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Should We Give Detailed Advice and Information Booklets to Patients With Back Pain?

A Randomized Controlled Factorial Trial of a Self-Management Booklet and Doctor Advice to Take Exercise for Back Pain

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Study Design. Randomized controlled factorial trial.

Objective. To assess the effectiveness of a booklet and of physician advice to take regular exercise.

Summary of Background Data. Educational booklets are one of the simplest interventions for back pain but have not been shown to alter pain and function. Although there is evidence that advice to mobilize is effective, doctors have also been advised to encourage regular exercise—but there is no evidence that such advice alone improves outcomes.

Method. Eight doctors from six practices randomized 311 patients with a new episode of back pain using sealed numbered opaque envelopes to receive a detailed self-management booklet, advice to take regular exercise, both, or neither. All groups were advised to mobilize and to use simple analgesia. Patients were telephoned during the first week after entry into the study, and after 3 weeks to assess a validated numerical pain/function score (0 = no pain normal activities to 100 = extreme pain no normal activities). Patients also returned a postal questionnaire in the first week with the Aberdeen pain and function scale, a knowledge score, and a reliable satisfaction scale (mean score of 4 items: 0 = not satisfied to 100 = extremely satisfied).

Results. Pain/function scores were obtained in 239 (77%) patients. There were interactions between exercise and booklet groups for both pain/function scores and the Aberdeen scale, which are unlikely to have been chance findings ($P = 0.009$ and $P = 0.012$, respectively). In comparison with the control group, there were reductions in the pain/function score in the first week with a booklet (−8.7, 95% CI −17.4 to −0.03) or advice to exercise (−7.9; −16.7 to 0.8) but much less effect with both together (−0.08, −9.0 to 8.9). Similarly, the Aberdeen scale was lower in the booklet group (−3.8, −7.7 to 0.07) and in the exercise advice group (−5.3; −9.3 to −1.38) but much less with both combined (−1.9, −5.8 to 2.1). There was no significant difference between groups in pain/function scores by week 3, when 58% reported being back to normal. Satisfaction was increased in booklet (7.9, 1.3 to 14.4) and exercise groups (7.4, 0.8 to 13.9)), and a booklet also increased knowledge (Kruskal-Wallis χ^2 27.2, $P = 0.001$).

Conclusion. Doctors can increase satisfaction and moderately improve functional outcomes in the period immediately after the consultation when back pain is worst, by using very simple interventions: either by endorsing a self-management booklet or by giving advice to take exercise. Previous studies suggest that simple advice and the *same* written information provide reinforcement. This study supports evidence that it may not be helpful to provide a detailed information booklet and advice together, where the amounts or formats of information differ. [Key words: low back pain, information booklets, exercise, primary care] **Spine 2001;26:2065—2072**

Back pain is one of the commonest conditions seen in primary care and is a cause of major morbidity.[8,26] However, there is very little evidence to inform doctors' management of back pain in primary care. In particular, there have been few trials to inform simple interventions in the consulting room, such as the provision of advice and the use of a booklet. Regarding advice, given the evidence that exercise is likely to provide long-term benefits,[8] doctors have been advised to encourage patients to take regular exercise.[8] However, there is no evidence that providing such advice in practice will alter functional outcomes for patients. Simple interventions that are likely to be the most cost-effective, such as advice or information booklets, should be assessed as a priority before more costly interventions are subject to trial.

What is the evidence for information booklets? There are two trials listed on the Cochrane database of randomized controlled trials of the effect of an information booklet for back pain.[7,29] The first trial used date of birth to allocate patients (*i.e.*, quasi-randomized) and demonstrated that a booklet can reduce repeat visits during the subsequent year, but did not assess satisfaction, pain or function.[29] A second trial compared a nurse consultation providing advice to exercise with a booklet or usual care, and showed no effect of any intervention on functional outcomes.[7] Another trial used an education intervention supplemented by a phone call; this improved follow-up appointments but did not document functional outcomes and was based in an accident and emergency department, *i.e.*, not in a typical primary care setting.[17] A trial based on mailing a pamphlet to those reporting back

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Table 1. Characteristics of Patients in Randomization Groups, and Follow-up Details

Characteristic	Control	Booklet	Exercise	Both
Baseline means (S.D.)				
Age when first had back pain	33 (14)	30 (14)	34 (16)	34 (16)
Days of pain in last 6 months	31 (56)	28 (48)	42 (66)	30 (49)
Attended doctor for back pain in last year	1.8 (2.7)	1.2 (1.2)	1.1 (1.4)	1.6 (3.1)
Years in full-time education since age 10	6.2 (1.8)	6.7 (2.7)	7.1 (2.9)	6.3 (1.7)
Age	47 (17)	42 (14)	47 (14)	47 (12)
Baseline proportions				
Married/living as married	30 (86%)	31 (71%)	30 (75%)	38 (81%)
Legal claims	4 (8%)	4 (7%)	1 (2%)	5 (9%)
Slow-onset back pain	14 (29%)	21 (38%)	20 (39%)	21 (36%)
Attack started >10 days ago	33 (57%)	25 (45%)	28 (54%)	23 (47%)
Back pain for more than 3 mos (acute on chronic pain)	14 (29%)	14 (26%)	13 (25%)	18 (32%)
Paid employment	34 (69%)	40 (71%)	35 (69%)	37 (64%)
Manual employment	12 (25%)	19 (34%)	9 (18%)	19 (33%)

Denominator varies: information subject to missing values.

pain in an occupational setting showed no effect at 3 or 6 months.[14] Other trials have used patients given booklets as a control group[6] but have not been designed to assess the effectiveness of booklets *per se*. The latest trial to assess an information booklet showed important changes in beliefs about backs but no changes in functional outcomes.[4] However, the latter trial was not designed to have the power to detect changes in pain and function and hence was probably underpowered (n = 127 for main outcomes) to detect important changes in pain and function.[4] Furthermore, the first outcome measurement was after 2 weeks, which may have missed benefit in the period immediately after the consultation, when pain is at its worst. Thus, there is a clear need to better assess the effectiveness of an information booklet for back pain and function, particularly when it is endorsed by a physician, which would be expected to maximize the likely impact of a booklet.

What is the evidence for advice by doctors? Advice by doctors that patients should not rest in bed and resume normal activities as soon as possible is based on evidence from several trials,[11,13,24,27] but it is still unclear what other advice from doctors is helpful. Exercise and intensive interventions designed to improve exercise are likely to be helpful in the longer term, particularly for chronic back pain.[1,8,12,15,18,19,20,33] However, regarding simple advice to take regular exercise by health professionals—as distinct from advice to mobilize and stay active—there has only been one trial based in primary care in the United States, to the authors' best knowledge.[7] This trial showed that a consultation with a nurse providing advice to take exercise improved satisfaction with care, self-reported knowledge, and self-reported exercise but did not modify pain and function. There is no evidence about the effect of advice given by doctors to take exercise. More evidence is needed on the effectiveness of advice given by doctors to take exercise, and whether there is any reinforcement when advice and booklets are used together.

Where multiple interventions are proposed, a factorial design is optimal, both to maximize the efficiency of assessing each intervention and to allow exploration of possible interactions between groups. Assessment of interactions is important for studies using verbal advice and booklets, given that a previous large factorial trial of educational intervention—in this case for contraceptive knowledge—showed that reinforcement of verbal advice occurred only when written information was both simple and in identical format, not when a more detailed information booklet was used.[22]

The authors here report the principal results of a factorial trial to assess the impact of a patient information booklet and advice by doctors to exercise on pain, function, satisfaction and knowledge for patients with back pain, compared with the standard advice to mobilize and use analgesia.

■ Method

Practice and Patient Characteristics. Eight doctors from six practices agreed to randomize consecutive patients seeking treatment for a new episode of low back pain. Two of the doctors were from training practices, four were from budget holding (the practices had a fund that allowed them control over a limited range of services [*e.g.*, drugs, referrals]), and two were women. The mean list size was 8,600. Of the eligible patients seeking treatment from their physicians with a "new" episode of back pain, 311 agreed to take part in the study, and 4 eligible patients declined to participate. Given the episodic nature of back pain, a "new" episode was operationally defined either as acute pain, *i.e.*, duration less than 3 months, or as an exacerbation of chronic low back pain. Exclusions were minimized to ensure that the sample was representative of most patients with a new episode of back pain; those excluded were patients with "stable" chronic back pain requesting repeat prescriptions, patients aged under 16 or over 80, and patients with dementia or current major psychiatric illness (unable to complete outcome measures), progressive or multilevel neurologic deficit, cauda equina syndrome, previous history of cancer or prolonged use of oral steroids, pregnancy (different natural history of back pain), and inability to walk 50 yards normally (unable to exercise). Ownership of a telephone was also a requirement, although in practice, no patients who were otherwise eligible were excluded because of the lack of a phone.

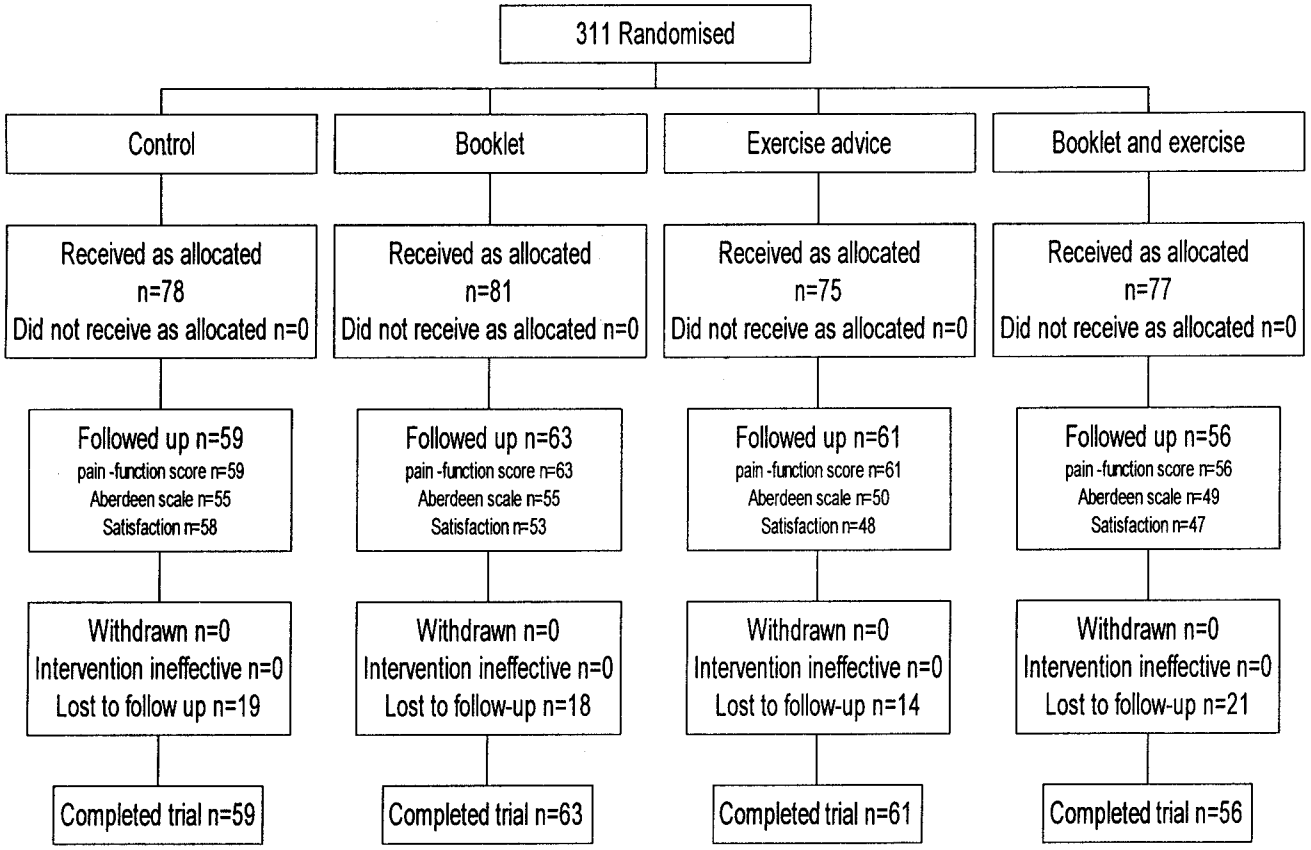

Figure 1. Study design and trial flow diagram.

There were no significant differences in the patient characteristics for patients in the four study groups (Table 1).[16,21,25,32]

Randomization. After informed consent, patients were randomized by opening of a sealed numbered opaque envelope to one of four groups defined by a 2 × 2 factorial design (Figure 1).

Factor 1 (booklet): (a) booklet ("Back Home"), (b) no booklet

Factor 2 (exercise): (a) physician advice to take exercise, (b) no advice to take exercise

All groups were given advice in a structured format using advice sheets with statements that the physician had to check off once the statement had been read or the content of the statement dealt with in the physician's own words. This format has been used successfully to clearly differentiate between groups in previous studies of advice and provision of booklets in primary care,[22,23] and it helps ensure that each group is supported by the physician in a structured and standard way. All groups were given advice to keep as mobile as possible, to minimize bed rest, and take simple analgesia (paracetamol, codydramol, ibuprofen, or equivalents as appropriate).[11,13,24,27] In the exercise group, doctors gave advice to take exercise as soon as back pain allowed, and to aim for regular exercise in the longer term (with a target of 20 minutes sufficient to bring about shortness of breath at least three times per week). In the booklet group, the physician endorsed the booklet by supporting the information enclosed and asking the patients to read the booklet carefully at home.

The "Back Home" booklet was developed in consultation with patients, back pain researchers, chartered physiotherapists, and rheumatologists to incorporate the basic information required by all groups and to encourage self-management of back pain.[5] The booklet cover gave positive messages: "you can ease your pain" and "most people do get better within 4 weeks." The booklet gave information about the following:

- Anatomy and causes of back pain, and the limited role of radiographs.

- An active self-management approach to back pain, encouraging the patient to identify positions/movements that are painful (examples given: lifting with bent back, bending, slouching, pulling/pushing) and also to identify positions to try to ease back pain (examples given to try: lying on back with knees bent, on back with legs on sofa, lying on front, sitting on firm chair with back support). Advice about mattresses and analgesia.

- Advice to minimize bed rest, keep mobile, and increase walking time each day.

- Practical tips about getting moving, getting off the bed, standing, chairs, back supports, getting washed, shoes, heat, ice, bracing for coughing or sneezing, driving, and how to lift.

- Advice about exercise: that those in poor physical are most likely to get back pain, that walking helps most recovering backs, and advice on some of the easier sports to get back to after one has had back pain (walking, swimming).

- Further reading (*Treat your own back* by Mackenzie and *Total back care* by Hayne) and helpful addresses (National

Table 2. Outcome Measures

Measure	Development of Measure
Pain and function score (0 = no pain, normal activities; 100 = extreme pain, no normal activities)	Validation study in 61 patients: Patients completed numerical rating scores for pain (0 = no pain to 100 = extreme pain) and function (0 = no normal activities to 100 = normal activities) and also well-validated criterion measures—Visual Analogue Scores (VAS), the McGill pain questionnaire,[25] and the Aberdeen back pain and function scale.[30] Numerical pain and function scores were closely and inversely correlated ($r = 0.73$). Thus, the validity and reliability of a combined pain/function score (pain score minus function score, and re-scaled to give a variable ranging from 0 (= no pain and normal activities) to 100 (= extreme pain, no normal activities) were assessed. The combined pain/function score had the best validation characteristics: it correlated well with criterion measures: McGill number of words chosen ($r = 0.78$), Aberdeen pain and function scale ($r = 0.80$), and was the most sensitive to change in the following week. Comparing the ratio of (mean change)/(S.D. change) for each measure with the same ratio for the Aberdeen pain and function scale, the pain/function score was 1.8 times more sensitive to change than the Aberdeen scale (compared with 1.4 times for the pain score alone, 1.5 function score, 0.96 McGill word count 0.89 VAS). The internal reliability of the pain/function score in the validation study was in the optimal range[32] (Cronbach's α 0.80) despite only two items, and at first and second follow-ups in the main study (α respectively 0.70 and 0.84).
Aberdeen pain and function scale	Well-validated criterion measure—includes 19 items documenting pain, range of movement, muscle weakness, analgesic use, and impact on function and daily life.[30]
Satisfaction (mean of 4 items: 0 = not at all satisfied to 100 = extremely satisfied)	Although simple Likert scales of overall satisfaction correlate well to much more extensive criterion measurements,[21] of particular interest were measurements of four specific elements of satisfaction: satisfaction with the visit to the doctor, with the amount of information provided, with the content of the information provided, and with the overall management of back pain. These components are not specifically dealt with in criterion measurements of satisfaction.[32] Using a similar format to the numerical analogue scales on a scale of 0 = not at all to 100 = extremely satisfied, four questions regarding the above items of satisfaction were included. Factor analysis of these questions indicated a 1 factor solution explaining 100% of the variance with factor loadings of 0.83, 0.94, 0.94, and 0.91, respectively. Cronbach's α for the scale comprising all four items was 0.95, *i.e.*, highly reliable.[32]
Knowledge	A simple knowledge score was constructed from nine multiple-choice questions (creating a score from 0 to 9) based on a previous questionnaire[16] and reflecting specific information provided in the booklet: posture as a cause of back pain, positions minimizing stress on the back, soft chairs making pain worse, lying down to put socks on when in acute pain, the use of ice, the use of heat, frequency of changing position while in pain, the use of a lumbar support when sitting, and walking as a good form of exercise during recovery.

Back Pain Association, the Chartered Society of Physiotherapy).

Measurement and Development of Outcomes. The principal outcome was ascertainment of pain and function by a phone call in the first week after entry into the study and after the third week: on average at a median of 6 days (interquartile range 4 to 8 days) and 27 days (22 to 30 days), respectively, after randomization, which did not differ between groups. The phone calls were made with the researcher blind to patient group, as was all handling of the data until final analysis. The main trial site was in a deprived urban area. A telephoned outcome was chosen because of concern that in a deprived area, poor response rates to a long questionnaire—which was made apparent in piloting the trial—would jeopardize the integrity of the randomized cohort and the power of the study. Thus, a brief pain and function measure was required that was both possible to ascertain over the phone in 1 or 2 minutes, and likely to be valid in the range of patients with acute pain, chronic pain, and no pain (because patients with acute back pain or acute exacerbation of chronic pain do become pain free or experience chronic pain, and any measure must be able to capture this range). A separate validation study was therefore conducted in 61 patients with chronic or acute pain and also 5 with no current back pain, which demonstrated that a pain/function score (0 = no pain normal activities to 100 = extreme pain no normal activities) had better validation characteristics than pain or function scores alone. The combined score was reliable, had criterion validity, and was sensitive to change (Table 2).

Week 1 Questionnaire. The physician gave a confidential questionnaire to patients, who were asked to complete it during the next week and return it to the research team. Two reminders were sent to patients who did not return the questionnaire. The questionnaire documented sociodemographic details, information about the current attack of back pain—*e.g.*, site, duration), past back pain, visits to the doctor, satisfaction with doctor's management of back pain (Table 2)—a simple knowledge score (Table 2), and the Aberdeen pain and function scale.[30]

Study Sample Size. The study sample size was for $\beta = 0.2$ and $\alpha = 0.05$, using the NQuery sample size program and sample size guidelines for factorial studies[10] Given a standard deviation of 25 (from pilot study data), the detection of a 10-point difference (10% of the range) in the pain/function score at week 1 between booklet and no booklet groups required 200 patients or a minimum of 250 total, allowing for 25% nonresponse. It was judged that differences much smaller than this (*e.g.*, 5% of the range) would be of marginal importance clinically. The factorial design meant that the study had the same power for exercise advice groups.[10]

Analysis. The null hypothesis was that there would be no difference between exercise and control, nor between booklet and control for pain and function (main outcome), overall satisfaction, and knowledge (secondary outcomes). The main analysis used general linear modeling for a factorial study in SPSS for Windows, version 8.0 (SPSS, Inc., Chicago, IL, USA). For the large numbers in this study, testing differences in means

Table 3. Pain and Function

		Mean Change		
	Control Mean	Booklet	Exercise	Both
Pain/function score				
Week 1	39.2 (33.0 to 45.5)	−8.7 (−17.4 to −0.03)	−7.9 (−16.7 to 0.8)	−0.1 (−9.0 to 8.9)
Week 3	19.8 (13.8 to 25.8)	−6.3 (−14.6 to 2.0)	−1.4 (−9.9 to 7.1)	−4.0 (−12.6 to 4.6)
Aberdeen pain and function scale	27.5 (24.8 to 30.3)	−3.8 (−7.7 to 0.1)	−5.3 (−9.3 to −1.4)	−1.9 (−5.8 to 2.1)

Estimated means (95% confidence intervals) for pain/function scores and Aberdeen pain and function scale and mean change compared with control group (95% confidence intervals).

between groups was robust to assumptions of the normality of the underlying distribution but not to assumptions of homogeneity of variance. For each model, the assumption of homogeneity of variance between groups was assessed by use of Levene's test: where there was significant heterogeneity, either the data were transformed or the nonparametric Kruskal-Wallis test was performed. The initial analysis for each outcome specified a factorial model to incorporate both main effects and the interaction terms between groups. If interaction terms were found to be significant at the 5% level, the results of the groups are presented separately; otherwise, the main effects are presented. The estimated group means in the control group are presented, and the estimated mean changes with intervention (and 95% confidence intervals). It was not considered that all possible comparisons between groups were of interest (see hypotheses), but the differences between intervention and control were of interest. Thus, the *t* test was used for each regression parameter to assess whether the parameter was significantly different from zero at the 5% level of significance rather than the much more conservative *post hoc* multiple comparison tests (which assume that all possible comparisons between groups are of equal interest).

■ Results

It was possible to contact 239 of 311 patients (77%) to document the main outcome (pain/function score in week 1). The reason for not completing the telephone interview was either inability to contact the patient (usually a wrong phone number) or sometimes the unavailability of the patient to talk on the phone, although several attempts were made to contact the patient at different times. Patients confirmed the main site of the pain as between the bottom of the ribs and the gluteal folds (*i.e.*, low back pain), but 16% of patients reported thoracic pain in addition (between the bottom of the neck and the bottom of the ribs).

Responding Bias

The information in the week 1 questionnaire for patients in whom the main phone outcome was ascertained (responders) was compared with that of nonresponders. There was no evidence of differences in randomization group (χ^2 1.7, = 0.64), in employment (69%, 62%, χ^2 0.76, $P = 0.38$), gender (57% female, 64%, χ^2 0.70, $P = 0.40$), years of full-time education since age 10 (means 6.5, 6.9, respectively, $t = 0.92$, $P = 0.36$), mean age (46, 46, $t = 0.22$, $P = 0.83$), back pain for more than 3 months (30%, 24%, χ^2 0.62, $P = 0.43$), age when patient first had back trouble (means 32 and 33 years, $t = 0.33$, $P = 0.74$). Thus, there was no evidence of significant responding bias in the sample.

Main Results

Pain and Function. There was no significant difference in variance between groups for the pain/function score (Levene's test $F = 0.14$, $P = 0.94$). The basic model incorporating both main effects and interaction between groups demonstrated a highly significant negative interaction between groups ($F = 6.98$, $P = 0.009$); thus, the results are presented for each group separately (Table 3). This demonstrates that there were modest (8%–9%) reductions in pain/function score by provision of either a booklet ($t = 1.98$, $P = 0.049$) or advice to exercise ($t = 1.78$, $P = 0.076$) in lessening the pain/function score in the first week. However, the provision of both a booklet and advice to exercise had little effect ($t = 0.02$, $P = 0.987$). There was no significant difference between groups in pain and function by week 3. The Aberdeen scale (returned after the first week) confirmed a significant interaction between the exercise and booklet groups ($F = 6.5$, $P = 0.012$ for the interaction term) and confirmed modest benefits of advice or booklets. In comparison with the control group, the Aberdeen score was lower in the booklet group ($t = 1.93$, $P = 0.055$) and in the exercise advice group ($t = 2.66$, $P = 0.009$) but very little different with both exercise advice and booklet combined ($t = 0.92$, $P = 0.36$). After 1 week, 14% of patients reported being back to normal, and after 3 to 4 weeks, 58% of patients gave a similar report, with no significant differences between groups (week 1 χ^2 4.4, $P = 0.22$; week 3 χ^2 2.0, $P = 0.57$). There was no evidence of a different effect in those with acute or chronic pain (back pain started up to 3 months ago) in comparison with those with acute pain (F for interaction term 0.55, $P = 0.65$).

Satisfaction. There was no evidence of significant heterogeneity in variance for satisfaction (Levene's test $F = 1.0$, $P = 0.39$) and no evidence for a significant interaction between information booklet and doctor's advice to exercise ($F = 0$, $P = 0.99$); thus, the results are presented as the factorial main effects (Table 4). The main satisfaction outcome (the satisfaction scale) was improved by both the booklet ($t = 2.4$, $P = 0.02$) and advice to exer-

Table 4. Satisfaction

	No Booklet	Change With Booklet	No Exercise	Change With Exercise
Satisfaction items				
With visit	68.8 (64.2 to 73.4)	4.1 (−2.5 to 10.7)	67.6 (63.1 to 72.1)	6.5 (−0.2 to 13.1)
Amount of information	63.1 (58.1 to 68.1)	11.0 (3.8 to 18.1)	64.3 (59.4 to 69.1)	8.6 (1.4 to 15.8)
Content of information	63.1 (58.1 to 68.1)	10.1 (3.0 to 17.2)	64.2 (59.4 to 69.1)	7.9 (0.9 to 15.0)
Back pain management	63.5 (58.4 to 68.7)	6.3 (−1.0 to 13.7)	62.7 (57.7 to 67.7)	8.0 (0.7 to 15.4)
Overall satisfaction scale	64.7 (60.1 to 69.3)	7.9 (1.3 to 14.4)	64.9 (60.5 to 69.4)	7.4 (0.8 to 13.9)

Estimated mean satisfaction (95% confidence intervals) with management in control level of each factor (exercise, booklet), and mean change with intervention (95% confidence intervals).

cise ($t = 2.2$, $P = 0.03$). However, regarding secondary analyses of the specific elements of satisfaction, a booklet did not significantly improve satisfaction with the visit ($t = 1.2$, $P = 0.2$) or with the management of back pain ($t = 1.7$, $P = 0.09$), but it did improve satisfaction with the amount of information ($t = 3.0$, $P = 0.003$) and the content of information ($t = 2.8$, $P = 0.005$). Advice to exercise significantly improved satisfaction with management ($t = 2.2$, $P = 0.03$) and with the amount ($t = 2.4$, $P = 0.02$) and content ($t = 2.2$, $P = 0.03$) of information and was close to significance for satisfaction with the visit ($t = 1.9$, $P = 0.06$).

Knowledge. There was highly significant heterogeneity of variance between groups (Levene's test $F = 7.1$, $P < 0.001$). Thus, the Kruskal-Wallis test was used to assess differences between groups, with highly significant results (χ^2 27.2, $P < 0.001$): there were higher median knowledge scores in individuals receiving the booklet (5; interquartile range, 3–7) or booklet and exercise advice (4; 3–6.5) than in control subjects (3; 2–5) or advice alone (3; 2–5).

■ Discussion

To the authors' best knowledge, this is the first sufficiently powered randomized trial for back pain in primary care to document the effect on pain and function, satisfaction, and knowledge of two simple and inexpensive interventions in the consultation: physician's advice to exercise, and endorsement of a self-management booklet by the physician. It demonstrates that either approach alone is likely to improve satisfaction with the consultation and also pain and function during the next week, and that a booklet changes knowledge. Because of a negative interaction, both advice and booklet together may have little effect on pain and function, which supports previous evidence that detailed information booklets may not reinforce verbal advice. Before the results are discussed in detail, the limitations of the study will be identified.

Internal Validity and Generalizability of Trial Results

Selection bias, nonresponse bias, and the use of a simple pain/function score potentially limit this study. Regarding selection bias, there were very few exclusion criteria to maximize the generalizability of the sample; thus, the characteristics of the study sample are similar to those in other representative studies of British primary care in terms of age, gender, previous duration of back pain, and previous consultation with doctors.[9] Hence, patients with both acute and chronic pain were included, although this raises the concern that these groups might respond to the intervention differently. In fact, there was no evidence of this, *i.e.*, there was no significant interaction between treatment and chronicity. The 20% nonresponse for the main outcomes is a potential threat to the internal validity of the study, but there was no evidence that the clinical or sociodemographic characteristics of nonresponding patients were different from those of responders.

Conventionally, pain and function are considered as separate domains. However, the distinction may be more important theoretically than practically. There is a reasonably close relation between pain and function, which was shown empirically because the pain and function scales correlated in both the validation study and the main study. Furthermore, other criterion measures, such as the well-validated Aberdeen scale,[30] include both pain and function, and other criterion measures such as the Roland scale, although nominally about function, measure the impact of pain on function. It was also shown that the simple pain/function score has internal reliability, criterion validity, and sensitivity to change, and the main results using the score (*i.e.*, moderate changes in pain and function, and the negative interaction between advice and booklet) using an established criterion measure of pain and function for low back pain were confirmed. Thus, the use of the particular instrument is not likely to limit the findings, which are likely to be robust and should generalize to the population of patients seeking treatment for low back pain in the UK. Although it is possible that patients' expectations and needs differ in other countries, it seems likely that these interventions could be used in other countries.

Main Results

This study indicates that either advice to exercise or a booklet is likely to increase satisfaction and make modest changes to pain and function, over and above advice to mobilize and use simple analgesia, during the first

week after a patient has sought treatment for back pain. These benefits are important because the week after the consultation is when pain is likely to be at its worst, and there is little evidence that doctors can do much else to help their patients. A booklet also increases knowledge. The evidence for the use of a booklet supports previous evidence that a booklet can have beneficial effects on patients' self-management of back pain,[29] and another study in which a booklet changed beliefs.[4] Given that both the advice to take exercise and the endorsement of a booklet require minimal resources—1 to 2 minutes of a doctor's time, and the booklet costs less than £1 to produce—these interventions are likely to be cost-effective. Advice to exercise has been shown to increase reported exercise[7] but not functional outcomes, as in this study. Whether advice to exercise helps by increasing patients' willingness to mobilize in an acute attack and reassurance that nothing serious is wrong, or whether it is specifically related to exercise, is unclear. The booklet probably improves knowledge, as is shown by the significant changes in knowledge regarding specific information contained in the booklet. The booklet may also provide patients with practical self-management skills, given that a smaller study in 63 patients using the same booklet demonstrated that the booklet facilitated changes in patients' back protection behavior.[31] It remains unproven whether advice to exercise or a booklet can improve pain, function, and absence caused by sickness in the longer term.

The highly significant negative interaction between the booklet and the provision of advice—*i.e.*, that they have less effect when given together—is very important clinically because it is usually assumed that advice and the provision of a booklet will be mutually reinforcing. The interaction is unlikely to be a chance finding, because the effect was highly significant and was found not only in the principal outcome measure (pain/function scores) but in a similar criterion measure (Aberdeen scale). This supports similar results from the use of an educational booklet to improve contraceptive knowledge in a previous large factorial trial.[22] The reason for the interaction is unclear. It may be that patients are overloaded by advice and a detailed booklet, or that the messages of the booklet (which concentrates on the management of pain, but also advocates walking and similar exercise) and advice to exercise (which encourages mobilization—*i.e.*, not concentrating on the pain at all) are not similar enough. Another plausible explanation is that to provide advice and information in a *similar* format is not enough: provision of the same simple information in identical written and oral forms enhances outcome,[3,2,22,28] but the same information in slightly different and more detailed formats results in no reinforcement.[22] Interactions between advice and a booklet can properly assessed only by the use of factorial designs: with the previous large study[22] the current study highlights the importance of using factorial designs in assessing advice and booklets.

■ Conclusion

The physician's advice to take exercise or endorsement of a self-management booklet is likely to help patients gain benefit in terms of pain and function during the time the back pain is at its worst, and also increases satisfaction with the consultation. Previous studies suggest that simple advice and the *same* written information provide reinforcement. This study supports evidence that it may not be helpful to provide a detailed information booklet and advice together if the amounts or formats of information differ.

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■ Key Points

- There is no previous evidence that advice to take regular exercise or use a self-management booklet can modify pain or function.
- Doctors can increase satisfaction and moderately improve pain and function immediately after the consultation when back pain is worst, by endorsing a self-management booklet or by giving advice to take exercise.
- It may not be helpful to provide a detailed information booklet and advice together, where the amounts or formats of information differ.

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Point of View

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There is still a popular misconception that low back pain is a benign condition and, as such, the majority of patients with this condition recover quickly and can function as normal. Recent epidemiologic work has shown that this is not the case; up to one third of subjects who seek treatment for a new episode of low back pain are still disabled 12 months later. What is true is that only a small proportion of those with persistent symptoms return to their general practitioners. Therefore, it is essential that whatever course of action the practitioner wishes to take, the treatment options are thoroughly discussed in this single episode of care.

Strong evidence exists for effective short-term pain relief by nonsteroidal anti-inflammatory agents and muscle relaxants, and policies of avoiding bed rest and encouraging normal activity. However, there is less strong evidence to support specific back exercises or physiotherapy. It is welcome, therefore, to have results from this study by Dr. Little and colleagues that support the usefulness of a booklet or verbal advice regarding simple exercise, as an adjunct to the standard primary care "package" of analgesia and advice to avoid bed rest and to keep active, which was given to all patients.

One intriguing discovery is that giving both verbal and written advice appeared to be counterproductive in terms of easing back pain symptoms. The finding was consistent across both pain and function, and the authors report other clinical areas of "patient education" where this phenomenon has occurred. The conclusion is therefore to "keep it simple" because the effects of mixed messages, or overloading the patients, or the use of different presentation formats, may conspire to have undesired effects. Encouraging patients with low back pain to participate in physical activities *as soon as is possible* seems a step in the right direction. Before we leap onto this new "treatment bandwagon," we need confirmatory evidence from other trials, in addition, evidence regarding any longer-term effect. In the meantime, Dr. Little's team has added to our developing view of the way to manage back pain in primary care.