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Physiotherapist-Directed Exercise, Advice, or Both for Subacute Low Back Pain

A Randomized Trial

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Background: Advice and exercise are widely recommended for subacute low back pain, but the effectiveness of these interventions is unclear.

Objective: To investigate the effectiveness of physiotherapist-prescribed exercise, advice, or both for subacute low back pain.

Design: Factorial randomized, placebo-controlled trial.

Setting: 7 university hospitals and primary care clinics in Australia and New Zealand.

Patients: 259 persons with subacute low back pain (>6 weeks and <3 months in duration).

Intervention: Participants received 12 physiotherapist-directed exercise or sham exercise sessions and 3 physiotherapist-directed advice or sham advice sessions over 6 weeks.

Measurements: Primary outcomes were average pain over the past week (scale, 0 to 10), function (Patient-Specific Functional Scale), and global perceived effect (11-point scale) at 6 weeks and 12 months. Secondary outcomes were disability (Roland–Morris Disability Questionnaire), number of health care contacts, and depression (Depression Anxiety Stress Scales-21).

Results: Exercise and advice were each slightly more effective than placebo at 6 weeks but not at 12 months. The effect of advice on the pain scale was −0.7 point (95% CI, −1.2 to −0.2 point; $P = 0.011$) at 6 weeks and −0.4 point (CI, −1.0 to 0.3 point; $P = 0.27$) at 12 months, whereas the effect of exercise was −0.8 point (CI, −1.3 to −0.3 point; $P = 0.004$) at 6 weeks and −0.5 point (CI, −1.1 to 0.2 point; $P = 0.14$) at 12 months. The effect of advice on the function scale was 0.7 point (CI, 0.1 to 1.3 points; $P = 0.014$) at 6 weeks and 0.6 point (CI, 0.1 to 1.2 points; $P = 0.023$) at 12 months, and the effect of exercise was 0.4 point (CI, −0.2 to 1.0 point; $P = 0.174$) at 6 weeks and 0.5 point (CI, −0.1 to 1.0 point; $P = 0.094$) at 12 months. The effect of advice on the global perceived effect scale was 0.8 point (CI, 0.3 to 1.2 points; $P < 0.001$) at 6 weeks and 0.3 point (CI, −0.2 to 0.9 point; $P = 0.24$) at 12 months, and the effect of exercise was 0.5 point (CI, 0.1 to 1.0 point; $P = 0.017$) at 6 weeks and 0.4 point (CI, −0.1 to 1.0 point; $P = 0.134$) at 12 months. When administered together, exercise and advice had larger effects on all outcomes at 6 weeks (effect on pain, −1.5 [CI −2.2 to −0.7 point; $P = 0.001$], with similar results for other primary outcomes); however, by 12 months, there was a statistically significant effect only for function (effect, 1.1 points [CI, 0.3 to 1.8 points]; $P = 0.005$).

Limitation: Physiotherapists were not blinded.

Conclusions: In participants with subacute low back pain, physiotherapist-directed exercise and advice were each slightly more effective than placebo at 6 weeks. The effect was greatest when the interventions were combined. At 12 months, the only effect that persisted was a small effect on participant-reported function.

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Back pain is 1 of the most frequent reasons for consultation with a general practitioner (1, 2). Most treatment guidelines provide advice for patients on managing acute or recent-onset low back pain but not chronic pain (3). This reflects the view that acute low back pain is typically self-limited and that only a small proportion of persons develop chronic pain. However, a recent systematic review of the prognosis of acute low back pain (4) showed that this view is inaccurate: Pain and disability are typically ongoing, and recurrences are common. Thus, effective treatments for patients whose pain and disability persist beyond the acute phase are needed. We are interested in the subacute phase, which is the transition period from acute (duration <6 weeks) to chronic (duration >3 months) low back pain.

All treatment guidelines (3) endorse advice as a treatment for subacute low back pain, and advice is the most frequently administered treatment in general practice (1). Exercise is the most common treatment for low back pain (2, 5, 6), and some guidelines recommend it for subacute low back pain (3). However, a systematic review of treatment for subacute low back pain (7) concluded that no high-quality evidence exists for the efficacy of any intervention. To address this knowledge gap, we conducted a factorial randomized, placebo-controlled trial of the effect of exercise, advice, or both on pain, function, and global perceived effect.

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Context

Exercise and advice are common treatments for patients with subacute low back pain, but their effectiveness is unclear.

Contribution

In this trial, 259 adults with subacute low back pain received 12 real or sham physiotherapist-directed exercise sessions and 3 real or sham advice sessions over 6 weeks. Compared with sham exercise and sham advice, patients who received real exercise and real advice had the most benefit at 6 weeks. However, only a small benefit on patient-reported function persisted at 12 months.

Implication

Compared with no exercise or advice, a combination of physiotherapist-directed exercise and advice seems to improve pain and function in the short term for patients with subacute low back pain.

—The Editors

METHODS

Setting

The trial was conducted at 7 physiotherapy clinics in Australia and New Zealand, of which 6 were in university teaching hospitals and 1 was in a primary care clinic. There were 16 physiotherapists. Each clinic had 1 to 5 therapists providing treatment. We enrolled participants from January 2001 to June 2003. The study protocol was approved by the institutional review boards of the University of Sydney, Sydney, Australia, and of each clinic.

Participants

We sought persons between 18 and 80 years of age with nonspecific low back pain lasting for at least 6 weeks but no longer than 12 weeks. Participants were recruited by direct referral to the trial by a health care professional ($n = 1$), invitations to patients on hospital waiting lists for physiotherapy treatment of low back pain ($n = 73$), and advertisements in newspapers ($n = 185$). Exclusion criteria were spinal surgery in the past 12 months, pregnancy, nerve root compromise, confirmed or suspected serious spinal abnormality (for example, infection, fracture, or the cauda equina syndrome), contraindications to exercise, and poor comprehension of the English language. We did not exclude participants who were receiving low back pain treatment other than spinal surgery. Potential participants who reported osteoarthritis; spondylitis; spondylolysis; spondylolisthesis; disc protrusion, herniation, or prolapse; or spinal stenosis were eligible. We asked participants not to take other treatments for low back pain during the 6-week treatment phase. Written informed consent was obtained from all participants before they enrolled in the trial.

Randomization and Interventions

After completing the baseline assessment, we randomly allocated participants to 1 of 4 intervention groups: exercise and advice, exercise and sham advice, sham exercise and advice, or sham exercise and sham advice. The allocation schedule was generated by using the random-number function in Microsoft Excel (Microsoft, Inc., Redmond, Washington), and the allocation codes were placed in sequentially numbered, sealed, opaque envelopes. At each site, the trial coordinator or the physiotherapist allocated participants to groups by opening the next numbered envelope. This process ensured that allocation was concealed from participants, referring medical practitioners, trial staff who determined eligibility, and the assessor of outcomes.

The 12 exercise or sham exercise sessions were delivered over 6 weeks: 3 sessions per week in weeks 1 and 2, 2 sessions per week in weeks 3 and 4, and 1 session per week in weeks 5 and 6. In weeks 1, 2, and 4, participants also received advice or sham advice. Sham treatments were designed to provide similar contact time with the treating clinician. The clinicians who provided the sham treatments were the same ones who provided the real treatments. Registered physiotherapists who received training from an experienced clinical psychologist delivered treatment. Treatment consistency was promoted at the initial staff meeting and at regular trial treatment meetings, and by providing a treatment manual to all treatment providers. To assess treatment validity, an investigator recorded and assessed sample treatment sessions. In addition, 1 investigator regularly visited each treatment site to monitor delivery of treatment. The comprehensive treatment manual is in the **Appendix** (available at www.annals.org).

Exercise

The exercise program was based on the program described by Lindström and colleagues (8). It included an individualized, progressive, submaximal program designed to improve the abilities of participants to complete functional activities that they specified as being difficult to perform because of low back pain. Each participant undertook aerobic exercise (for example, a walking or cycling program); stretches; functional activities; activities to build speed, endurance, and coordination; and trunk- and limb-strengthening exercises. Physiotherapists used principles of cognitive-behavioral therapy, including setting goals of progressively increasing difficulty, encouraging self-monitoring of progress, and promoting self-reinforcement (9). Physiotherapists provided individualized home exercise programs, which they regularly reviewed, and they encouraged continuation of the home program after the intervention finished.

Sham Exercise

The control for the exercise intervention consisted of sham pulsed ultrasonography (5 minutes) and sham pulsed short-wave diathermy (20 minutes). The sham units were identical to active units (for example, the on and off lights illuminated and the output dial moved) except that they did not provide output. To optimize treatment credibility, physiotherapists followed the usual clinical routine for delivering these treatments. The active forms of these treatments delivered in pulsed mode do not produce heat; thus, previous experience with the treatments would not unblind participants. Participants allocated to exercise did not receive the active forms of these treatments.

Advice

Advice sessions were based on the program by Indahl and colleagues (10) and aimed to encourage a graded return to normal activities. The physiotherapist explained the benign nature of low back pain, addressed any unhelpful beliefs about back pain, and emphasized that being overly careful and avoiding light activity would delay recovery.

Sham Advice

During sham advice sessions, participants were given the opportunity to talk about their low back pain and any other problems. The physiotherapist responded in a warm and empathic manner, displaying genuine interest in the participant, but did not give advice about the low back pain (11). Participants were told that the trial included active and placebo physiotherapy treatments and that they would receive 2 treatments, but they were not told whether the interventions they received were active or sham.

Outcomes and Measurements

We determined participants' perceptions of the effectiveness of treatment at the beginning of the trial and at 12 months. We assessed treatment adherence by the number of appointments attended, session duration, and amount of time the physiotherapist spent with each participant. Participants were asked not to seek other treatments during the 6-week treatment period. Participants who discontinued treatment were encouraged to return for follow-up.

Immediately before randomization, we obtained baseline measurements. We collected additional data on work status, medication use, side effects, adverse events, and number and type of co-interventions at 6 weeks, 3 months, and 12 months after randomization.

We chose primary and secondary outcomes a priori. The primary outcomes were pain, global perceived effect, and functional ability at 6 weeks and 12 months. Secondary outcomes were pain, global perceived effect, and functional ability at 3 months; number of health care contacts during the past 6 weeks (determined at 12 months); and disability and depression at 6 weeks, 3 months, and 12 months.

We rated pain as average pain over the past week on a scale of 0 (no pain) to 10 (worst pain possible) (12). We measured functional ability by using the Patient-Specific Functional Scale (score range, 0 [cannot perform activity] to 10 [can perform activity at preinjury level]) (13). We measured global perceived effect of treatment on an 11-point scale, ranging from −5 (vastly worse) to 5 (completely recovered), with 0 being no change. We measured disability with the Roland–Morris Disability Questionnaire (score range, 0 to 24) (14). We measured depression, anxiety, and stress by using the 21-item Depression Anxiety Stress Scales (DASS-21) (score range for each subscale, 0 to 42) (15). These measures have acceptable psychometric properties and are widely used in trials of low back pain (16).

Participants rated treatment credibility after the first treatment (17) (**Appendix Table**, available at www.annals.org). At 12 months, participants rated how helpful, understanding, and friendly they found the therapists on a 7-point scale.

The assessor who collected outcomes was blinded to treatment. To evaluate success of blinding, we asked the assessor to nominate the participant's treatment group at each follow-up. We evaluated the agreement between the assessor's nomination and treatment group by using percentage-exact agreement and the κ statistic. Agreement ranged from 38% to 41% (the expectation with complete blinding was 25%), and the κ statistic ranged from 0.18 to 0.21, suggesting that blinding was successful in most but not all cases.

Statistical Analysis

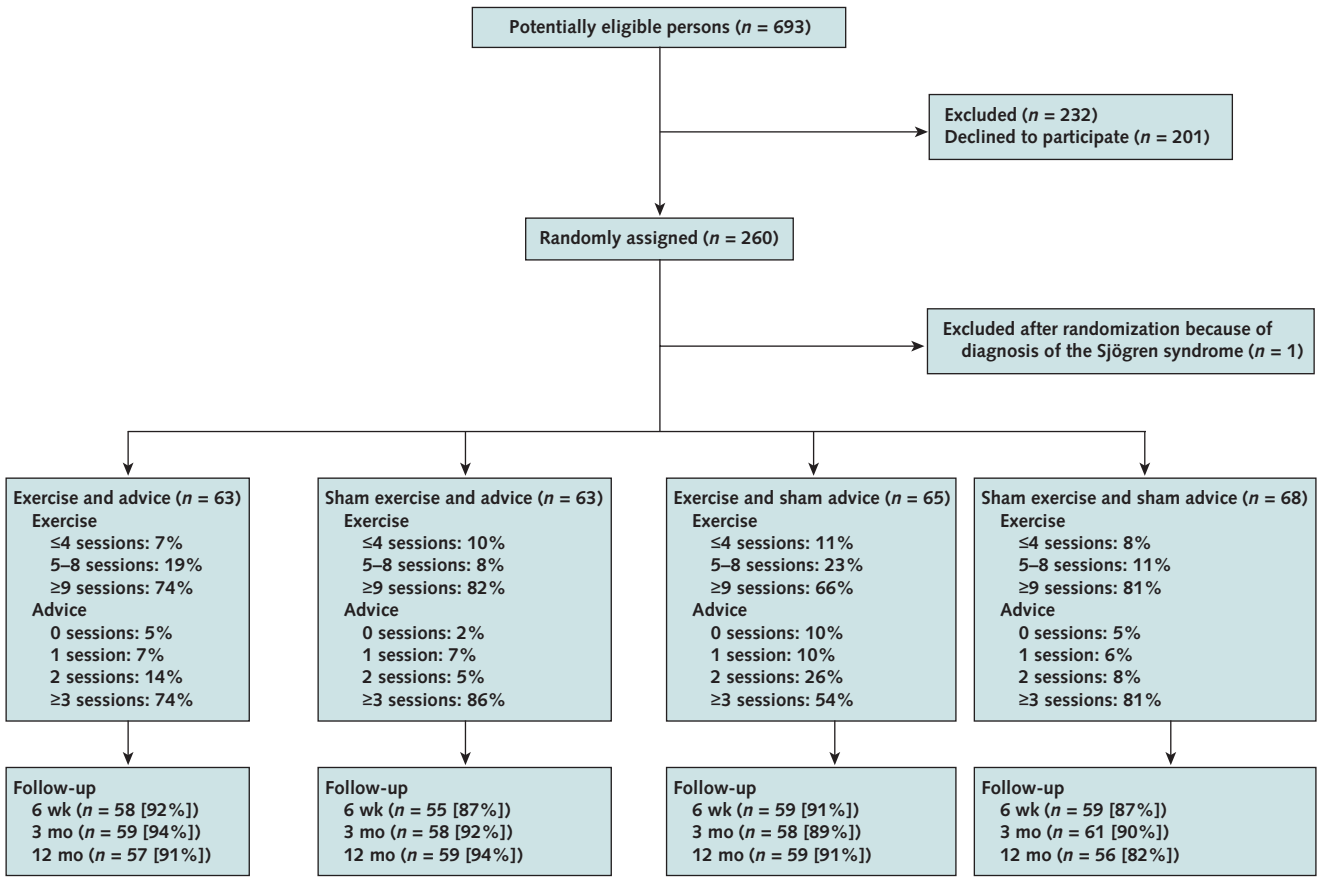
A sample size of 208 participants, determined a priori, provided 80% power to detect an effect of exercise or advice of 1 point on each of the pain, function, and global perceived effect scales. We regarded these effects as minimal important differences for these outcomes (18). To allow for loss to follow-up, we recruited 259 participants.

We double-entered and analyzed the data on an intention-to-treat basis. When an item response was missing from the DASS-21 (1.6% of scale items), we replaced it with the mean response for the other items of the scale for that participant.

We analyzed the effects of exercise and advice separately for each outcome with linear mixed models by using the MIXED procedure of SAS, version 9.1 (SAS Institute, Inc., Cary, North Carolina), in which time was defined as a repeated factor. We conducted analyses by using all measurements (including baseline measurements) as outcome variables under a mixed-model longitudinal analysis that accounted for correlation over time within participants and correlation within clinics.

To allow for correlation of participants within physiotherapy clinics, we included clinic in the mixed models as a random effect and the clinic-by-time interaction. We constructed models with dummy variables representing the ex-

Figure 1. **Study flow diagram.**



ercise and advice interventions, time and the intervention-by-time interactions, and potential confounders (current pain medication use, current smoker, current exercise activity, low back pain treatment in the previous 6 weeks, and previous surgery for low back pain). Because the relationships between outcomes and time were not linear, we modeled time as a categorical variable.

We obtained estimates of the effect of the interventions by constructing linear contrasts to compare the mean change in outcome from baseline to each time point between the treatment and control groups of each intervention, with adjustment for the other variables. For this analysis, we sought to assess the effects of the exercise and advice interventions independently. We also compared the effect of combined exercise and advice with no exercise or advice by using a model that included the interaction between the 2 interventions (and interventions with time) and constructing linear contrasts to compare the mean change in outcome between the no exercise and no advice group and the combined exercise and advice group.

We considered interactions between treatments and site (modeled as a random effect) by using the following procedure. For each outcome, we compared 2 models: model 1 (did not include interactions) and model 2 (included interactions between interventions and site and their interactions with time, entered as random effects). We assessed the effect of the intervention-by-site interactions by using estimated restricted log likelihoods (multiplied by −2) and by comparing the difference with a chi-square distribution with degrees of freedom defined by the number of extra random effects in model 2 compared with model 1 (19). However, we assessed only the outcome of pain because models including the interactions between treatments and site did not converge for other outcomes.

We analyzed the effects of exercise and advice on the number of health care contacts at 12 months with factorial analysis of covariance by using a linear regression approach in SPSS, version 14.0 for Windows (SPSS, Inc., Chicago, Illinois).

Role of the Funding Sources

The study was funded by the National Health and Medical Research Council of Australia and the Australasian Low Back Pain Trial Committee. The funding sources had no role in study design; collection, analysis, or interpretation of the data; or writing of the report. The investigators

had final responsibility in the decision to submit the report for publication.

RESULTS

Participant Recruitment and Follow-up

Of the 693 potential participants identified by trial staff during the recruitment period (**Figure 1**), 232 were ineligible and 201 chose not to participate. The reasons for ineligibility were symptom duration less than 6 weeks (n = 7) or greater than 3 months (n = 147), confirmed or suspected serious spinal abnormality (n = 9), nerve root compromise (n = 4), pain not in low back region (n = 10), a resolved episode (n = 30), pregnancy (n = 1), poor understanding of the English language (n = 18), advice against participation in exercise by a general practitioner (n = 3), age older than 80 years (n = 1), and recent or scheduled surgery (n = 2). Of the 201 eligible persons who chose not to participate, 57 were initially willing to participate, but we could not arrange mutually suitable appointment times or venues. Only 3 potential participants chose not to participate because of the possibility of receiving sham treatment. We excluded 1 person after randomization because of diagnosis of the Sjögren syndrome. Of the 259 included participants, 231 (89%) attended the 6-week follow-up, 236 (91%) attended the 3-month follow-up, and 231 (89%) attended the 12-month follow-up.

Baseline Characteristics

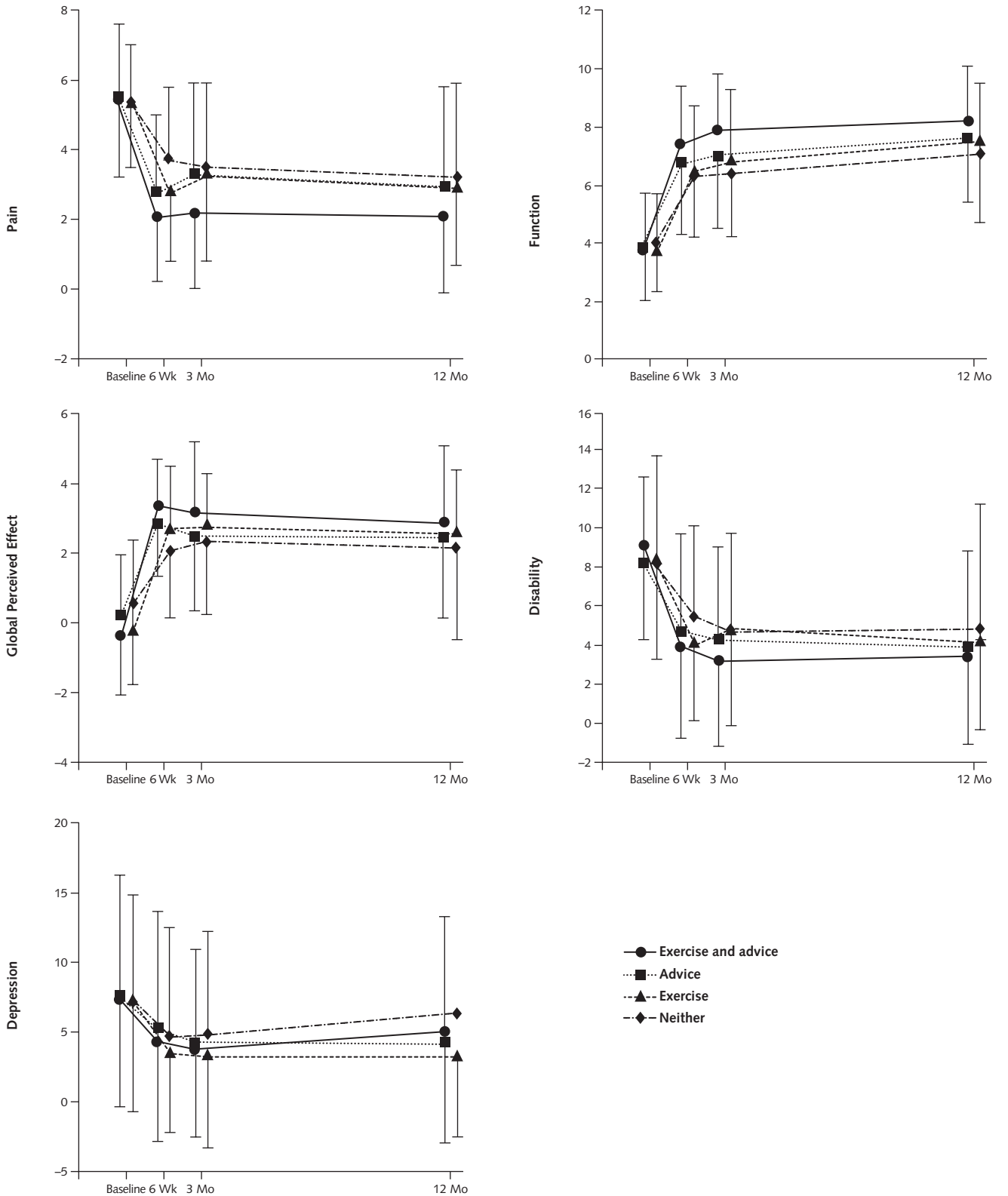
The groups were similar at baseline (**Table 1**), except that slightly more participants in the sham exercise and sham advice group (6%) than in other groups had had

Table 1. **Baseline Characteristics***

Characteristic	Exercise plus Advice (n = 63)	Sham Exercise plus Advice (n = 63)	Exercise plus Sham Advice (n = 65)	Sham Exercise plus Sham Advice (n = 68)	All Participants (n = 259)
Mean age (SD), *y*	50.1 (15.4)	51.2 (16.1)	48.0 (16.1)	50.0 (15.6)	49.9 (15.8)
Women, %	46	44	46	54	48
Working before LBP, %	62	54	59	53	57
Working now, %	56	49	52	47	51
Smoker, %	17	14	12	21	16
Currently performs regular exercise, %	52	59	62	46	55
LBP history, %					
Previous episodes of LBP	71	69	60	65	66
Previous sick leave for LBP	21	18	16	21	19
Previous surgery for LBP	0	6	3	0	2
Duration of current LBP episode, %					
6–8 wk	48	51	45	47	47
9–11 wk	34	41	38	37	38
12 wk	18	8	17	16	15
Pain referred to the leg, %	29	38	31	29	32
Pain in areas other than the back or leg, %	28	30	26	19	26
LBP treatment in past 6 weeks, %	60	62	72	62	64
Taking pain medication, %	37	33	35	38	36
Mean Tampa Scale for Kinesiophobia score (SD)†	39.0 (8.0)	38.9 (7.9)	39.5 (8.6)	38.1 (8.2)	38.8 (8.1)
Mean pain self-efficacy questionnaire score (SD)‡	44.4 (12.8)	46.3 (11.1)	44.3 (11.3)	43.7 (13.4)	44.6 (12.2)
Mean PRSS score (SD)					
Coping§	30.4 (6.8)	30.1 (8.4	30.2 (7.3)	30.5 (6.3	30.3 (7.2)
Catastrophe‖	17.3 (9.1)	18.0 (10.5)	17.9 (8.6)	18.0 (7.9	17.8 (9.0)
Mean outcome scores at baseline (SD)					
Pain¶	5.4 (2.2)	5.5 (2.1)	5.4 (1.9)	5.3 (1.7)	5.4 (2.0)
Patient-Specific Functional Scale**	3.8 (1.9	3.8 (1.8)	3.7 (2.0	4.0 (1.7	3.8 (1.9
Global perceived effect††	−0.4 (2.3)	0.2 (2.3)	−0.3 (2.6)	0.5 (2.3)	0.0 (2.4)
Roland–Morris Disability Questionnaire‡‡	9.1 (4.8)	8.2 (4.4)	8.3 (5.0)	8.1 (5.6)	8.4 (5.0)
DASS					
Depression§§	7.3 (8.8)	7.4 (7.7)	7.1 (7.8)	7.1 (7.6)	7.2 (8.0)
Anxiety‖ ‖	4.7 (6.7)	5.2 (7.4)	6.2 (7.6)	5.4 (6.9)	5.4 (7.1)
Stress¶¶	10.1 (9.0)	11.7 (8.7)	12.6 (9.1)	11.7 (10.0)	11.5 (9.2)

* DASS = Depression Anxiety Stress Scales; LBP = low back pain; PRSS = pain-related self-statement scale.
† 17 (low fear of movement) to 68 (high fear of movement).
‡ 0 (low self-efficacy) to 60 (high self-efficacy).
§ 0 (poor coping strategies) to 45 (strong coping strategies).
‖ 0 (low catastrophe) to 45 (high catastrophe).
¶ 0 (no pain) to 10 (worst pain possible).
** 0 (cannot perform activity) to 10 (can perform activity at preinjury level).
†† −5 (vastly worse) to 5 (completely recovered), with 0 being unchanged.
‡‡ 0 (no disability) to 24 (high disability).
§§ 0 (no depression) to 42 (high depression).
‖ ‖ 0 (no anxiety) to 42 (high anxiety).
¶¶ 0 (no stress) to 42 (high stress).

Figure 2. **Outcomes in the 4 treatment groups.**



Values shown are unadjusted means (SDs). Measurements were obtained at baseline, 6 weeks, 3 months, and 12 months, but the data are slightly offset in the figure for clarity.

surgery for back pain (3% in the exercise and sham advice group and 0% in the other 2 groups). Baseline measurements of the primary outcome variables were similar for participants seeking medical care and those recruited from the community (data not shown). Participants had moderate levels of pain and fear avoidance beliefs and were mildly disabled and distressed but were generally confident that they could manage normal activities despite their pain.

Study Treatments

On average, participants attended a mean of 9.4 exercise sessions (SD, 3.2) and 10.2 sham exercise sessions (SD, 3.0) of the planned 12 sessions. Participants attended a mean of 2.9 advice sessions (SD, 1.1) and 2.5 sham advice sessions (SD, 1.1) of the planned 3 sessions. The mean duration of exercise sessions was 54.0 minutes (SD, 16.3), of which 35.6 minutes (SD, 12.6) were spent with a physiotherapist. The mean duration of sham exercise sessions was 47.0 minutes (SD, 25.0), of which 22.9 minutes (SD, 8.4) were spent with a physiotherapist. Mean durations of advice and sham advice sessions were 20.0 minutes (SD, 4.9) and 19.0 minutes (SD, 5.3), respectively.

The median score for each treatment credibility item was 5 of 6 (**Appendix Table**, available at www.annals.org). Participants receiving sham exercise typically rated each credibility item 1 point lower than did participants receiving exercise, whereas the credibility item ratings for advice and sham advice were similar. At 12 months, the mean group ratings for therapist helpfulness, understanding, and friendliness ranged from 6.1 to 6.8 of 7 points.

Other Treatments

At baseline, nearly two thirds (64%) of the participants had received some form of treatment for their current episode of low back pain. Although participants were discouraged from seeking additional treatment, 4 (6%) participants in the exercise and advice group, 3 (5%) in the advice and sham exercise group, 7 (11%) in the exercise and sham advice group, and 9 (13%) in the sham exercise and sham advice group received co-interventions during the treatment phase. The most frequently reported co-interventions were other forms of physiotherapy (spinal manipulative therapy, massage, exercise, ultrasonography, shortwave, traction, and heat), drug therapy, acupuncture, and chiropractic and osteopathic treatment.

Effectiveness of Treatment

Figure 2 shows the unadjusted outcomes over time. **Table 2** shows the effects of exercise, advice, and the treatments together from the fully adjusted, multivariable

Table 2. **Effects of Exercise, Advice, and Combined Exercise and Advice***

Variable	Exercise versus No Exercise		Advice versus No Advice		Exercise and Advice versus No Exercise or Advice	
	Relative Change (95% CI)†	*P* Value	Relative Change (95% CI)†	*P* Value	Relative Change (95% CI)†	*P* Value
Pain						
6 wk‡	−0.8 (−1.3 to −0.3)	0.004	−0.7 (−1.2 to −0.2)	0.011	−1.5 (−2.2 to −0.7)	<0.001
3 mo	−0.5 (−1.1 to 0.1)	0.092	−0.6 (−1.2 to 0.0)	0.050	−1.1 (−2.0 to −0.3)	0.009
12 mo‡	−0.5 (−1.1 to 0.2)	0.138	−0.4 (−1.0 to 0.3)	0.27	−0.8 (−1.7 to 0.1)	0.069
Patient-Specific Functional Scale						
6 wk‡	0.4 (−0.2 to 1.0)	0.174	0.7 (0.1 to 1.3)	0.014	1.1 (0.3 to 1.9)	0.006
3 mo	0.5 (0.0 to 1.1)	0.063	0.8 (0.2 to 1.4)	0.005	1.3 (0.6 to 2.1)	0.001
12 mo‡	0.5 (−0.1 to 1.0)	0.094	0.6 (0.1 to 1.2)	0.023	1.1 (0.3 to 1.8)	0.005
Global perceived effect						
6 wk‡	0.5 (0.1 to 1.0)	0.017	0.8 (0.3 to 1.2)	<0.001	1.3 (0.7 to 1.9)	<0.001
3 mo	0.5 (0.1 to 1.0)	0.030	0.3 (−0.2 to 0.8)	0.24	0.8 (0.2 to 1.5)	0.017
12 mo‡	0.4 (−0.1 to 1.0)	0.134	0.3 (−0.2 to 0.9)	0.24	0.8 (0.0 to 1.6)	0.059
Roland–Morris Disability Questionnaire						
6 wk	−0.8 (−1.8 to 0.3)	0.141	−0.5 (−1.6 to 0.5)	0.34	−1.3 (−2.7 to 0.2)	0.085
3 mo	−0.1 (−1.2 to 1.1)	0.901	−0.9 (−2.1 to 0.2)	0.099	−1.0 (−2.6 to 0.6)	0.20
12 mo	−0.3 (−1.6 to 0.9)	0.597	−0.6 (−1.9 to 0.6)	0.34	−0.9 (−2.7 to 0.8)	0.29
DASS for depression						
6 wk	−0.7 (−2.5 to 1.2)	0.47	0.8 (−1.0 to 2.7)	0.37	0.2 (−2.5 to 2.8)	0.91
3 mo	−0.3 (−2.1 to 1.6)	0.78	0.4 (−1.4 to 2.2)	0.65	0.2 (−2.4 to 2.7)	0.91
12 mo	−0.6 (−2.6 to 1.3)	0.51	0.3 (−1.7 to 2.2)	0.78	−0.4 (−3.1 to 2.3)	0.76

* Effects presented are from the completely adjusted multivariable mixed model, with adjustment for the following baseline variables: currently taking pain medication, currently smoking, currently exercising, low back pain treatment in previous 6 weeks, and previous surgery for low back pain. For the pain, disability, health contacts, and depression outcomes, negative values provide evidence of treatment effectiveness. For the function and global perceived effect outcomes, positive values provide evidence of treatment effectiveness. Participants were asked to describe their back compared with when their episode first started. DASS = Depression Anxiety Stress Scales.
† Confidence intervals are asymmetric because the analysis was performed on log of (number health care contacts in the past 6 weeks assessed at 1 year + 0.5).
‡ Primary outcome.

mixed-model analysis. The effect of exercise (the adjusted difference in outcomes between exercise and sham exercise groups) at 6 weeks was −0.8 point (95% CI, −1.3 to −0.3 point) on the pain scale and 0.5 point (CI, 0.1 to 1.0 point) on the global perceived effect scale. That is, exercise reduced pain and improved perceptions of global effect. The effect of advice at 6 weeks was −0.7 point on the pain scale (CI, −1.2 to −0.2 point) and 0.8 point on the global perceived effect scale (CI, 0.3 to 1.2 points). These differences were smaller and were no longer statistically significant at 12 months. The effects of advice at 6 weeks (0.7 point [CI, 0.1 to 1.3 points]) and 12 months (0.6 point [CI, 0.1 to 1.2 points]) on the function scale were statistically significant. The effect of exercise at 6 weeks (0.4 point [CI, −0.2 to 1.0 point]) and 12 months (0.5 point [CI, −0.1 to 1.0 point]) on the function scale was not statistically significant.

Benefits of exercise or advice on pain were not statistically significant at 3 months. The effect of advice at 3 months (0.8 point [CI, 0.2 to 1.4 points]) on the function scale was statistically significant, but the effect of exercise was not. The effect of exercise, but not advice, on the global perceived effect scale was statistically significant at 3 months (0.5 point [CI, 0.1 to 1.0 point]). The effects of advice or exercise on the disability scale were not statistically significant at 6 weeks, 3 months, or 12 months.

Effects on depression were not statistically significant at any time point. The effect of exercise or advice on the number of health care contacts was not statistically significant at 12 months.

For pain, function, and global perceived effect, the effect of combined treatment was larger than the effect of exercise or advice alone. The effect of combined treatment was statistically significant for function at all time points and for pain and global perceived effect at 6 weeks and 3 months but not at 12 months (**Table 2**). Combined treatment had no effect on disability, number of health care contacts, or depression outcomes.

Interventions did not vary by site (chi-square, 3.1; $P = 0.5$) for the pain outcome. Primary outcomes were similar for participants seeking medical care and those recruited by advertisement from the community (data not shown).

Adverse Events

Twenty-one participants reported mild adverse effects that they attributed to the intervention (10 participants in the exercise and advice group, 3 in the sham exercise and advice group, 6 in the exercise and sham advice group, and 2 in the sham exercise and sham advice group). These effects did not result in withdrawal from any intervention. They included muscle soreness, increased pain, tiredness, nausea, weight gain, itchy scalp, and numbness in the legs.

DISCUSSION

Our study provides evidence on the effects of physiotherapist-prescribed exercise and advice, alone and in combination, on pain, function, and global perceived effect for persons with moderately painful and mildly disabling subacute low back pain. Advice was slightly more effective than placebo in improving pain, function, and global perceived effect at 6 weeks of follow-up. Exercise was more effective than placebo in improving pain and global perceived effect at 6 weeks of follow-up. However, the effects of each treatment were smaller at 3 months and were smaller again and not statistically significant at 12 months. When both treatments were combined, the effect was larger and significant at 6 weeks, 3 months, and 12 months for function and at 6 weeks and 3 months for pain and global perceived effect. This result is important because no other efficacious treatments for subacute low back pain are known (7).

Currently, the mechanisms underlying the effect of exercise and advice on spinal pain are unclear. For example, back exercises have been justified on the basis that they improve back muscle function, but how improved muscle function results in a reduction in low back pain is unclear. Of more importance, when muscle function and pain have been investigated in trials of exercise for low back pain, the relationship between improvement in pain and improvement in muscle function often has been found to be weak (20, 21). From a psychological perspective, the reassurance from advice and the experience of exercising could help participants gain confidence and overcome fears of pain, leading to increased functioning (22). Research that investigates the mechanism of action of these 2 treatments is needed.

Before our study, little evidence existed on the effectiveness of advice or exercise as treatments for subacute low back pain. Many trials that studied patients with subacute low back pain (23–30) included patients with symptom duration outside the interval that the Cochrane Back Review Group uses to define subacute low back pain (6 to 12 weeks) (31). For example, Staal and colleagues' study (30) was categorized in a recent systematic review (6) as a trial of subacute low back pain, yet approximately 25% of participants had acute symptoms (duration <6 weeks) and approximately 25% had chronic symptoms (duration >12 weeks). Only 4 trials potentially meet the Cochrane criterion (8, 10, 32, 33). However, these studies apply the criterion to the duration of work absence, not to the duration of the low back pain episode. The comparison treatment in these 4 trials was usual care. Both advice trials (10, 32) found that advice significantly improved return to work rates; for example, in Hagen and colleagues' study (32), the relative risk for return to work at 6 months was 1.40. Lindström and colleagues (8) found that exercise improved rates of return to work, with a relative risk for return to work at 3 months of 1.38. These 3 trials (8, 10, 32) measured only return to work as an outcome; whether the treatments had an effect on other outcomes, such as pain and disability, was unclear. The fourth exercise trial (33) found that a group exercise program had no effect on any

primary outcome, including pain, disability, or sick leave. To our knowledge, no study has assessed the combined effects of exercise and advice or has included a placebo group, as we did in our study.

Whether the treatment effects observed are sufficiently large to be clinically important is an important consideration. Farrar and colleagues' study (34) of 2700 patients with chronic pain noted that an improvement of 1.0 point on an 11-point pain scale most accurately classified patients who considered themselves to have at least minimal improvement of pain, and 1.7 points was the best cut-off for patients who considered themselves to have much improvement of pain. Applying these cut-offs to our trial results (**Table 2**), we estimate that most patients may not consider the effects of exercise or advice as single treatments clinically worthwhile, whereas they may consider the effect of combined exercise and advice worthwhile. We say "may" because a variety of patient opinions were evident in Farrar and colleagues' study (34). This suggests that it is important to consult with the individual patient when trying to judge whether a treatment is likely to be clinically worthwhile.

Caution should be used when generalizing our findings to other groups and to exercise programs other than those in our trial. In the same way that different types and doses of drugs are used to treat pain, different types and doses of exercise can be used. It is unlikely that all exercise programs are equally effective. In our opinion, the program we evaluated had the following key characteristics: It focused on the specific functional problems of each patient; it was supervised, individualized, submaximal, and progressive; a home exercise program was provided; and therapists used principles underlying cognitive-behavioral therapy.

A recent systematic review (6) found that supervision, individualized treatment, and high workout intensity were associated with greater effects in trials of exercise for chronic low back pain.

Although it may be tempting to consider replacing 3 sessions of advice with more easily administered advice in the form of booklets or videos, this may be inappropriate for 2 reasons. First, trials of passive educational materials for subacute back pain have failed to provide clear evidence of efficacy (35). In addition, the advice sessions aim to change patient behavior and although information is important, it is not sufficient to achieve change in health behavior (36). The initial advice session was preceded by a thorough clinical examination, sessions were tailored to the participant, and the participants had the opportunity to ask questions.

Our study has limitations. The care providers could not be blinded, which is unavoidable when such treatments as advice and exercise are being studied. Participants were blinded, but the nature of the sham interventions was such that blinding was probably not as complete as can be achieved in a drug trial. In addition, because our outcome measures were self-reported, incomplete blinding of participants implies incomplete blinding of outcome assessments. To minimize bias, we blinded the assessor who collated and scored the test (and could be asked to clarify the meaning of an item). To maximize blinding of participants, we took great care in our interactions with the participants to mask the true identity of the treatments. The success of this is seen in the treatment credibility ratings, which are very similar across the treatment groups. Another limitation was that we replaced missing responses to DASS-21 items with the mean of the scale for that participant. Although we used this strategy for only 1.6% of scale items, the effect is to exaggerate the precision of our estimates of the treatment effects on depression outcomes. However, because only 1.6% of responses were missing, the exaggeration of precision is probably small. Also, we could test for an interaction between treatment and site for only the pain outcome because models that included interactions between treatments and site did not converge for other outcomes. Thus, treatments may have been efficacious for outcomes other than pain at some sites but not at others.

Our study provides evidence that exercise and advice are slightly more effective than placebo in improving pain at 6 weeks in persons with subacute low back pain. When both treatments were administered together, the effects were large enough that they could be considered clinically worthwhile by some participants at 6 weeks. However, the effects of each treatment alone and combined were smaller at 3 months and were smaller again and not statistically significant at 12 months. These results suggest that the interventions could be considered for their short-term effects in persons with subacute low back pain.

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Appendix Table. **Median Scores for the 4 Items on the Treatment Credibility Scale***

Variable	Exercise plus Advice	Sham Exercise plus Advice	Exercise plus Sham Advice	Sham Exercise plus Sham Advice	All Participants
Confident that treatment will relieve pain	5	4	5	4	5
Confident that treatment will help manage pain	5	5	5	4	5
Confident to recommend treatment to friend	5	4	5	4	5
How logical is the treatment?	6	5	6	5	5
Total score	21	18	20	18	20

* Participants were asked to rate each of the 4 questions on a 7-point scale, with scores ranging from 0 (not confident or not logical) to 6 (absolutely confident or very logical). Data were collected after the first treatment ($n = 236$).