# Predictors of functional outcome in patients with chronic low back pain undergoing back school, individual physiotherapy or spinal manipulation

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*Background*. Recent studies on chronic low back pain (cLBP) rehabilitation suggest that predictors of treatment outcome may be differ according to the considered conservative treatment.
*Aim*. To identify predictors of response to back school (BS), individual physiotherapy (IP) or spinal manipulation (SM) for cLBP.
*Population*. outpatients with cLBP.
*Setting*. Outpatient rehabilitation department.
*Design*. Retrospective analysis from a randomized trial.
*Methods*. Two hundred and ten patients with cLBP were randomly assigned to either BS, IP or SM; the Roland Morris Disability Questionnaire (RM) was assessed before and after treatment: those who decreased their RM score <2.5 were considered non-responders. Baseline potential predictors of outcome included demographics, general and cLBP history, life satisfaction.
*Results*. Of the 205 patients who completed treatment (140/205 women, age 58+14 years), non-responders were 72 (34.2%). SM showed the highest functional improvement and the lowest non-response rate. In a multivariable logistic regression, lower baseline RM score (OR 0.82, 95% CI 0.76-0.89, P<0.001) and received treatment (OR 0.32, 95% CI 0.21-0.50, P<0.001) were independent predictors of non-response. Being in the lowest tertile of baseline RM score (<6) predicted non response to treatment for BS and IP, but not for SM (same risk for all tertiles).
*Conclusions*. In our patients with cLBP lower baseline pain-related disability predicted non-response to physiotherapy, but not to spinal manipulation.
*Clinical rehabilitation impact*. Our results suggest that, independent form other characteristics, patients with

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cLBP and low pain-related disability should first consider spinal manipulation as a conservative treatment.
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The prognosis of patients affected by chronic low back pain is generally described to be poor, despite evidence based treatment.[1-3] Systematic reviews do provide consistent reports of some improvement associated to conservative treatment, including physiotherapy and spinal manipulation, but the magnitude of these effects is generally small.[4, 5]

Recent studies identify some baseline characteristics of patients with chronic low back pain that are associated with better prognosis in inception cohort studies.[6] In facto, since "chronic low back pain" is a broad definition that reflects our difficulty to better categorize a highly heterogeneous group of clinical conditions with similar symptoms,[7] it is possible that different subgroups of patients with chronic low back pain may benefit more from one treatment than from another. Although the identification of which patients are more likely to respond to which type of treatment would have high clinical value and would be highly relevant to health service planning

and resource allocation, the literature on this issue is still scarcely represented.[8, 9]

Recently, we conducted a pragmatic randomized controlled trial, [10] comparing the effects of three recommended treatment approaches to patients with chronic non-specific low back pain. The interventions included back school, designed referring to the original Swedish model, [11] individually delivered physiotherapy, focused on teaching therapeutic exercise and associated with manual therapy (excluding spinal manipulation), and spinal manipulation, delivered according to the Manual Medicine approache described by Robert Maigne. [12] Significant improvement was found in all three intervention groups, with spinal manipulation providing more functional recovery and pain relief than either exercise-focused intervention, while back school had similar short-term and better long-term outcome than individually delivered treatment. [10] Since clustering low back pain patients with specific problems may predict best treatment outcome, [13,14] we hypothesized that some of the patient baseline characteristics may identify specific patterns of response to treatment. The aim of this study was to perform a retrospective analysis of the previous randomized sample, to identify predictors of poor outcome among the demographic, psychosocial and clinical information collected on baseline, and to search for possible treatment effect modifiers.

## Materials and methods

Our original study sample included 210 consecutively recruited patients visited in our outpatient department between April 2002 and October 2006 for a complaint of low back pain, reported 'often' to 'always' at least for the past six months, who received a specialist's diagnosis of chronic, non-specific low back pain. Exclusion criteria were: neurological signs or symptoms, spondylolisthesis (2nd degree or more), spinal stenosis, lumbar scoliosis (20 degrees or more), rheumatoid arthritis or spondylitis, previous vertebral fractures, psychiatric disease, cognitive impairment or pain-related litigation. All recruited patient provided standard radiographs of the lumbar spine; 99 patients also provided computed tomography (CT) or magnetic resonance (MR) scans. All patients gave their written consent to be randomly

assigned to either Back School, individually delivered physiotherapy or spinal manipulation.[10]

A booklet with evidence based, standardized educational information on basic back anatomy and biomechanics, optimal postures, ergonomics, and the advice to stay active was given to each participant and discussed with physicians or physiotherapists, either in group or in individual sessions.

The two physiotherapy interventions were both delivered by expert physiotherapists according to standard protocols, both scheduling fifteen one-hour sessions, five days a week.

The back school protocol included first five sessions devoted to information and group discussions on back physiology and pathology, with reassurance on the benign character of common low back pain, and with education in ergonomics at home and in different occupational settings by slides and demonstrations. The next 10 sessions included relaxation techniques, postural and respiratory group exercises, and individually tailored back exercises. Back school groups included eight patients each; two therapists together ran all 15 sessions for each group.

Individual physiotherapy was focused on teaching therapeutic exercise and on patient education; it also included manual therapy (except spinal manipulation) as neeeded, including passive and assisted mobilization, massage, treatment of the soft tissues.

Spinal manipulation was performed according to the manual medicine approach described by Robert Maigne.[12] The whole spine was examined by static and dynamic assessment; treatment consisted of vertebral direct and indirect mobilization and manipulation, with associated soft tissue manipulation, aimed at restoring the physiological movement in the dysfunctional vertebral segment(s). Patients assigned to spinal manipulation received 4-6 (as needed) weekly sessions of 20 minutes each for a total of 4-6 weeks of treatment (80-120 minutes of treatment altogether). Two physicians specialized in physical medicine and rehabilitation, expert in manual medicine, performed manipulations; the same physician delivered the whole cycle of manipulations. Discharge was a clinical decision, when there was no indication of prosecute manipulation (i.e. no more dysfunctional vertebral segments to manipulate) or desired results were obtained. [10]

The primary outcome measure was low back pain-related functional disability, assessed by the Roland Morris Disability Questionnaire;[15] in the

original trial we assessed Roland Morris on baseline, discharge, and 3, 6 and 12 months from discharge. The Roland Morris scores from 0, representing no low back pain related disability, to 24, representing maximum low back pain-related disability. We regarded as clinically important a difference of the Roland Morris score among groups equal or greater than 2.5 points, considered the minimal clinical significant difference relevant in low back pain trials,[15] and we defined those whose Roland Morris score improved less than 2.5 on discharge compared to their baseline score as non-responders.

Potential predictors of response to treatment included baseline disability and pain intensity (measured by the Roland Morris Pain intensity scale, ranging 0-6).[16] Furthermore, potential predictors of treatment outcome were selected from the baseline questionnaire, based on the literature on prognostic factors in paatients with low back pain.[4, 10] Considered variables included demographics, pain onset, reports of BP related previous treatments, BP related drug intake; since our sample included many housewives and pensioners, we did not include working parameters in our analysis. Life satisfaction was investigated by one-item question "How would you rate your overall satisfaction with life from 0=completely unsatisfied to 5=completely satisfied?

## Statistical analysis

Data are presented as mean ± SD or as absolute value, along with the percentage in brackets. Statistical analysis was performed using the software STATA 7.0, from Stata Corporation (College Station, Texas, USA) [17] and carried out using a three-step strategy. Differences between responders and non-responders were first analyzed using the Student t test, for continuous variables, the Pearson $\chi^2$ test, for dichotomic variables, or the Kruskaal-Wallis rank test, for ordinal variables. Then, variables showing a significant difference between responders and non-responders were entered into a multivariable backward logistic regression predicting the probability of non-response. Finally, interaction terms were also entered into the model. Type 1 error was set at the two-sided 0.05 level for comparisons between responders and non-responders and at the two-sided 0.01 level for internal (intra-group) comparisons.

## Results

Of the 210 patients enrolled on baseline, 5 interrupted treatment for concurrent illness or family problems (two in back school, two in individual physiotherapy and one in spinal manipulation), thus analysis was conducted on 205 patients (140/205 women, age 58+14 years). All participants who completed back school (BS) and individual physiotherapy (IP) attended at least 12 of the 15 sessions. The 69 participants who completed spinal manipulation (SM) attended 4–6 once-a-week sessions (mean 4.2+SD 0.6). At the end of the treatment all three groups reported a significant improvement in disability score, beyond minimal clinically important difference (mean reduction 3.7+4.1 for back school, 4.4+3.7 for individual physiotherapy and 6.7+3.9 for spinal manipulation, P<0.001), significantly greater in the manipulation group. Considering patients who improved their disability score less than 2.5 points or did not improve at all, non-responders were 72 (34,2%); spinal manipulation showed the lowest rate of non-responders.

Table I shows patients characteristics according to the response to treatment. Non-responders were younger patients who reported lower disability scores and lower frequency of previous treatment for low back pain. Furthermore, the distribution of non-responders in each treatment subgroup was uneven (P<0.001), with the back school subgroup showing the highest percentage of non-responders (Figure 1).

When the above variables were entered into the multivariable backward logistic regression, a low disability score and received treatment remained independent predictors of non response to treatment (Table II).

We then verified specific predictors of treatment outcome for each of the considered interventions, finding that a lower Roland Morris score still predicted poor outcome for back school and for individual physiotherapy but not for those treated with spinal manipulation (Table III).

Finally, the Roland Morris scores were divided into tertiles (1st tertile ≤6, 2nd tertile >6 and ≤12, 3rd tertile >12), thus considering separately those with lower, intermediate and higher disability.

The distribution of non-responders among the received treatment subgroups was uneven (P<0.001), with the 1st tertile subgroup showing the highest percentage of non-responders (Figure 2).

TABLE I.—*Patients' characteristics according to the response to treatment, N.=205.*

|  | Responders N.=133 | NON responders N.=72 | P (*) |
|---|---|---|---|
| General characteristics |  |  |  |
| – Age, years (mean±SD) | 60.3±13.8 | 56.0±15.3 | **0.038** |
| – Female sex [n, (%)] | 95 (71) | 45 (63) | 0.355 |
| – Weight, Kg (mean±SD) | 69.9±11.7 | 71.8±11.8 | 0.255 |
| – Height, cm (m  ean±SD) | 166±9 | 167±9 | 0.160 |
| – Previous physical activity [N., (%)] | 63 (47) | 34 (47) | 0.829 |
| – Current physical activity [N., (%)] | 29 (22) | 19 (26) | 0.379 |
| – Smoking [n, (%)] | 48 (36) | 30 (42) | 0.327 |
| – Working [n, (%)] | 62 (47) | 34 (47) | 0.751 |
| – Living alone [N., (%)] | 31 (23) | 11 (15) | 0.217 |
| – Life satisfaction [N., (%)] | 127 (95) | 70 (97) | 0.138 |
| Pain characteristics |  |  |  |
| – RM score (mean±SD) | 10.4±4.2 | 7.3±4.8 | **<0.001** |
| – PRS (mean±SD) | 2.0±0.9 | 2.0±0.9 | 0.882 |
| – Reported LBP for 2 years or more [N., (%)] | 105 (79) | 51 (71) | 0.408 |
| – LBP-related use of drugs [N., (%)] | 77 (58) | 34 (47) | 0.237 |
| – Previous treatments for LBP [N., (%)] | 99 (74) | 41 (57) | **0.031** |

*From Student *t* test, Pearson $\chi^2$ test or Kruskaal-Wallis rank test, as appropriate.
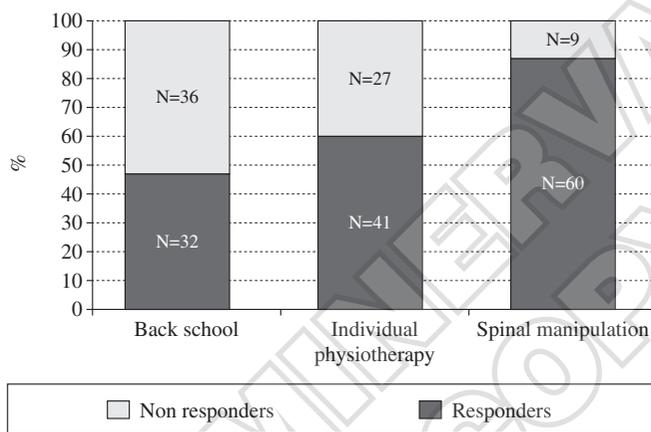


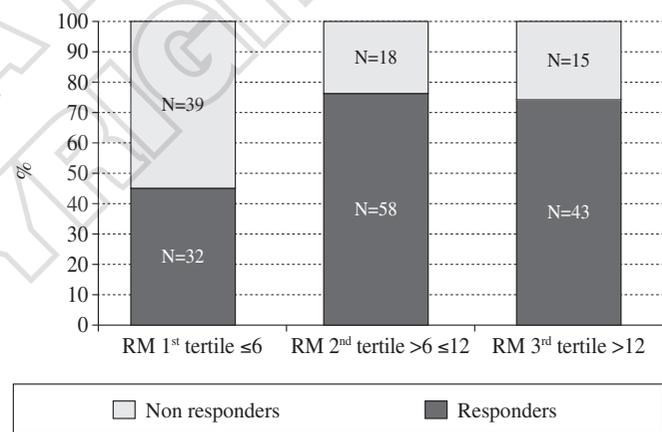Figure 1.—Response according to the received treatment (P<0.001).



Figure 2.—Response according to Roland Morris (RM) tertiles (P<0.001).

TABLE II.—*Independent predictors of non response to treatment: multivariable backward logistic regression.*

Obs: 205; Final Model: LR chi² = 55.06; Prob > $\chi^2$<0.001; Pseudo R²=0.204

| NON RESPONDERS | OR (95% CI) | P |
|---|---|---|
| Age | 1.00 (0.98-1.03) | 0.662 |
| Previous treatment | 0.61 (0.31-1.24) | 0.174 |
| Disability score | 0.82 (0.75-0.89) | <0.001 |
| Received treatment | 0.32 (0.21-0.50) | <0.001 |

Interaction terms, treatment x Roland Morris score tertile, were entered into the model. The interaction of back school (lower rate of responders) and the 1st Roland Morris score tertile (lower disability score) were considered as reference values. When compared with those who received back school, responders were significantly more frequent in those who received spinal manipulation but not in those

TABLE III.—*Independent predictors of non response to treatment on basis of received treatment: multivariable logistic regression.*

| NON RESPONDERS | Back school | | Individual physiotherapy | | Spinal manipolation | |
|---|---|---|---|---|---|---|
| | Obs: 68; Final Model: LR $\chi^2$=17.94; Prob > $\chi^2$<0.001; Pseudo R²=0.191 | | Obs: 68; Final Model: LR $\chi^2$=15.72; Prob > $\chi^2$<0.001; Pseudo R²=0.172 | | Obs: 69; Final Model: LR $\chi^2$=5.75; Prob > $\chi^2$<0.125; Pseudo R²=0.108 | |
| | OR (95% CI) | p | OR (95% CI) | P | OR (95% CI) | P |
| Age | 1.01 (0.97-1.05) | 0.659 | 1.00 (0.97-1.04) | 0.781 | 1.01 (0.94-1.08) | 0.756 |
| Previous treatment | 0.25 (0.07-1.12) | 0.123 | 1.51 (0.43-5.23) | 0.517 | 0.34 (0.07-1.59) | 0.171 |
| Disability score | 0.82 (0.71-0.95) | 0.006 | 0.81 (0.71-0.92) | 0.001 | 0.80 (0.62-1.04) | 0.101 |

TABLE IV.—*Interaction term analysis treatment x RM tertiles.*

Obs: 205; Final Model: LR $\chi^2$(8)=53.94; Prob > $\chi^2$<0.001; Pseudo R²=0.199

| Non responders | | OR (95% CI) | P |
|---|---|---|---|
| Treatment | Back school | reference | |
| | Individual physioterapy | 0.66 (0.18-2.46) | 0.540 |
| | Spinal manipulation | 0.09 (0.02-0.35) | <0.001 |
| RM Tertile | 1st RM tertile | reference | |
| | 2nd RM tertile | 0.25 (0.07-0.88) | 0.031 |
| | 3th RM tertile | 0.17 (0.04-0.66) | 0.010 |
| Treatment x RM Tertile | Back school x 1st RM tertile | reference | |
| | Individual physioterapy x 2nd RM tertile | 0.49 (0.08-3.18) | 0.458 |
| | Individual physioterapy x 3th RM tertile | 0.84 (0.13-5.29) | 0.852 |
| | Spinal manipulation x 2nd RM tertile | 0.46 (0.04-5.70) | 0.545 |
| | Spinal manipulation x 3th RM tertile | 4.16 (0.45-38.76) | 0.211 |
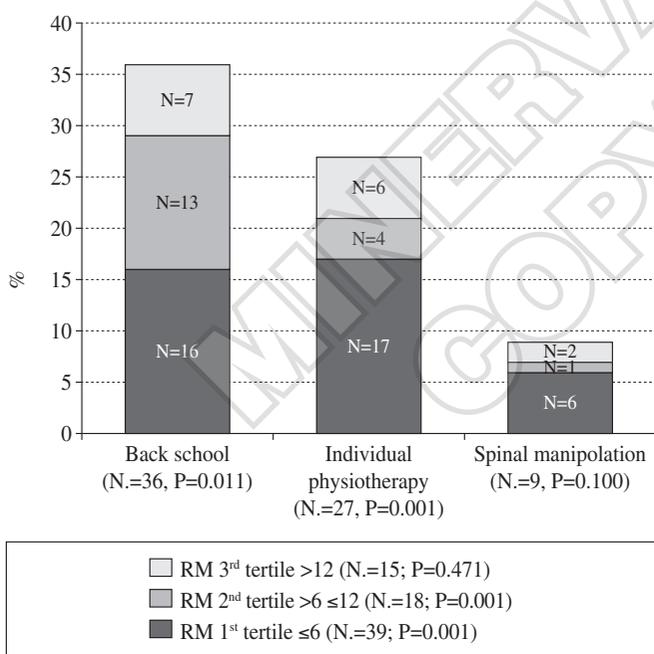


Figure 3.—Distribution of non-responders (n=72) according to the received treatment and RM tertiles.

who received individual physiotherapy. Thus, comparing different treatments, those treated with spinal manipulation had the highest recovery rates compared to either physiotherapy intervention, confirming that, on the short term, our patients were more likely to benefit from spinal manipulation than from physiotherapy, independent of baseline disability score and other clinical characteristics. When compared with the 1st Roland Morris score tertile (lower disability score), higher disability scores were associated to better response rates, while those in the lower disability tertile had the lowest recovery rate. There was no significant treatment x Roland Morris score tertile interaction (Table IV).

Figure 3 show the distribution of non responders according to received treatment and Roland & Morris Tertile.

## Discussion

In our cohort of patients affected by chronic low back pain, short term disability improvement

by minimal clinically important difference was independently predicted by received treatment, with spinal manipulation providing the highest rate of recovery, followed by individually delivered physiotherapy and then by back school, and by higher disability score on baseline.

A separate analysis conducted for each specific intervention branch showed that the Roland Morris score was the only independent predictor of outcome for back school and for individual physiotherapy, while no significant predictor of treatment outcome was found for the spinal manipulation group. Although we could not find an interaction between received treatment and disability, we also found that patients in the lowest disability score tertile (Roland Morris less than 6) were at higher risk of non recovery if they received back school or individual physiotherapy, while they had the same risk of non recovery as those with higher disability if they received spinal manipulation.

Other potential predictors considered in our analysis, except from baseline disability score, such as pain duration, pain intensity, previous treatments, as well as patient's general characteristics such as age, gender, working status and overall life satisfaction could not predict functional outcome in our cohort of patients randomly assigned to either of the considered treatments.

Results of recent randomized trials investigating predictors of response to conservative treatment in patients affected by low back pain are somehow conflicting. A Finnish study, investigating predictors of response to a mini-intervention (physician's and physiotherapist's assessment and advice) for patients with sub-acute low back pain, identified the fear of non recovery on baseline as the strongest predictor of better outcome,[18] while a study conducted in Norway, [19] considering a similar intervention, identified constant low back pain and concern about being unable to work as predictor of better outcome at three months. Since the mini intervention in both cases consisted basically of advice and reassurance, it is reasonable to suppose that it should have worked best for those who were in higher psychological distress. However, when we consider a large British study comparing the effects of exercise, manipulation and combined treatment in patients with low back pain, results were similar to ours with the relevant exception of baseline disability predicting outcome in our sample but not

in theirs.[8] Neither age, nor work status, quality of life, patients' beliefs, pain duration over time, nor a variable combining pain and disability predicted response to treatment in this study cohort, using the Roland Morris Disability Questionnaire reduction as the main outcome. However, these authors in their analysis chose to combine baseline pain and disability in a single score, while we maintained these factors separate, and this may explain why our results are partially different.

Our finding that receiving manipulation predicted overall a better outcome compared to either back school or individual physiotherapy is in line with a recent large British randomized trial (UK BEAM), suggesting that spinal manipulation alone is more cost effective than physiotherapy in addition to best care for chronic low back pain.[20] In fact, as we have discussed in our previous paper, our results showed that spinal manipulation provided the best outcome both in the short and in the long term, but it also required more further treatment (manipulation) in the follow-up.[10]

The finding that a lower Roland Morris baseline score predicts lower response rate in our study cohort is in line with another recent study evaluating potential predictors to response to acupuncture in patients with chronic back pain, reporting that patients with the worst clinical complaints right before treatment were those showing better response to treatment, at least in the short term.[9] These data are also consistent with previous studies suggesting that patients with lower baseline complaints may have a reduced change potential compared with those who are more compromised.[21] We must also acknowledge that our choice of definition of non-responders by an absolute score difference [15] may have played a role in producing this result: in fact, although all our patients reported a minimum baseline disability score above 2.5, improving by the same absolute magnitude may have a different meaning for those who start with a high Roland Morris score than for those who start with already low scores.[22]

On the contrary, a high baseline Roland Morris disability score was identified as a predictor of non recovery at 1-year in a large inception cohort study on the natural history of low back pain.[8] Indeed our results seem to suggest that treatment does make a difference especially for those patients who are in a highly disabling and perhaps more acute condition, who, if under-treated or not treated at all, have a

higher risk of poor outcome in the natural history of chronic low back pain. However, since we chose not to include a control group in our original trial, no definite conclusion can be drawn on this issue.

Similar research on neck pain combined data from different studies, while out data come from the same study sample: this may be a strength in terms of homogeneity of setting, approaches and patient selection, but is a strong limitation as to the generalisability of our findings.[23] Furthermore, our case mix included mostly elderly and middle aged women, who were somewhat older than the general population of persons affected by chronic, non-specific low back pain. Finally, since our study was a secondary retrospective analysis, we could not take into consideration many psychological factors that in recent literature were associated to response to low back pain treatment, such as fear of non recovery,[18] fear of not being able to work,[19] expectations regarding specific treatment,[8] that we had not introduced in the original baseline assessment. As a psychological factor we only recorded one single question about overall life satisfaction, that was not significantly related to treatment outcome.

Both studies conducted by Underwood and by Shearmen concluded that there is little evidence that general patient's characteristics and pain history may identify back pain patients' subgroups that respond better to different treatment.[8, 9] Although confirming that most of the variables we considered as potential predictors were not independently related to response to treatment, our study presents the original finding that a low disability score predicts poor outcome in patients treated by either group or individual physiotherapy, but not in patients treated with spinal manipulation. A possible explanation for this finding is that spinal manipulation provides a less global, more specific approach to the mechanical dysfunction producing low back pain. [12] The specificity of this approach may be particularly effective when low back pain is associated with low disability levels, whereas in patients in the higher disability tertiles, either manipulation or physiotherapy may obtain improvement, if through different pathways (*i.e.* direct spinal mobilization/manipulation versus active exercise). Our failure to find a treatment interaction with disability score tertiles does not allow us to consider the Roland Morris baseline score as a treatment effect modifyer,[24] suggesting that the higher benefit of spinal manipulations in our sam-

ple was independent from disability levels on baseline. On the other hand, sub-group analises did have reduced statistical power compared to the analisys performed on the whole study sample, and, indeed, we also found that lower disability scores did not predict worse outcome in patients treated by spinal manipulation. Thus, a larger randomized controlled trial should verify if the Roland Morris Disability questionnaire assessment on baseline may be a useful tool to classify which patients are less likely to respond to physiotherapy and may first consider spinal manipulation.

## Conclusions

In our patients with chronic non-specific low back pain, receiving manipulation rather than physiotherapy, and reporting more baseline disability were independent predictors of a higher treatment response rate. A lower disability baseline score predicted treatment failure for back school and individual physiotherapy, but not for spinal manipulation.

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