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ORIGINAL ARTICLE

Independent evaluation of a clinical prediction rule for spinal manipulative therapy: a randomised controlled trial

Mark J. Hancock · Christopher G. Maher · Jane Latimer · Robert D. Herbert · James H. McAuley

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Abstract A clinical prediction rule to identify patients most likely to respond to spinal manipulation has been published and widely cited but requires further testing for external validity. We performed a pre-planned secondary analysis of a randomised controlled trial investigating the efficacy of spinal manipulative therapy in 239 patients presenting to general practice clinics for acute, non-specific, low back pain. Patients were randomised to receive spinal manipulative therapy or placebo 2 to 3 times per week for up to 4 weeks. All patients received general practitioner care (advice and paracetamol). Outcomes were pain and disability measured at 1, 2, 4 and 12 weeks. Status on the clinical prediction rule was measured at baseline. The clinical prediction rule performed no better than chance in identifying patients with acute, non-specific low back pain most likely to respond to spinal manipulative therapy (pain $P = 0.805$, disability $P = 0.600$). At 1-week follow-up, the mean difference in effect of spinal manipulative therapy compared to placebo in patients who were rule positive rather than rule negative was 0.3 points less on a 10-point pain scale (95% CI −0.8 to 1.4). The clinical prediction rule proposed by Childs et al. did not generalise to patients presenting to primary care with acute low back pain who received a course of spinal manipulative therapy.

Keywords Low back pain · Spinal manipulative therapy · Subgroup analysis

Introduction

One use of clinical prediction rules is to identify patients who are most likely to respond to particular treatments. This is important when substantially different outcomes could be expected in a heterogeneous group of patients [2]. Low back pain is considered by many researchers and clinicians to be a heterogeneous condition [19] and this is a possible reason why many interventions have only small effects [9]. Spinal manipulative therapy (SMT) is recommended in most international guidelines for the management of acute low back pain [20]. Recent systematic reviews have concluded that SMT produces small improvements in patients with non-specific low back pain [1]. Some authors believe these conclusions may underestimate the true benefit of SMT in certain patients with non-specific low back pain [11].

Recently, a clinical prediction rule was derived in an uncontrolled trial to identify patients with low back pain who respond best to SMT [10]. The same group of authors then evaluated the rule in a randomised controlled trial [7] and found similar results. The effect of SMT compared to control was greater in patients positive on the rule than for patients negative on the rule. The study by Childs et al. [7] has been highly cited and is the basis of many arguments to use SMT in patients with low back pain and as an example of the importance of clinical prediction rules more generally [2, 6]. However, as we were unaware of any

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M. J. Hancock (✉) · C. G. Maher · J. Latimer · R. D. Herbert · J. H. McAuley
Back Pain Research Group, Faculty of Health Sciences, University of Sydney, PO Box 170, Lidcombe, NSW 1825, Australia
e-mail: M.Hancock@usyd.edu.au

C. G. Maher · J. Latimer · R. D. Herbert · J. H. McAuley
Musculoskeletal Division, The George Institute for International Health, 341 George St, Sydney, NSW 2000, Australia

plausible biological rationale to explain why the rule should identify patients who respond to SMT and the rule has not been independently evaluated by other authors, or shown to generalise in other settings, we believed it required further evaluation before widespread acceptance of its use. The methodology literature on the development of clinical prediction rules, reports that the external validity of rules must be tested in different settings, with different patients and a range of clinicians before the generalisability of the rule can be established [2, 22, 24].

The treatment used to both derive and validate the clinical prediction rule involved a single, non-specific manipulation on all patients regardless of presentation. This approach to treatment is not typical of current clinical practice where a course of spinal manipulative therapy is usually provided and adjusted according to the patient's clinical presentation [17, 21, 26, 29]. We were, therefore, interested to see if the clinical prediction rule would generalise when spinal manipulation was delivered in a manner that was more representative of current clinical practice. An additional limitation to the generalisability of the clinical prediction rule [7] is that it was tested in participants recruited primarily from US Air Force facilities. We wanted to test if the rule generalised to a typical primary care population.

The aim of this study was, therefore, to independently evaluate if a recently proposed clinical prediction rule [7] would generalise to a different setting, in a new group of patients receiving SMT as practised by many physiotherapists. The study involved a pre-planned analysis of data from a placebo-controlled trial of SMT conducted on patients with acute low back pain presenting to primary care.

Materials and methods

Design overview

The data for this paper comes from a factorial trial evaluating the effectiveness of SMT and/or diclofenac (a non-steroidal anti-inflammatory drug) for patients with acute low back pain. The full details of the trial have been published previously [15, 16]. Neither SMT nor diclofenac, or both combined, was found to significantly reduce time to recovery from pain in patients receiving baseline care of advice and regular paracetamol [15].

Setting and participants

All patients presenting with low back pain of less than 6 weeks duration to one of 40 general practitioners working in primary practice across Sydney (Australia) were invited to participate in the study. The inclusion criterion was a primary complaint of pain in the area between the 12th rib and buttock crease causing moderate pain and moderate disability (measured by adaptations of items 7 and 8 of the SF-36). Exclusion criteria were: current episode not preceded by a pain-free period of at least 1 month in which no care was provided; known or suspected serious spinal pathology; nerve root compromise; currently receiving non-steroidal anti-inflammatory drugs or SMT; surgery within the preceding 6 months; contraindication to paracetamol, diclofenac or SMT.

Recruitment and baseline care

All patients received general practitioner advice (to remain active and avoid bed rest, and reassurance of a favourable prognosis) and were supplied with paracetamol to be taken 1 g 4× daily. Patients were asked to continue taking paracetamol until recovery (defined as 0 or 1 pain score for seven consecutive days) up to a maximum of 4 weeks. A researcher then met with the patient within 2 days (excluding Sundays) to collect baseline data and randomise the patient to a treatment arm. A follow-up visit, 1 week after the initial visit, was scheduled with the patient's general practitioner to monitor recovery. A further follow-up visit was scheduled if the general practitioner believed it necessary.

Randomisation and interventions

A statistician not involved in data collection or analysis developed a randomisation schedule and produced 240 consecutively numbered, sealed opaque envelopes containing each participant's allocation. Randomisation was performed using randomly permuted blocks of 4, 8 and 12. Immediately after collecting baseline data, the blinded researcher opened the randomisation envelope and supplied the patient with a bottle containing diclofenac (active or placebo). Active and placebo bottles were identically labelled. The randomisation envelope also contained a second envelope with the participant's allocation to active or placebo SMT. This envelope was given to the treating physiotherapist to open after the blinded researcher had left. Therefore, all participants were allocated to one of four groups as follows:

- Placebo SMT and placebo diclofenac group
- Placebo SMT and active diclofenac group
- Active SMT and placebo diclofenac group
- Active SMT and active diclofenac group

For the purposes of this report, both the placebo SMT groups will be considered the control group and both the active SMT groups will be considered the SMT group.

Status on clinical prediction rule

Each participant's status on the clinical prediction rule was determined using identical criteria to those originally proposed by Childs et al. [7]. Participants who met four or more of the five criteria were classified as positive on the clinical prediction rule (Table 1). A researcher blinded to the patients' treatment group collected data on two of the five clinical prediction rule criteria (Fear Avoidance Beliefs Questionnaire-work subscale [28] and duration of current episode) during the baseline assessment. The treating physiotherapist collected data on the other three criteria (extent of distal symptoms, segmental hypomobility, and hip internal rotation range of motion) during the initial assessment. The physiotherapists were given copies of the descriptions provided by the developers of the rule [7] to help rate these three criteria. One of the researchers met with all physiotherapists prior to their participation in the trial to discuss implementation of the trial protocol and ensure adequate assessment of the criteria.

Intervention

SMT was delivered by 15 physiotherapists, in 13 private clinics across Sydney, who had, as a minimum, university-based post-graduate training in manipulative therapy and who regularly used manipulative therapy in their clinical practice. Participants allocated to receive SMT, received treatment 2 or 3× per week (at the therapist's discretion) for a maximum of 12 treatments over 4 weeks. If the subject recovered before 4 weeks, the SMT was stopped. Patients received SMT according to a treatment algorithm (Appendix 1) developed by the researchers based on the views of expert clinicians and researchers in the field [12, 18, 21]. The algorithm permitted the use of low and/or high velocity procedures that aimed to produce motion at the joints of the lumbar spine, thoracic spine, sacroiliac joint, pelvis and hip, and involved forces generated by the therapist. Consistent with contemporary clinical practice, the therapist adjusted the treatment to the clinical presentation [17, 21, 26, 29] of the patient rather than applying the same treatment to all patients. A review of patient records revealed that most participants received a variety of low velocity techniques (97%) with a small proportion also receiving high velocity thrust techniques (5%). A full description of the SMT protocol has been previously published [16].

The placebo therapy used was detuned pulsed ultrasound. The sham ultrasound aimed to match the treatment duration and patient/therapist contact with active SMT. Active and placebo SMT sessions were matched in time (30–40 min for the initial session and approximately 20 min for follow-up sessions) [14].

Table 1 Criteria for clinical prediction rule

Criterion	Definition of positive
Duration of current episode	<16 days
Extent of distal symptoms	No symptoms distal to the knee
FABQ work subscale score	<19 points
Segmental mobility	≥1 hypomobile segment in the lumbar spine
Hip internal rotation range of motion	≥1 hip with >35° of internal rotation range of motion

Participants who met ≥4 positive criteria were classified as positive on the clinical prediction rule

Outcomes and follow-up

Pain was measured using an 11-point scale (0 = no pain, 10 = worst possible pain). Disability was measured using the 24-point Roland Morris disability questionnaire [25] (RMDQ, 0 = low disability and 24 = high disability). Pain and disability were recorded at 1 2, 4 and 12 weeks.

Statistical analysis

All data were double entered and analysed by intention to treat. To assess the primary question of whether the clinical prediction rule identifies patients who respond to SMT, we performed 3-way (treatment group × time × prediction rule status) repeated measures analysis of variance (ANOVA), as this was the method of analysis used by Childs et al. [7]. A P value of <0.05 for the 3-way interaction was required to support the validity of the clinical prediction rule. Treatment group (SMT vs. placebo) and status on the clinical prediction rule (positive or negative) were between-patient factors and time (baseline, 1, 2, 4 and 12 weeks) was a within-patient factor. Separate ANOVAs were performed for pain and disability.

In the secondary analysis, to describe the effect of the clinical prediction rule, we used the regression coefficients from linear regression. We developed separate models for the dependent variables of pain and disability at each time point. The independent variables were treatment group, prediction rule status, the interaction between treatment group and prediction rule status, and the baseline score for the dependent variable. The size of the interaction coefficient represents the additional benefit of SMT (compared to placebo) in the rule positive group (compared to the rule negative group). All analyses were performed using SPSS for Windows version 14.0 (SPSS Inc., Chicago, IL).

Results

Participant flow and follow up

Two hundred and forty patients were recruited by 19 general practitioners from 14 practices between June 2005 and October 2006 (Fig. 1). The practices were located across a full range of socio-economic areas, reflecting an urban population. One participant was excluded after randomisation but prior to receiving treatment when both the physiotherapist and the referring general practitioner became concerned that the patient might have a serious pathology as the source of the low back pain. An experienced clinical researcher, who was not involved in the trial and was unaware of the participant's allocation, reviewed the case and recommended the subject be withdrawn from the trial and referred to a specialist for further examination. Full data on at least 98% of the patients was available for all follow-up time points (1, 2, 4 and 12 weeks) for both change in pain and change in disability.

Baseline data

The baseline demographic and clinical characteristics of the patients are presented in Table 2. Participants had high levels of baseline pain, moderate disability, and low levels of fear avoidance. Differences in baseline pain and disability scores between the SMT group and the placebo group were small and statistically non-significant.

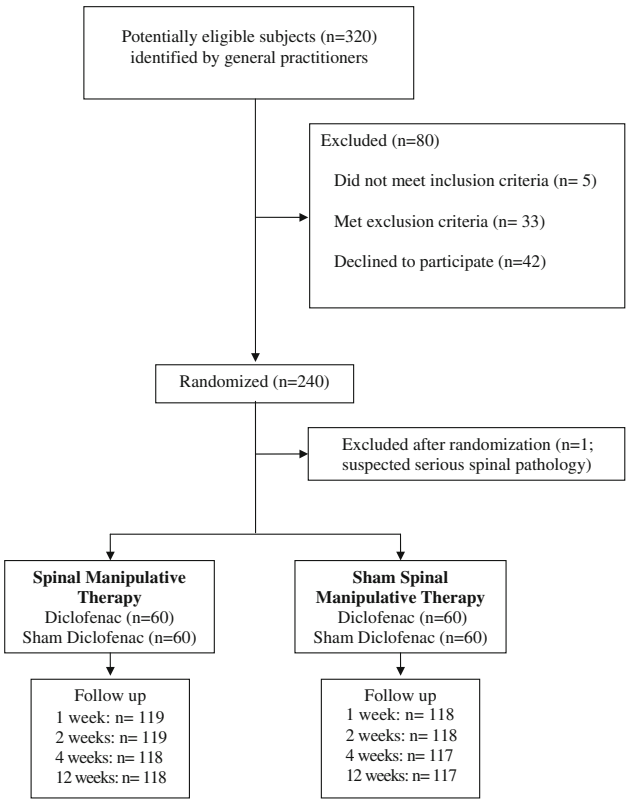

Fig. 1 Flow chart of subject progress through the study

In the primary analysis, the 3-way interaction term (group × clinical prediction rule status × time) from the repeated measures ANOVA was not statistically significant for either pain ($P = 0.805$) or disability ($P = 0.600$) (Fig. 2).

Secondary analyses did not find statistically significant or clinically worthwhile interaction effects between treatment group and status on the prediction rule for either pain or disability at any time point (Table 3). Positive status on the rule tended to predict better prognosis regardless of treatment received and this was statistically significant for pain at 2 weeks and disability at 2 and 12 weeks.

Discussion

The first independent evaluation of the clinical prediction rule recently proposed by Childs et al. [7] found that the rule did not generalise to patients with acute low back pain referred from primary care for SMT as practised by many physiotherapists. The rule did not identify those patients who were more likely to respond to SMT. This was the case regardless of whether the effect was measured as pain or disability or at 1, 2, 4 or 12 weeks. The effect of SMT compared to placebo was not greater in patients who were rule positive than in patients who were rule negative. Our study provided precise estimates of the interaction effect and we are confident that we have not missed a clinically worthwhile interaction effect.

There are a number of possible reasons for the lack of agreement between this study and that of Childs. The disagreement may be due to differences between the studies including the application of the SMT, the setting and the patients, suggesting that the rule does not generalise. Another explanation for the disagreement is that subgroup analyses within trials are notorious for generating spurious results [5, 23]. In the absence of a plausible rationale, and as the rule is based upon the results of a single randomised controlled trial, the original positive result may simply be a type I error.

The SMT delivered in our trial was not the same as that delivered in the earlier study [7]. In the Childs et al. study [7], the intervention was a single high velocity thrust delivered on two separate occasions. Our intervention was reflective of contemporary clinical practice and involved a course of treatment individually selected by the therapist based on the patient's presentation [17, 21, 26, 29]. In the majority of cases, this included a variety of low-speed mobilisation techniques, with high-velocity thrusts used in a minority of cases (5%). The SMT prediction rule appears

Table 2 Baseline characteristics of participants

Characteristic	SMT ($n = 119$)	Placebo SMT ($n = 120$)	All subjects
Age	41.4 (15.4)	40.0 (15.9)	40.7 (15.6)
Sex *n* (% female)	55, 46%	50, 42%	105, 44%
Duration of current symptoms (days)	9.0 (9.6)	9.2 (9.0)	9.13 (9.31)
Previous episodes	4.3 (7.6)	3.0 (4.9)	3.7 (6.4)
Disability[a]	13.8 (5.0)	12.5 (5.6)	13.1 (5.4)
Function[b]	3.8 (1.6)	4.0 (1.9)	3.9 (1.8)
Pain[c]	6.7 (1.6)	6.3 (1.8)	6.5 (1.7)
PRSS-coping[d]	3.5 (0.8)	3.7 (0.8)	3.56 (0.78)
PRSS-catastrophising[e]	1.8 (0.9)	1.9 (1.0)	1.85 (0.94)
FABQ-work subscale[f]	14.7 (10.5)	14.3 (10.3)	14.5 (10.4)
FABQ-activity subscale[g]	17.2 (5.0)	16.7 (5.7)	17.0 (5.4)
Clinical prediction rule positive *n* (%)	69, 58%	72, 60%	141, 59%
Criterion 1 positive n (%)[h]	98, 82%	97, 81%	195, 82%
Criterion 2 positive n (%)[i]	107, 90%	106, 88%	213, 89%
Criterion 3 positive n (%)[j]	77, 65%	82, 68%	159, 66%
Criterion 4 positive n (%)[k]	100, 84%	94, 78%	194, 81%
Criterion 5 positive n (%)[l]	57, 48%	53, 44%	110, 46%
3 or more of 5 criteria positive	109, 92%	104, 87%	213, 90%
5 of 5 criteria positive	23, 19%	22, 18%	45, 19%

Values other than % are means (SD)

SMT spinal manipulative therapy

[a] RMDQ: Roland Morris disability questionnaire—0 (no disability) to 24 (high disability)

[b] PSFS: Patient specific functional scale—0 (unable to perform activity) to 10 (able to perform activity at pre-injury level)

[c] NPRS: Numerical pain rating scale—0 (no pain) to 10 (worst pain possible)

[d] PRSS-coping: Pain-related self statement scale-coping—0 (poor coping strategies) to 5 (strong coping strategies)

[e] PRSS-catastrophising: Pain-related self statement scale-catastrophising—0 (low catastrophising) to 5 (high catastrophising)

[f] FABQ-work: Fear avoidance beliefs questionnaire-work—0 (no fear avoidance beliefs) to 42 (high fear avoidance beliefs)

[g] FABQ-physical activity: Fear avoidance beliefs questionnaire-physical activity—0 (no fear avoidance beliefs) to 24 (high fear avoidance beliefs)

[h] Criterion 1: Duration of current episode <16 days

[i] Criterion 2: No symptoms distal to the knee

[j] Criterion 3: FABQ work subscale score <19 points

[k] Criterion 4: ≥1 hypomobile segment in the lumbar spine

[l] Criterion 5: ≥1 hip with >35° of internal rotation range of motion

not to generalise to SMT as widely practised by physiotherapists, limiting its usefulness in clinical practice. In clinical practice, SMT is delivered by different professionals using a range of techniques and the prediction rule needs to be shown to generalise before it should be used to guide clinical decision-making regarding the delivery of SMT. It is possible that the rule is useful for the high-velocity manipulation technique used in the Childs study; however, this needs to be demonstrated in a new setting with different patients and clinicians before being recommended for clinical practice.

Participants in the original [7] study primarily attended US Air force facilities while our patients were seeking care from general (medical) practice clinics in Sydney (Australia). The inclusion and exclusion criteria in both studies were quite similar, but the current study included only patients with acute low back pain (less than 6 weeks) while the original [7] study did not stipulate the duration of the current episode. The median duration of symptoms in the original [7] study was 27 days compared to 5 days in our study. SMT is recommended in international back pain guidelines for patients with acute low back pain and as such it is important that the rule generalises to patients such as those in our trial with acute low back pain presenting to primary care.

A difference between the original [7] trial and our trial is that the original trial found modest and statistically significant effects of SMT (vs. no treatment), whereas we

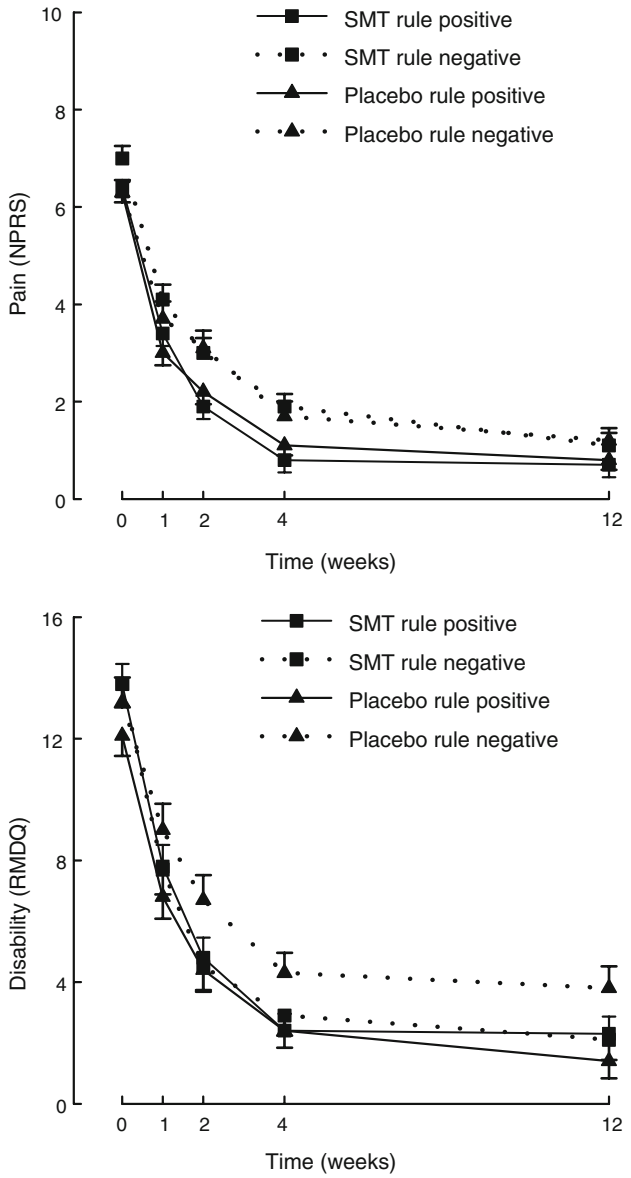

Fig. 2 Graphical representation of the role of treatment group, rule status and time on outcomes of pain and disability. *Error bars* represent standard errors. *RMDQ* Roland Morris disability questionnaire

found small and statistically non-significant effects of SMT (vs. placebo) at most time points (Table 3). A possible reason for this is that, in our trial, all patients received widely recommended first line care of advice and paracetamol while in the original [7] study, all patients received exercise which is generally not recommended for acute low back pain [27]. When the main effect of an intervention is small, it is potentially harder to identify worthwhile subgroups [4]. However, there is reason to believe that the lack of main effect of SMT in our trial does not explain why we did not find the clinical prediction rule useful: we found modest and statistically significant effects of SMT on 2-week disability scores, and yet, this is precisely the outcome for which the clinical prediction rule was least useful (Table 2). It is, therefore, unlikely that the overall favourable prognosis and lack of main effect of SMT in our trial is hiding the true value of the clinical prediction rule.

We found that rule status predicted small, statistically significant effects on change in pain and disability at 2 weeks and change in disability at 12 weeks (Table 3). This implies that patients who were positive on the rule tended to improve more quickly regardless of treatment but does not imply that the rule predicts response to SMT. This is not a surprising result as three of the five criteria contributing to the rule (shorter duration of symptoms, pain not extending past the knee, and low fear avoidance scores) have been previously suggested to be associated with a favourable prognosis [3, 8, 13, 28].

Methodological quality is another factor that may explain the different results. Loss to follow-up in the current study was less than 2% at all time points while in the original [7] study, loss to follow-up was up to 30% in the primary analysis and different between groups. Assessors in our trial were blinded to treatment allocation and status on the clinical prediction rule while in the original [7] study they were only blinded to clinical prediction rule status. Patients in the original [7] study were not blinded to treatment allocation while in our study they were. These differences may produce an inflated main effect of SMT in the original study but should not directly influence the efficacy of the clinical prediction rule.

We wanted to ensure that the results of our study would not change if a different cut-off was used for the number of criteria required to be classified as positive on the rule. Therefore, we performed post-hoc sensitivity analyses to assess the validity of the rule when a stricter cut-off criterion (five of five) or a looser cut-off criterion (three of five) was used. In both cases, the primary test of the clinical prediction rule remained statistically non-significant for all outcomes.

The results of this trial have important implications for the development and implementation of any clinical prediction rule. Several authors have previously published a hierarchy for the development of clinical prediction rules [2, 22, 24]. The original [7] study represents a stage 2 or narrow validation of a previously developed rule [2, 22]. Our paper represents a stage 3 or broad validation where the rule is tested in varied settings with a wide range of patients and clinicians [2, 22]. When tested in different settings and in different patients, clinical prediction rules typically do not perform as well, and therefore, this is an essential step before the validity of the rule in a variety of settings can be established.

We conducted the first independent evaluation of the clinical prediction rule recently proposed by Childs et al. [7] for identifying patients with low back pain more likely

Table 3 Secondary outcomes, influence of manipulation, clinical prediction rule and interaction on pain and disability

	Pain	*P* value	Disability (RMDQ)	*P* value
1 week				
SMT	0.013 (−0.826 to 0.852)	0.976	−1.753 (−3.853 to 0.348)	0.102
Rule status	−0.693 (−1.462 to 0.076)	0.077	−1.802 (−3.749 to 0.144)	0.069
SMT × rule status	0.308 (−0.781 to 1.396)	0.578	1.763 (−0.970 to 4.496)	0.205
2 weeks				
SMT	−0.455 (−1.330 to 0.420)	0.306	−2.669 (−4.782 to −0.556)	0.014
Rule status	−0.995 (−1.796 to −0.193)	0.015	−2.139 (−4.101 to −0.178)	0.033
SMT × rule status	0.114 (−1.021 to 1.248)	0.843	2.378 (−0.381 to 5.136)	0.091
4 weeks				
SMT	−0.113 (−0.823 to 0.597)	0.754	−1.501 (−3.307 to 0.306)	0.103
Rule status	−0.540 (−1.191 to 0.110)	0.103	−1.625 (−3.301 to 0.052)	0.057
SMT × rule status	−0.215 (−1.135 to 0.705)	0.645	1.081 (−1.268 to 3.431)	0.366
12 weeks				
SMT	−0.208 (−0.969 to 0.554)	0.592	−1.751 (−3.622 to 0.120)	0.066
Rule status	−0.367 (−1.066 to 0.333)	0.303	−2.164 (−3.901 to −0.428)	0.015
SMT × rule status	0.051 (−0.934 to 1.036)	0.919	2.314 (−0.120 to 4.747)	0.062

Results of linear regression models for pain and disability. For both pain and disability, *negative* values represent *improved* outcomes. Results regarding the ability of the prediction rule to identify patients who respond most to SMT are presented in the line *SMT × rule status*

RMDQ Roland Morris disability questionnaire, *SMT* spinal manipulative therapy

to respond to SMT. In patients referred from primary care for a course of SMT delivered by physiotherapists, the rule did not discriminate between those who do and do not respond to SMT.

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References

1. Assendelft WJJ, Morton SC, Yu EI, Suttorp MJ, Shekelle PG (2004) Spinal manipulative therapy for low back pain. Cochrane Database Syst Rev CD000447
2. Beattie P, Nelson R (2006) Clinical prediction rules: what are they and what do they tell us? Aust J Physiother 52:157–163
3. Bekkering GE, Hendriks HJM, van Tulder MW, Knol DL, Simmonds MJ, Oostendorp RAB et al (2005) Prognostic factors for low back pain in patients referred for physiotherapy: comparing outcomes and varying modeling techniques. Spine 30:1881–1886
4. Brookes ST, Whitely E, Egger M, Smith GD, Mulheran PA, Peters TJ (2004) Subgroup analyses in randomized trials: risks of subgroup-specific analyses; power and sample size for the interaction test. J Clin Epidemiol 57:229–236
5. Brookes ST, Whitley E, Peters TJ, Mulheran PA, Egger M, Davey Smith G (2001) Subgroup analyses in randomised controlled trials: quantifying the risks of false-positives and false-negatives. Health Technol Assess 5:1–56
6. Childs JD, Cleland JA (2006) Development and application of clinical prediction rules to improve decision making in physical therapist practice. Phys Ther 86:122–131
7. Childs JD, Fritz JM, Flynn TW, Irrgang JJ, Johnson KK, Majkowski GR et al (2004) A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. Ann Intern Med 141:920–928
8. Croft PR, Dunn KM, Raspe H (2006) Course and prognosis of back pain in primary care: the epidemiological perspective. Pain 122:1–3
9. Deyo RA (2004) Treatments for back pain: can we get past trivial effects? Ann Intern Med 141:957–958
10. Flynn T, Fritz J, Whitman J, Wainner R, Magel J, Rendeiro D et al (2002) A clinical prediction rule for classifying patients with low back pain who demonstrate short-term improvement with spinal manipulation. Spine 27:2835–2843
11. Fritz JM, Delitto A, Erhard RE (2003) Comparison of classification-based physical therapy with therapy based on clinical practice guidelines for patients with acute low back pain: a randomized clinical trial. Spine 28:1363–1371
12. Grieve G (1984) Mobilisation of the spine. Notes on examination, assessment and clinical method, 4th edn. Churchill Livingston, Edinburgh
13. Grotle M, Brox JI, Veierod MB, Glomsrod B, Lonn JH, Vollestad NK (2005) Clinical course and prognostic factors in acute low back pain: patients consulting primary care for the first time. Spine 30:976–982
14. Hancock MJ, Maher CG, Latimer J, McAuley JH (2006) Selecting an appropriate placebo for a trial of spinal manipulative therapy. Aust J Physiother 52:135–138
15. Hancock MJ, Maher CG, Latimer J, McLachlan AJ, Cooper CW, Day RO et al (2007) Addition of diclofenac and/or manipulation to advice and paracetamol does not speed recovery from acute low back pain: a randomised controlled trial. Lancet 370:1638–1643
16. Hancock MJ, Maher CG, Latimer J, McLachlan AJ, Cooper CW, Day RO et al (2005) Manipulative therapy and/or NSAIDs for

acute low back pain: design of a randomized controlled trial [ACTRN012605000036617]. BMC Musculoskelet Disord 6:57
17. Hurley DA, McDonough SM, Baxter GD, Dempster M, Moore AP (2005) A descriptive study of the usage of spinal manipulative therapy techniques within a randomized clinical trial in acute low back pain. Man Ther 10:61–67
18. Jull G, Treleaven J, Versace G (1994) Examination of the articular system. In: Boyling JPN (ed) Grieve's modern manual therapy. The vertebral column, 2nd edn. Churchill Livingston, Edinburgh
19. Kent P, Keating J (2004) Do primary-care clinicians think that nonspecific low back pain is one condition? Spine 29:1022–1031
20. Koes BW, van Tulder MW, Ostelo R, Kim Burton A, Waddell G (2001) Clinical guidelines for the management of low back pain in primary care: an international comparison. Spine 26:2504–2513
21. Maitland GD, Hengeveld E, Banks K, English K (2005) Vertebral manipulation, 7th edn. Butterworths, London
22. McGinn TG, Guyatt GH, Wyer PC, Naylor CD, Stiell IG, Richardson WS (2000) Users' guides to the medical literature: XXII: how to use articles about clinical decision rules. Evidence-Based Medicine Working Group. JAMA 284:79–84
23. Oxman AD, Guyatt GH (1992) A consumer's guide to subgroup analyses. Ann Intern Med 116:78–84
24. Reilly BM, Evans AT (2006) Translating clinical research into clinical practice: impact of using prediction rules to make decisions. Ann Intern Med 144:201–209
25. Roland M, Morris R (1983) A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. Spine 8(2):141–144
26. Team UBT (2004) United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. BMJ 329:1377
27. van Tulder M, Becker A, Bekkering T, Breen A, del Real MTG, Hutchinson A et al (2006) Chapter 3. European guidelines for the management of acute nonspecific low back pain in primary care. Eur Spine J 15(Suppl 2):S169–S191
28. Waddell G, Newton M, Henderson I, Somerville D, Main CJ (1993) A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 52:157–168
29. Wand BM, Bird C, McAuley JH, Dore CJ, MacDowell M, De Souza LH (2004) Early intervention for the management of acute low back pain: a single-blind randomized controlled trial of biopsychosocial education, manual therapy, and exercise. Spine 29:2350–2356