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# Does the UK BEAM trial really support the use of manipulation?

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Francisco M. Kovacs,[1] Pablo Lázaro,[2] Alfonso Muriel,[3] Víctor Abraira,[3] Javier Zamora,[3] Carmen Fernández,[4] Ignacio Méndez,[2] José Luis Martín,[5] Francisco Martínez,[6] Luis González Luján,[7] Sergio Luna,[8] and Bartolomé Leal,[8] for the Spanish Back Pain Research Network.

[1]: Departamento Científico. Fundación Kovacs. Palma de Mallorca. Spain.
[2]: Técnicas Avanzadas de Investigación en Servicios de Salud (TAISS), Madrid. Spain.
[3]: Unidad de Bioestadística Clínica. Hospital Ramón y Cajal. Madrid. Spain.
[4]: Centro de Salud de Valldargent, Palma de Mallorca, Spain.
[5]: Servicio de Medicina Preventiva, Hospital de Rehabilitación y Traumatología Virgen de las Nieves, Granada, Spain.
[6]: Centro de Salud de Bembibre, Area de Salud del Bierzo, León, Spain.
[7]: Centro de Salud de Serrería II, Valencia, Spain.
[8]: Centro de Salud de La Codosera, Badajoz, Spain.

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An interesting pragmatic clinical trial in patients with low back pain[1] concludes that spinal manipulation achieves better results at 3 and 12 months than general practitioner care, including advice to continue normal daily activities and to avoid rest. Spinal manipulation appears to be also superior to a light exercise programme with group classes incorporating cognitive behavioural principles. A total of 1,334 patients participated in the study, which involved 181 general practices and 63 community settings for physical treatment around 14 centres in the UK. Despite the impressive huge of data and the rigorous study design, planning and execution, we believe that the conclusions are not properly supported by the results obtained. There are two important shortcomings that may jeopardise the findings presented.

Firstly, losses to follow-up in the different study groups varied between 22 and 31%. However, neither a sensitivity analysis was performed nor the potential effect of this problem in the interpretation of results is discussed.

Secondly, the size of the observed differences amongst groups is irrelevant from a clinical point of view. Disability, measured by the Roland Morris questionnaire, was the main outcome of the trial. The sample size was calculated to detect intergroup differences of 2.5 points on that scale. This is the lowest cut-point for a clinically relevant effect,[2] although 3 or 4 points are considered the optimal thresholds.[3,4] Actual differences in favour of manipulation as compared to general practitioner care were only 1.6 and 1.0 points at 3 and 12 months, respectively. Therefore, relevant differences as claimed in the paper were in fact non-existent. This important consideration is apparently unnoticed in the discussion.

Since differences in effectiveness are actually irrelevant, cost/effectiveness benefits of spinal manipulation, as shown in the accompanying paper,[5] are attributable to cost reduction. The study design prevents to assess whether cost reduction and minimal differences in effectiveness are due to a potential biological effect of manipulation itself, which seems unlikely,[6] or to the influence of other factors.[7] These may well include acceptance by patients of the approach and explanations given by spinal manipulators, physical contact with the therapist or the longer time of individualised care in the manipulation group, as compared to a standard general practitioner consultation or a group exercise class.

Losses to follow-up and the lack of a sensitivity analysis of the effect of this confounder on the results make it difficult to draw unequivocal conclusions. On the other hand, although validity of results would have been assumed, a fair interpretation of the findings could be that the three treatment modalities achieve similar clinical results, in spite of longer time of individualised care in the spinal manipulation group, the fact that patients could not be blinded to treatment assigned and that no attempt was made to mask the assessment of patients' evolution or the statistical analysis of data.

In our opinion, the results of this study do not support the use of spinal manipulation in the routine treatment of patients with low back pain and certainly do not suggest either the convenience of implanting spinal manipulation in the different National Health Services in which, such in the case of our country, this therapeutic strategy is not currently being offered.

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