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A Randomized Trial Investigating a Chiropractic Manual Placebo: A Novel Design Using Standardized Forces in the Delivery of Active and Control Treatments

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ABSTRACT

Objectives: To evaluate the proposed manual placebo in terms of success in blinding patients to treatment group assignment and outcomes between the treatment groups.

Design: Randomized controlled trial.

Setting: A chiropractic college research clinic in the midwestern United States.

Subjects: One hundred and eleven (111) individuals aged 18 years and over with subacute or chronic low-back pain.

Interventions: The active treatment consisted of flexion-distraction chiropractic manipulation and trigger point therapy and the control treatment of sham manipulation and effleurage; both groups received eight treatments over a 3-week period. The application of prescribed ranges of biomechanical forces for each treatment was standardized using specialized computerized equipment. "Nontreatment" aspects of the clinical encounter were to be standardized across groups. A primary clinician blinded to treatment assignment provided interpersonal interactions and treating clinicians delivered treatments with a minimum of interaction.

Outcome measures: The accuracy of the patient's perception of group assignment at visit 4 and the mean change in the Pain Disability Index (PDI) over the treatment period were the primary outcome variables.

Results: Patients in the control group were more likely to perceive their treatment assignment accurately than those in the active group (78% versus 54%, respectively). Patients in both treatment groups improved on the PDI and the Roland-Morris Questionnaire; there were no significant differences in improvement between the groups. Age, gender, prior chiropractic experience and expectation of treatment at baseline had no effect on outcomes.

Conclusions: Patients in the control group were not successfully blinded; however, patients' perceptions of treatment group assignment did not significantly affect outcomes. The clinically significant improvement in both groups, independent of patient or clinician expectations, suggests the presence of therapeutic factors common to both groups, other than biomechanical force. Further studies examining other aspects of the clinical encounter, considered separately from biomechanical force, are warranted before arbitrarily designating any intervention as a "placebo."

INTRODUCTION

Investigation of the concept of placebo is a major challenge in clinical trials of complementary and alternative therapies (Kaptchuk, 1999; Turner et al., 1994). Key characteristics of placebos are that they are nonspecific rather than inactive, and that they yield marginal clinical benefit (Jamison, 1999; Shapiro and Shapiro, 1984). Another es-

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sential component is believability to the patient (Basoglu et al., 1997).

In investigations of manual therapies, it is particularly important to control for the nonspecific effect of touch. A number of randomized controlled trials (RCTs) investigating chiropractic have used manual placebos, usually some form of massage and/or "sham" manipulation (Meeker and Haldeman, 2002). The assumption (often unstated) underlying these trials is that the "active" treatment produces a specific biomechanical effect, correcting joint dysfunctions known by chiropractors as "subluxations" (Meeker and Haldeman, 2002). However, none of these trials provided convincing evidence that both (1) the manual placebo had a nonspecific effect because the specific effect was not clearly defined and (2) the patients were successfully blinded. These two points are critical in interpreting the trials' findings, because the between-groups outcomes were often nonsignificant (statistically or clinically) (Balon et al., 1998; Bove and Nilsson, 1998; Hondras et al., 1999).

In the absence of a definitive specific effect (that is, biomechanical correction of specific joint dysfunction), manual placebos in chiropractic RCTs have differed greatly in biomechanical force, induced spinal movement, and area of application (Assendelft et al., 2003). Placebos ranged from deep-friction massage and trigger point therapy to light pressure exerted by a hand-held instrument.

Although some chiropractic techniques have been biomechanically assessed, few clinical studies have attempted to standardize such forces or test an association between specified levels of biomechanical force and specific treatment effects (Brennan et al., 1992; Hondras et al., 1999; Kokjohn et al., 1992). There is still no definitive evidence for a threshold value of biomechanical force below which a chiropractic treatment has only a nonspecific effect.

This study is one of several (Cambron et al., 2004; Hawk et al., 1997, 1999, 2002; Hawk & Long, 2000) laying the groundwork for controlled studies of the effects of a particular chiropractic procedure, flexion–distraction technique (FDT) for treating the low-back pain (LBP) component in different patient populations. We designed the study on the assumption that the "specific" component in an active chiropractic treatment is the application of biomechanical force within the range typically used in practice. Control procedures used forces well below those ranges. The chief goals of this study were to assess the success of blinding patients to treatment group and to evaluate low back pain outcomes between the treatment groups.

MATERIALS AND METHODS

Participants

The study took place at the research clinic of a chiropractic college in the midwestern United States after approval by the Institutional Review Board. Volunteers were recruited through newspaper and radio advertisements and screened by telephone and at a baseline evaluation visit.

Inclusion criteria were: (1) 18 years of age and over and (2) subacute (onset 4–12 weeks prior to contact) or chronic (onset more than 12 weeks prior to contact) LBP. Exclusion criteria were: (1) pregnancy; (2) radiation of pain distal to the knee with evidence of neurologic involvement; (3) contraindications to manipulation; (4) no indications of musculoskeletal dysfunction; (5) litigation for a health-related claim (in process or pending); (6) chiropractic care within the last month; or (7) unwillingness to postpone other types of manual therapy during the study.

Interventions

Manual procedures were performed by four experienced licensed doctors of chiropractic trained in FDT and trigger point therapy. A prescription for application of biomechanical forces was developed for each component of the two treatments, based on usual and customary practice, and using equipment previously tested for this purpose (Hawk et al., 2002; Hondras et al., 1999; Kokjohn et al., 1992); see Figure 1.

Active treatment group procedures. Patients received FDT and trigger point therapy. In FDT, the clinician moves the patient's spine in small increments while manually directing inferior-to-superior force against the vertebrae, assisted by movable table sections and manual posterior-to-anterior stabilizing pressure. Indications for treatment were presence of lumbar intervertebral joint hypomobility or hypermobility. Trigger point therapy involves manual ischemic compression to muscles with localized regions of painful contracted tissue. Patients were evaluated for trigger points in the lumbar, sacral, and gluteal musculature.

Control treatment group procedures. Patients received sham manipulation and effleurage. The sham procedure was by design dissimilar to the active technique to minimize the biomechanical force delivered and avoid moving the spinal joints. We did this because, until the "active" element of the chiropractic adjustment has been isolated and documented, a supposed sham maneuver that flexes and rotates the spinal joints may accomplish an active effect. Furthermore, because patients received only one type of treatment, it was only necessary that the control treatment be believable in itself, not appear similar to the active treatment. Our previous studies suggested that this treatment was believable, although no formal hypothesis test was done (Hawk et al., 1999, 2002). The sham manipulation was performed with a hand-held instrument.

Standardization and biomechanical forces. Forces were measured at the patient–table interface in a posterior-to-an-

FIG. 1. Flexion–distraction table with force plates installed in the thoracic and pelvic sections.

terior (PA) vector. The clinicians were trained to follow the protocol for time, pressure and repetition and "recalibrated" the procedures weekly with nonstudy volunteers and real-time computer feedback. After each visit, they completed a form reporting any deviations from protocol.

- Active treatment: Pressure was applied to the lumbar/lumbosacral region with PA force of 80–160 Newtons (N). The table movement was approximately 2 inches. Repetitions were determined by a formula based on the patient's reported visual analogue Scale (VAS), with fewer repetitions for higher pain levels; the maximum was 15. For trigger point therapy, forces were 40–75 N for 4–7 seconds, releasing for 3–5 seconds, with a maximum of three repetitions.
- Control treatment: The instrument was set to its "zero point," delivering only the weight of the instrument. It was applied at least 2 inches lateral to the spine and was not to exceed 12 N. Effleurage was applied to the patient's low to middle back for 5–10 seconds at 10–20 N.

Eight treatments were delivered over 3 weeks. "Non-treatment" aspects, such as time spent, were standardized across groups. To minimize possible effects of the clinician's expectations, while still maintaining the doctor–patient relationship equally, we used a blinded primary clinician. The treating clinicians delivered the manual treatments with a minimum of interaction.

Outcomes

The accuracy of the patient's perception of group assignment at visit 4 and the mean change on the Pain Disability Index (PDI), a patient self-report instrument with demonstrated reliability and validity (Gronblad et al., 1994; Tait et al., 1987), at the end of 3 weeks were the primary outcome variables. Based on the literature and our previous experience, we considered six points on the PDI to be a clinically important improvement (Hawk et al., 1997, 2002; Hawk and Long, 2000; Nordstrom et al., 1996). Patients indicated their perception of group assignment on a six-point scale ("certainly," "probably," or "definitely" placebo/active) (Moscucci et al., 1987). Patient expectation of improvement was indicated on a 100-mm VAS at baseline and prior to treatment at visit 4. We assessed their perceptions after three visits, so they would be familiar with the treatment but not yet experiencing enough clinical improvement to bias their perception. Previous use of chiropractic was ascertained at baseline, using photographs. The Roland Mor-

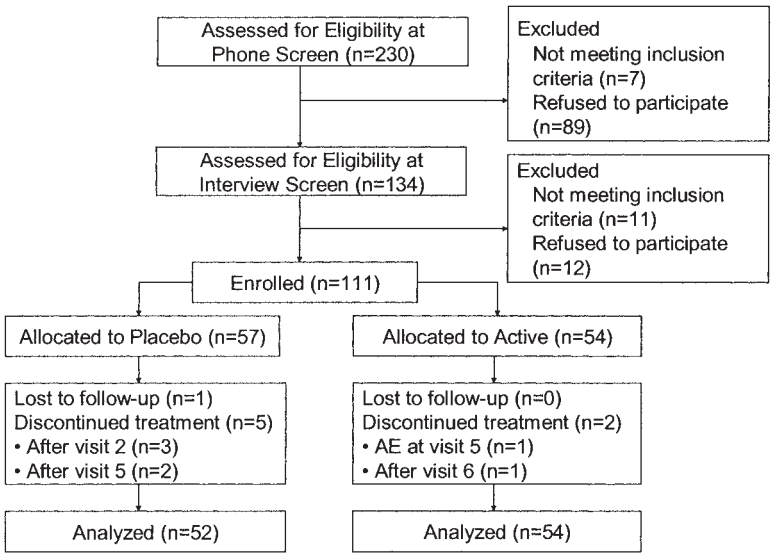

FIG. 2. Flow of participants through study stages. AE, adverse event.

Table 1. Sample Demographics[a]

	Control group (n = 57)	*Active group (n = 54)*
Female	36 (63%)	28 (52%)
Age—mean (SD)	53 (15.2)	51 (14.2)
Ethnicity		
Hispanic	1 (2)	1 (2)
Non-Hispanic	50 (88)	47 (87)
Race		
Black/African American	4 (7)	2 (4)
White	53 (93)	51 (94)
Educational level		
High school diploma or less	16 (28)	20 (37)
Some college or college degree	33 (58)	29 (53)
Postgraduate or professional degree	7 (13)	5 (9)
Current tobacco use	14 (25)	12 (22)
Health insurance	53 (93)	46 (85)
Insurance covers chiropractic	21 (37)	14 (26)

[a]Number (%) unless otherwise noted. Subcolumns may not total 100% because of missing values.
SD, standard deviation.

ris Back Pain Questionnaire (RMQ) (Riddle et al., 1998; Stratford et al., 1996), VAS for Pain (Wewers and Lowe, 1990), Beck Depression Inventory (BDI; Beck et al., 1988), and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36; Ware et al., 1993) were administered at baseline and at visit 9.

Sample size

To have 80% power to detect as significant (two-sided, 5% level) a six-point difference between the two groups in the mean PDI, with an assumed standard deviation of 10.8 and 6% attrition (both estimated from the preliminary study), 55 patients (110 total) in each group were required.

Treatment assignment

The treatment allocation sequence was determined dynamically with adaptive computer-generated randomization to minimize group differences on baseline PDI and prior chiropractic use (Begg and Iglewicz, 1980; Pocock and Simon, 1975). A coded treatment assignment was obtained by accessing the centralized algorithm through a screen interface on the internet-based database system. The treating clinicians, but not the patients or primary clinician, had the treatment codes. Blinding success was assessed of patients and the primary clinician prior to visits 4 and 9, and they were unblinded after visit 9.

Statistical methods

The change between outcome scores at baseline and end of treatment were compared between groups with a two-tailed *t* test. Analysis of covariance methods were used to adjust the change scores for other baseline variables. A two-tailed exact binomial test was used to assess the success of blinding. The influence of other factors on success of blinding was investigated using logistic regression models. All analyses were conducted on an intention-to-treat basis.

RESULTS

Recruitment took place from May 2002 to February 2003. A total of 230 volunteers were phone-screened; 134 had a baseline evaluation and 111 enrolled (57 control and 54 active treatment) (Fig. 2). Patient demographics are shown in Table 1, their health habits in Table 2, and their relevant health history in Table 3. There were no striking differences between the two groups with the exception of duration of low-back pain, which was greater in the control group (median 7 versus 4 years).

A similarly high proportion of patients in both groups had prior chiropractic experience (Table 4). Although the pro-

Table 2. Use of Health Care for Low-Back Pain[a]

	Control group n (%)	*Active group n (%)*
Medical care	21 (37%)	24 (44%)
Chiropractic care	46 (81)	43 (80)
Physical therapy	18 (32)	14 (26)
Massage therapy	17 (30)	19 (35)
Acupuncture	4 (7)	4 (7)
Prescription medication	23 (40)	22 (41)
Nonprescription medication	25 (44)	25 (46)

[a]Patients were asked if they had ever used the provider or procedure for low-back pain (LBP).

Table 3. Baseline Characteristics—History and Symptoms[a]

	Control group (n = 57)	*Active group (n = 54)*
Duration of symptoms in years (median, range)	7 (0.1–50)	4 (0.1–45)
Pain Disability Index	26.1 (12.0)	26.8 (12.1)
Roland Morris Questionnaire	7.4 (3.9)	7.8 (4.6)
VAS for current pain (mm)	34.3 (23.9)	32.3 (20.8)
Beck Depression Inventory	4.1 (3.3)	4.8 (3.1)
Global Well-Being Scale (mm)	61.9 (18.2)	60.9 (17.9)
Short Form-36		
Physical function	64.2 (24.6)	64.4 (21.1)
Role physical	37.5 (34.7)	40.7 (39.2)
Bodily pain	44.8 (16.1)	44.1 (14.8)
General health	70.1 (18.4)	68.5 (14.8)
Vitality	48.6 (17.4)	44.8 (19.2)
Social function	73.9 (22.6)	70.6 (23.1)
Role emotional	66.1 (40.4)	72.5 (36.2)
Mental health	68.4 (13.8)	60.9 (17.9)
Physical Composite Score	38.8 (9.1)	38.8 (8.0)
Mental Composite Score	48.5 (9.7)	47.9 (9.6)
Days of missed work in past month (median, range)	0 (0–6)	0 (0–5)
Days of reduced activity in past month (median, range)	3 (0–30)	4 (0–30)
Days stayed in bed in past month (median, range)	0 (0–20)	0 (0–10)
Expectation of improvement[b]	63.2 (18.6)	62.5 (19.8)

[a]Mean (standard deviation [SD]) unless otherwise noted.

[b]Patients used a 100-mm visual analogue scale to mark how confident they felt about the care they were about to receive in the chiropractic clinic, anchored by "very sure it will *not* work" (0) and "very sure it will work" (100); $n = 50$ in control group, $n = 47$ in active group.

VAS, visual analogue scale; SF-36, Short Form-36.

portion who had experienced either FDT or Activator technique (a technique employing the hand-held instrument) was much smaller, more patients in the active than the control group had experienced FDT (28% versus 16%, respectively).

Of patients who completed the study, four had seven treatment visits and the remainder had eight. The primary clinician spent a median of 2 minutes (range, 1–11) per patient per visit. The median time patients spent with the treating clinician was 5 minutes (range, 2–15) in the control and 8 minutes (range, 2–18) in the active group. There were no reported deviations from prescribed protocols in either group. One patient in the active treatment group was withdrawn at visit 5 because of a nonserious adverse event (Fig. 2): her back pain became worse during that visit. Of the five patients in the control group who discontinued, only one provided a reason: after her first treatment visit, the patient was sure she was receiving a placebo and was in too much pain to continue.

The overall accuracy of patients' perception of group assignment was 66% (significantly different from chance, $p < 0.001$). As shown in Table 5, control group patients were more likely than active group patients to accurately perceive their treatment (78% versus 54%, respectively). Age, length of symptoms, prior experience with FDT or activator techniques, and baseline expectation of treatment did not influence patients' accuracy. However, females in the active group were more likely than males to correctly perceive their group status (68% versus 38%), but not in the control group (75% versus 84%) ($p = 0.05$, group by gender interaction in logistic regression model).

Patients' expectations of improvement at visit 4 varied by their perception of treatment assignment and actual treatment assignment (Table 6). Patients who correctly perceived that they were in the control group had a much lower mean expectation of improvement than those who believed they

Table 4. Previous Experience of Chiropractic[a]

	Control group (n = 57)	*Active group (n = 54)*
Previous use of chiropractic (any technique)	53 (93%)	48 (89%)
How long ago?		
< 5 years	42	41
5–10 years	6	4
> 10 years	5	3
Previous use of chiropractic (just the named technique)		
Flexion–distraction	9 (16)	15 (28)
Activator	21 (37)	21 (39)

[a]Number (%).

Table 5. Accuracy of Perception of Treatment Assignment Prior to Treatment at Visit 4[a]

	Actual treatment assignment	
Perceived treatment assignment[b]	*Control (n = 55)*	*Active (n = 54)*
Placebo	43 (78%)	25 (46)
Certainly	13	0
Probably	17	9
Possibly	13	16
Active	12 (22)	29 (54)
Certainly	0	1
Probably	4	11
Possibly	8	17

[a]Number (%).
[b]$p < 0.001$, Wilcoxon rank sum test over six categories anchored by "certainly" placebo or active.

were in the control group but were actually in the active group (29.6 mm versus 49.9 mm). However, those who believed they were in the active group had a similarly high mean score regardless of actual treatment assignment, markedly higher than those of patients who believed they were in the control group.

The primary clinician reported that he based his perception of each patient's treatment group assignment on the patient's response to treatment. His accuracy was 68% (significantly different from chance, $p < 0.001$). His expectations differed markedly by group; he expected active group patients to improve a little ($n = 83$) or a lot ($n = 28$); he expected control group patients to not improve at all ($n = 95$). Patients in both treatment groups improved on the PDI and the RMQ, but there were no differences in improvement between groups (Table 7, unadjusted). Age, gender, and prior chiropractic experience had no effect on outcomes. The effect of expectation of treatment at both baseline and visit 4, accuracy of perceived treatment group, group by accuracy interaction, and length of symptoms were also considered. Only length of symptoms was statistically significant in the model of PDI change scores; both length of symptoms and expectation of treatment at visit 4 were significant in the model of RMQ change scores. After adjusting for only those significant covariates, there were still no between-group differences (Table 7, adjusted). However, patients in the two treatment groups differed on final improvement based on a six-level response (Table 8). Yet, the between-group differences were less clear when the scores are broken down by patients' perception of group assignment (Table 8).

DISCUSSION

These patients were fairly typical of U.S. chiropractic low-back pain patients. (Coulter et al., 2002). There are several issues to consider in interpreting the results. First, although we were able to standardize the delivery of the treatments in both groups in most respects, the median time spent with patients in the control group was slightly shorter than in the active group (5 versus 8 minutes). However, the time the primary clinician spent with patients was equal. Although there are no data on the amount of time needed to deliver the nonspecific effect of physical touch, 5 minutes is well within the normal range of time spent in chiropractic practice (Hawk et al., 2001). Consequently, we believe that time spent was not a major factor in believability.

Second, a longer interval of care might have demonstrated differences not apparent at 3 weeks. However, we chose this interval based on evidence that 3 weeks of chiropractic care is usually adequate to demonstrate clinically significant effects (Haldeman et al., 1992; Hawk and Long, 2000; Hawk et al., 2002).

Third, use of FDT and trigger point therapy as the active treatment might limit generalizability, because it differs biomechanically from the high-velocity, low-amplitude procedure (diversified technique) most commonly used. However, FDT is among the most commonly used chiropractic techniques, especially for patients with low-back pain, used by 58% of U.S. chiropractors (Christensen and Morgan 2000).

Fourth, it might be argued that using a biomechanically dissimilar control treatment affects our conclusions. We counter this by emphasizing that the requirements for the control treatment were that it be (1) believable and (2) yield only a marginal clinical benefit. Because patients did not cross over, there was no need for the two treatments to appear similar. This is important to note, since it is likely that parallel treatment designs will continue to be used far more than crossover designs in studies of manual therapies.

Last, we had few patients without previous chiropractic experience, and it is possible that this affected blinding and expectations of improvement. However, as chiropractic be-

Table 6. Expectation of Improvement as Assessed by Patients Prior to Treatment at Visit 4, by Actual Treatment Assignment and Perceived Treatment Assignment[a]

	Actual treatment assignment	
Perceived treatment assignment	*Control (n = 55)*	*Active (n = 54)*
Placebo	29.6 (23.3, 35.9)	49.9 (41.5, 58.4)
Active	74.3 (61.7, 86.9)	69.2 (61.7, 76.7)

[a]Patients used a 100-mm visual analogue scale to mark how confident they felt about the care they were receiving in the chiropractic clinic, anchored by "very sure it will *not* work" (0) and "very sure it will work" (100). Mean scores (95% confidence interval) adjusted for expectation of improvement at baeline ($p = 0.04$); actual treatment group, accuracy of perceived treatment group, and group by accuracy interaction ($p < 0.001$).

Table 7. Mean Changes from Baseline to End of Treatment, by Group[a]

	Unadjusted scores			*Adjusted scores*[b]		
	Control (n = 52)	*Active (n = 54)*	*Between-group difference*	*Control (n = 52)*	*Active (n = 54)*	*Between-group difference*
Pain Disability Index	7.9 (4.9, 11.0)	9.1 (6.6, 11.5)	1.1 (−2.7, 5.0)	8.2 (5.4, 10.9)	8.8 (6.1, 11.5)	0.6 (−3.3, 4.5)
Roland Morris Questionnaire	1.5 (0.7, 2.3)	2.2 (1.3, 3.2)	0.8 (−0.5, 2.0)	2.1 (1.2, 3.0)	1.6 (0.7, 2.4)	−0.5 (−1.8, 0.8)

[a]Mean (95% confidence interval [CI]).
[b]Pain Disability Index (PDI) change scores adjusted for length of symptoms ($p = 0.10$); Roland Morris Questionnaire (RMQ) change scores adjusted for length of symptoms ($p = 0.05$) and expectation of improvement at visit 4 ($p < 0.001$).

comes more commonly used, it is increasingly important to assess the use of nonnaïve patients.

The main purpose of this study was to evaluate whether our control treatment functioned as a placebo in that it was believable and yielded only a marginal clinical benefit. Believability was not achieved; 78% of control group patients correctly perceived group assignment. Interestingly, only 54% of active group patients correctly perceived their assignment. Also, patients' perception did not alter from visit 4, when presumably they had not had time to experience much improvement, to visit 9, when clinically significant improvement had occurred.

It appears that patients' perceptions of group assignment did not significantly alter outcomes even when control group patients correctly identified their assignment. Other factors that may affect outcomes, such as natural history or information on self-care (Hsieh et al., 2002), were equally distributed. However, perception of group assignment and expectation of improvement do appear to influence outcomes to some extent, although the effect did not reach clinical significance. Mean PDI change scores were lowest for those who correctly believed they were in the control group, while those who were in the active group had similar scores regardless of which group they believed they were in. Thus it may be important, in future studies, to adjust outcomes for expectations (Kalauokalani et al., 2001).

Another consideration for future studies is that our primary clinician had markedly different expectations for the two treatments. This would suggest that our attempt to blind the primary clinician to treatment assignment may have merit.

Also relevant to blinding was that previous experience with FDT or the hand-held instrument did not appear to influence outcomes or expectations.

The criterion that the control treatment yielded only a marginal clinical benefit was also not met. However, it is important to recognize that both groups showed clinically significant improvement on the PDI and RMQ. In the improvement response scale, active group patients showed significantly greater improvement than the control group. However, the between-group differences were less clear when viewed according to patients' perception of group, suggesting that this retrospective scale may be dependent upon their perception of group assignment. Another point is that even well-established patient-centered instruments such as the PDI and RMQ may fail to capture outcomes other than pain and disability that are important to the patient.

Although expectations appeared to influence outcomes, they did not affect final outcomes in the regression analysis. The clinically significant improvement in both groups, which was independent of patient or clinician expectations, argues against concluding that chiropractic treatment is no better than a placebo.

Instead, we conclude that the placebo treatment was, in fact, active, implying that some factor or combination of fac-

Table 8. Improvement of Symptoms at End of Treatment[a]

	Actual treatment assignment	
Perceived treatment assignment	*Control (n = 52)*	*Active (n = 52)*
Placebo		
Improved completely	0	0
Got a lot better	4	11
Got a little better	6	8
Stayed the same	29	6
Got a little worse	1	1
Got a lot worse	0	1
Active		
Improved completely	1	0
Got a lot better	4	5
Got a little better	5	5
Stayed the same	2	15
Got a little worse	0	0
Got a lot worse	0	0
Overall[b]		
Improved completely	1	0
Got a lot better	8	16
Got a little better	11	13
Stayed the same	31	21
Got a little worse	1	1
Got a lot worse	0	1

[a]Number.
[b]$p = 0.10$, Wilcoxon rank sum test.

tors other than biomechanical force common to both groups produced a beneficial effect. Further studies examining other aspects of the clinical encounter, considered separately from biomechanical force, are warranted before arbitrarily designating any intervention as a "placebo."

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