clinics). Most of the reactions in the letters to the editor were directed at this interpretation problem (2). Although *The Chiropractic Report* states that the length of time under care and the frequency of treatment certainly played a role in the success of chiropractic in this trial (4), the authors of several letters to the editor correctly posed the question whether chiropractic would still be superior if practice characteristics, workload, duration and frequency of treatment would have been comparable in both groups. Only then the unique qualities of the chiropractor [personal attention, proper diagnosis and skills in manipulation (15)] would have been tested.

The second problem in the interpretation of the results is the possible interference of co-interventions. Some of the patients, especially after having finished the assigned treatment, will probably seek and receive other treatments besides physiotherapy and chiropractic, for instance medication, injections, acupuncture or an operation. For studies with a long follow-up period this can be a serious problem, which is difficult to avoid. Meade et al. (1) only present data on the patients receiving “any further treatment” (not specified) and on the patients that continued the assigned chiropractic or physiotherapy treatment during the second year of follow-up. In addition, the proportion of the patients using drugs was recorded. Co-interventions may have a considerable influence on the long-term outcome. Therefore, all treatments received by the patients during the follow-up period should have been described explicitly. Contamination (physiotherapy patients later switching to the chiropractor and vice-versa) and other interventions are not described at all. Therefore, the reader is not able to determine whether the long-term effects might be biased by co-interventions.

### Generalizability

In evaluating the results of an RCT, the external validity or generalizability is important. Are patients in the study sufficiently similar to the population of back pain patients that the authors address in their conclusions? Or, for the practitioner: are the patients in the

trial sufficiently similar to the patients he usually treats or refers? Two of the 11 centers kept records of all patients presenting with back pain. Of the 751 patients initially presenting at the hospital only 108 (14%) entered the trial. Of the 543 patients presenting at the chiropractic clinic 67 (12%) entered the trial. The reasons for nonparticipation turned out to be very different for these two groups. The exclusion criteria involved contraindications for manipulation, but also factors only relevant to study purposes (e.g., litigation pending). A large proportion of the patients fell in the not specified category "other reasons for ineligibility." After application of the exclusion criteria to the patients presenting at these two different types of health care facilities, a smaller percentage of the hospital patients (18%) than chiropractic patients (44%) remained. It was striking that a large proportion of the eligible chiropractic patients refused to enter the trial, because they did not want to take the risk of being randomly allocated to the physiotherapy group. The nonparticipation of this group, very likely to have high expectations of the effectiveness of chiropractic, could have led to an underestimation of the effectiveness of chiropractic.

Even for patients who did participate in the study, the original preference for one of the interventions probably continued to play a role, as is illustrated in the article, which shows in a table that at follow-up measurements at 6 wk, 6 months and 1 yr only the patients who originally sought treatment at a chiropractic clinic ("chiropractic referrals") reported a better result for chiropractic. For the group originally attending the hospital ("hospital referrals") there appeared to be no difference in the effectiveness of chiropractic and physiotherapy. In their discussion paragraph Meade et al. (1) describe this as follows:

"The fact that chiropractic treatment tended to be more effective in those initially presenting to the chiropractors than in those presenting to the hospital raises the possibility that the self-assessment by the patients who presented to the chiropractors may have been influenced by their expectations that chiropractic would be effective" (1).

The authors present some possible explanations for this phenomenon, but fail to provide some form of statistical adjustment for the different distributions of the variables involved. So, if one is prepared to conclude that chiropractic is more effective than physiotherapy, one should add that this only seems to be the case for

patients seeking chiropractic treatment at their own initiative.

## CONCLUSION

Planning and conducting an RCT with therapies for low back pain is extraordinarily difficult. The study by Meade et al. constitutes a tremendous achievement, which in the chiropractic profession has been hailed by some as the obvious or even final evidence for the effectiveness of chiropractic (4). Most of the data does indeed indicate a greater effectiveness of chiropractic compared to physiotherapy. However, we think that definite conclusions can only be drawn when all randomized patients have completed their 2 yr follow-up period. Even then, the remarkably large difference between the "early starters" (group II) and "late starters" (group III) will probably remain. A detailed analysis of this phenomenon is certainly indicated for a proper interpretation of the data. More studies, with a more explicit treatment protocol, are needed before definite conclusions can be drawn. This need was also expressed in an editorial in the *Lancet*:

"The very strong results this trial has produced needs to be confirmed by other studies, which should attempt to dissect the causes of the observations" (14).

Fortunately, the chiropractic colleges currently have many RCTs which are at the planning stage, in execution, or even nearly finished (16). We are looking forward to the results of these studies. For the members of the chiropractic profession who are interested in scientific proof of the benefits of chiropractic treatment, exciting times lie ahead.

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