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# Information and Advice to Patients With Back Pain Can Have a Positive Effect

## A Randomized Controlled Trial of a Novel Educational Booklet in Primary Care

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**Study Design.** A double-blind, randomized controlled trial of a novel educational booklet compared with a traditional booklet for patients seeking treatment in primary care for acute or recurrent low back pain.

**Objective.** To test the impact of a novel educational booklet on patients' beliefs about back pain and functional outcome.

**Summary of Background Data.** The information and advice that health professionals give to patients may be important in health care intervention, but there is little scientific evidence of their effectiveness. A novel patient educational booklet, *The Back Book,* has been developed to provide evidence-based information and advice consistent with current clinical guidelines.

**Methods.** One hundred sixty-two patients were given either the experimental booklet or a traditional booklet. The main outcomes studied were fear-avoidance beliefs about physical activity, beliefs about the inevitable consequences of back trouble, the Roland Disability Questionnaire, and visual analogue pain scales. Postal follow-up response at 1 year after initial treatment was 78%.

**Results.** Patients receiving the experimental booklet showed a statistically significant greater early improvement in beliefs which was maintained at 1 year. A greater proportion of patients with an initially high fear-avoidance beliefs score who received the experimental booklet had clinically important improvement in fear-avoidance beliefs about physical activity at 2 weeks, followed by a clinically important improvement in the Roland Disability Questionnaire score at 3 months. There was no effect on pain.

**Conclusion.** This trial shows that carefully selected and presented information and advice about back pain can have a positive effect on patients' beliefs and clinical outcomes, and suggests that a study of clinically important effects in individual patients may provide further insights into the management of low back pain. [Key words: advice, back pain, booklet, primary care, randomized controlled trial] **Spine 1999;24:2484–2491**

Nonspecific low back pain is a common and recurring symptom that most people usually deal with themselves and for which there is no effective cure. Hence, the information and advice that health professionals give to patients may be a potent element of the health care intervention. Von Korff and Saunders[36] and Bush et al[12] found that one of the main reasons patients consult physicians is to seek information and reassurance. Bush et al[12] suggested that these patients have practical and realistic desires to learn about their low back pain, what to expect, and what they can do about it. There is some evidence that greater congruence among the patient's and clinician's perception of the problem, the prognosis for the disorder, and its long-term management is associated with higher patient satisfaction and better short-term outcomes.[14]

Qualitative studies[8,33] have demonstrated the complexity and heterogeneity of patients' perceptions of back pain, which may raise questions about how easily these can be modified by simple information and advice. Deyo and Diehl[18] and Bush et al[12] found that, for patients in the United States, the most frequent reason for dissatisfaction with medical care was failure to receive an adequate explanation of their back pain. Patients who believed that the physician's explanation was inadequate wanted more diagnostic tests, did not cooperate as well with treatment, and had poorer clinical outcomes at 3 weeks. Skelton et al[33] found that patients in the United Kingdom were skeptical of medical explanations for their back pain either because they doubted its validity or because it did not fit their own understanding of the problem. Borkan et al[8] found that Israeli patients also were quite critical of the medical system and more interested in "what works."

The first U.S. and U.K. clinical guidelines for acute low back pain[3,16] recommended that patients should be given accurate and up-to-date information and advice about back pain and its management; however, that recommendation was based on theoretical considerations and general clinical consensus rather than on any firm scientific evidence that such information improves outcomes. These guidelines gave few practical details on precisely what the content of that information and advice should be, apart from general reassurance about the absence of serious disease and that most back pain improves quickly with simple symptomatic measures and activity modification. There has been a progressive shift in subsequent international guidelines.[10] Based on additional evidence that is now available,[40] the more recent U.K.[31] and New Zealand[2] guidelines suggest that the physician provide more positive advice to stay active and continue ordinary activities as normally as possible. The New Zealand guidelines also provide a detailed assess-

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ment of psychosocial "yellow flags" (risk factors for chronic pain and disability) and suggest general behavioral principles for how patients with these features should be managed.[23]

Discussion at the Second International Forum for Primary Care Research on Low Back Pain[9] identified the continuing need for a simple and convincing explanation of back pain that is acceptable to patients and that would form a logical basis for active management. Most guidelines recommend that printed educational material should be made available, though this recommendation is based on limited evidence.[10] There are hundreds of leaflets and booklets about back pain, but remarkably few have been submitted to any sort of scientific evaluation.[11] Roland and Dixon[28] reported on the only randomized controlled trial (RCT) of a traditional clinical booklet that showed any significant impact on patients: those receiving the booklet consulted less frequently and had fewer specialist referrals for back pain over the next year. Cherkin et al[15] reported on an RCT that compared a 15-minute session with an educational nurse with a booklet that was similar to the material accompanying the Agency for Health Care Policy and Research (AHCPR) guidelines.[3] The nurse intervention yielded higher patient satisfaction, perceived knowledge, and exercise participation in the short term. The booklet showed similar trends, but they did not reach statistical significance compared with the outcomes of usual care. Neither of these trials showed any effect of a booklet on pain or functional status.

The aim of the current study was to determine the impact of a novel educational booklet on the beliefs and functional outcome of patients seeking treatment in primary care for an acute or recurrent episode of low back pain.

## ■ Background to the Novel Educational Booklet

Traditional information and advice about back pain has been based on a biomedical model, with emphasis on the anatomy and biomechanics of the spine, disc disease and injury, activity restriction or modification, and ergonomic advice. There is a theoretical argument that this emphasis actually may have contributed to iatrogenic disability.[38] Nachemson[26] discussed the "labelling effect," and Hirsch et al[20] demonstrated experimentally how labelling may influence the pain experience. Abenhaim et al[1] found that the back pain in patients who were given a specific pathologic diagnosis for a work-related back injury was more likely to progress to chronicity. Rose et al[30] observed that medical advice and conflicting information from health professionals seemed to contribute to fear-avoidance beliefs and pessimism about future recovery. Jones et al[22] showed that an intervention that deliberately increased patients' perceived susceptibility to the complications of back pain increased their subsequent health care consumption, which, at that time, those authors regarded as improved compliance.

Malmivaara et al[25] and Indahl et al[21] showed that reassuring workers and encouraging them to resume ordinary activities yielded better results than usual care, bed rest, or specific back exercises. A systematic review of 16 RCTs confirmed that advice to stay active and to continue ordinary activities as normally as possible produced faster recovery, faster return to work, less chronic disability, and fewer recurrent problems than did the traditional prescription of rest.[39] There is also increasing evidence that back pain and disability are better understood and managed according to a biopsychosocial model,[37] and that psychosocial issues may be at least as important as physical management in preventing chronicity.[23] Symonds et al[34] tested a simple pamphlet, based on the fear-avoidance model,[24] that stressed the advantages of being a "coper" rather than an "avoider." In a controlled trial of industrial workers with and without back pain, the pamphlet produced a positive shift in beliefs and reduced the amount of extended work loss caused by back pain.

The experimental booklet in the current study, *The Back Book,* was developed to accompany the U.K.'s 1996 Royal College of General Practitioners (RCGP) guidelines.[31] Development started with the only two previous educational items that have been shown to have any effect on outcome in patients with back pain (the Roland and Dixon booklet[28] and the industrial pamphlet by Symonds et al[34]). The main aim of this booklet is to change beliefs and behavior, which is quite different from imparting factual information.[13] Table 1 compares features of the experimental booklet with those of the traditional control used in the current trial. Pilot studies showed the experimental booklet to be well accepted by patients and capable of shifting beliefs in a positive direction.[32]

## ■ A Randomized Controlled Trial of the Novel Educational Booklet

### Trial Design

This was a double-blind, randomized controlled trial comparing the new booklet with a traditional educational booklet, when used as an adjunct to usual care for patients being treated in primary care for an acute or recurrent episode of low back pain.

### Hypotheses

The first three hypotheses listed below were developed *a priori* from theory before the trial, whereas the fourth was developed *a priori* from theory at an early stage of the analysis.

1. The booklet will produce clinically important, positive shifts in patients' beliefs, and there will be relatively little erosion in these beliefs over 1 year.
2. The booklet will have no substantial effect on the severity of pain.
3. The booklet will produce clinically important improvement in disability and, to a lesser extent, will reduce work loss and subsequent health care use.

**Table 1. Comparison of the Main Messages Given in the Experimental and Control Booklets**

| *Handy Hints* (Control Booklet) | *The Back Book* (Experimental Intervention) |
|---|---|
| • Traditional biomedical concepts of spinal anatomy, injury, and damage. (Implicit messages that the spine is easily damaged and that medicine should diagnose and treat the problem, but that there is often permanent damage.)<br>• Avoid activity when in pain; your general practitioner may advise bed rest.<br>• Describes further investigations and surgery. (Reinforces the message that back pain is a medical problem, and that there is little the patient can do.)<br>• Concentrates on pain rather than activity. (Implicit message that restoring activity and function must await relief of pain.)<br>• Encourages patient to be passive. | • There is no sign of any serious disease.<br>• The spine is strong. There is no suggestion of any permanent damage. Even when it is very painful, that does not mean there is any serious damage to your back: hurt does not mean harm.<br>• Back pain is a symptom that your back is simply not moving and working quite as it should. It is unfit or out of condition.<br>• There are a number of treatments that can help to control the pain, but lasting relief then depends on your own effort.<br>• Recovery depends on getting your back moving and working again and restoring normal function and fitness. The sooner you get active, the sooner your back will feel better.<br>• Positive attitudes are important. Do not let your back take over your life. "Copers" suffer less at the time, get better quicker and have less trouble in the long term. |

**4.** Those patients with high baseline fear-avoidance beliefs will be more likely to have a clinically important improvement in fear-avoidance beliefs with the experimental booklet, and those whose beliefs improve will be more likely to have a clinically important improvement in disability.

## ■ Methods

Six primary care practices in the northeast section of England participated: Five were National Health Service general practices (GP), and one was a private osteopathic practice. The patients were aged 17–70 years and initially sought treatment for a new episode of acute or recurrent nonspecific low back pain, with or without referred leg pain. The present duration of pain was less than 3 months, and patients had not received any health care, nor lost any time from work as a result of back pain, during the 3 months preceding this episode. Patients with possible serious spinal disease or nerve root pain were excluded.[31] All patients had English as their native language and were able to read and write. Those with a primary psychiatric illness or a history of alcohol or drug abuse were excluded. Of 188 patients meeting the selection criteria, 162 agreed to take part in the study and returned their baseline questionnaires.

The experimental intervention was *The Back Book*,[5] as described above. The control intervention was *Handy Hints,*[6] a booklet published by a patient-support group, which is typical of the traditional booklets described above. In view of a previous RCT showing that a similar booklet had no effect,[15] *Handy Hints* was considered to be a neutral control. The experimental and control interventions were matched as well as possible for equality of strength and face validity. Both booklets were professionally produced and commercially available in the U.K., and would be perceived to carry a similar weight of authority. They were similar in size, presentation, and overall appearance, and coincidentally were printed in the same colors. The trial did not introduce any other change in clinical management. The caring clinicians were instructed to provide their usual information and advice and to undertake clinical management entirely as usual, without making any allowance for the fact that their patients had received an educational booklet or that they were in a trial. The GP patients received general reassurance and advice, together with sick certification and analgesics as appropriate. The osteopathic patients received similar general reassurance and advice, as well as a number of sessions of manipulative therapy (mean, 4.3 sessions), with individual recommendations about nonprescription analgesics and sick leave as appropriate. Apart from mailing the follow-up questionnaires and reminders, there was no direct research contact with any of the patients and no reinforcement of the educational intervention. The caring clinician explained that this was a trial of a booklet that provided information and advice about back pain, and gave the patient the research material in a sealed, opaque envelope at the end of the routine consultation. Assignment of booklets was randomized by individual and completely concealed according to a previously generated, random list for each practice.[28] The outer envelope contained an instruction sheet and baseline questionnaires, and an inner (sealed and unmarked) envelope contained either the experimental or the control booklet. Patients and clinicians were completely blinded as to whether the envelopes contained the experimental or control booklet. The patients were not even aware that there were two different booklets, and they did not open the envelope in the presence of the clinician. Patients were instructed to complete the baseline questionnaires when they went home and to return them to the research office in a postage-paid, addressed envelope before opening and reading the booklet.

The same set of self-report questionnaires was used at baseline and at each follow-up assessment: 1) the Fear-Avoidance Beliefs Questionnaire[40] (the main focus of this study was the subscale for beliefs about physical activity [FABphys]); 2) the Back Beliefs Questionnaire (BBQ),[35] which measures beliefs about the inevitable consequences of back trouble; 3) the Roland Disability Questionnaire (RDQ)[29]; and 4) visual analogue scales for usual pain "at worst" and "at best." At baseline, the General Health Questionnaire[7] controlled for any differences in psychological distress, and at 1 year there were questions about other treatment received to control for any extraneous interventions.

Postal follow-up assessment was done at 2 weeks, at 3 months, and at 1 year after baseline. The 2-week follow-up assessment was intended to measure short-term effects on beliefs and any early clinical change; the 3-month follow-up was targeted at the progression to chronic disability; and the 1-year follow-up was intended to explore longer-term outcomes. One postal reminder was sent to nonrespondents at 2 weeks and at 3 months, and two reminders were sent at

**Table 2. Baseline Variables for the Two Groups**

| | Experimental | Control |
|---|---|---|
| Number of patients | 83 | 79 |
| Females (n) | 41 | 48 |
| Age (years) | 42.6 (10.9) | 44.7 (12.2) |
| FABphys | 15.3 (6.1) | 13.5 (5.5) |
| BBQ | 27.3 (7.2) | 27.8 (7.9) |
| RDQ | 10.9 (5.0) | 9.7 (4.6) |
| Pain at worst | 71.5 (19.2) | 68.7 (18.5) |
| Pain at best | 15.8 (17.5) | 15.6 (18.7) |
| GHQ | 14.5 (7.4) | 14.5 (6.2) |

Note: Values are mean (SD) for continuous variables. All differences between groups are statistically nonsignificant.
FABphys = fear-avoidance beliefs about physical activity; BBQ = beliefs about consequences of back trouble; RDQ = Roland Disability Questionnaire; GHQ = General Health Questionnaire.

1 year. At 1 year, each GP patient's clinical record was reviewed to note the number of return visits (for back pain and for any reported symptoms), number of prescriptions for medication, amount of certified sick leave, and number of referrals for specialist investigation or treatment. These data were not available for the osteopathic patients. Outcome assessment was completely blinded. A research assistant processed all questionnaires, and clinical records were reviewed by the caring clinicians (or practice nurses); all remained unaware of treatment allocation, and there was no code break before the final stage of the analysis.

One hundred sixty-two patients entered the trial: 133 GP patients and 29 osteopathic patients. The recruitment rate was 86% of those invited. One hundred twenty-seven patients (77%) returned their questionnaires at 2 weeks, 117 (72%) at 3 months, and 126 (78%) at 1 year, with very similar follow-up proportions between the experimental and control groups. The clinical records were reviewed for 92% of the GP patients.

Randomization put 83 patients in the experimental group and 79 in the control group, with no statistically significant differences in baseline scores (Table 2). Only one patient denied reading the booklet. There were no statistically significant differences in baseline scores between those who were followed up and those who dropped out.

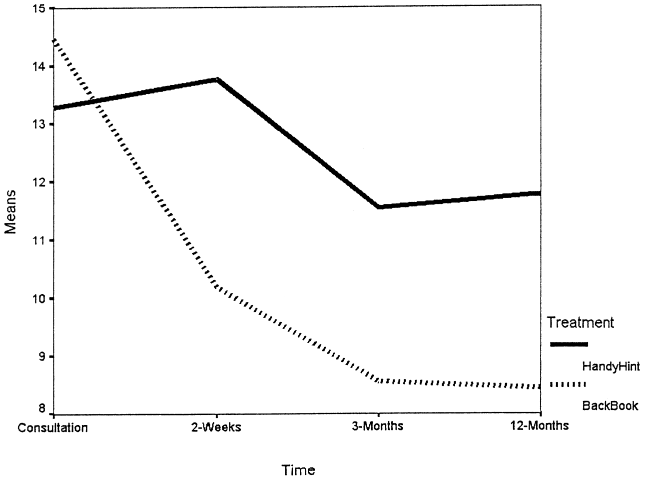

Figure 1. Mean belief scores (FABphys) for the two groups at baseline, 2 weeks, 3 months, and 1 year. The means are based on the scores of the patients who completed all four assessments for this measure. Differences between groups: $P =$ NS (not significant) at baseline; $P = 0.02$ at 2 weeks and 3 months; $P = 0.05$ at 1 year.

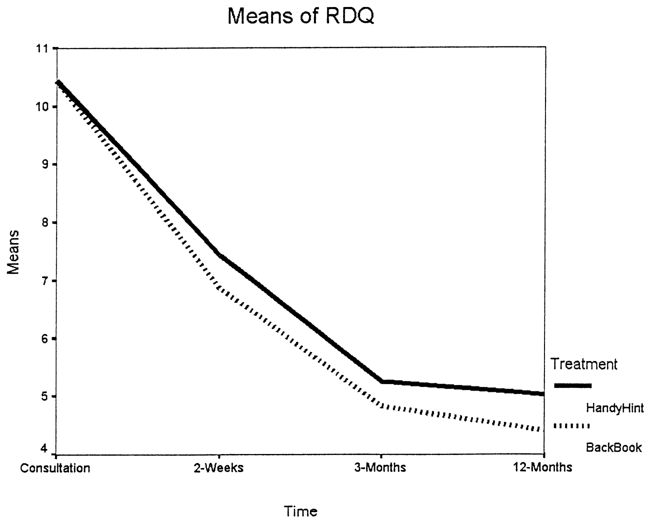

Figure 2. Mean disability scors (RDQ) for the two groups at baseline, 2 weeks, 3 months, and 1 year. The means are based on the scores of the patients who completed all four assessments for this measure. All differences between groups are statistically nonsignificant.

The main outcome measures were self-reported changes in fear-avoidance beliefs (FABphys) and disability related to activities of daily living (RDQ). Analysis was focused on differences between the experimental and control groups and included first comparing mean values in the two groups and then analyzing clinically important improvements in individual patients. Statistical analysis with the SPSS package (SPSS Inc., Chicago, IL) used analysis of sample means, analysis of repeated measures, and assessment of relative risk (RR), the latter being the recommended approach for clinical trial data where the events concerned are common.[4] An RR of, for example, 2.5 indicates that the probability of a given outcome for a person receiving the experimental treatment is 2.5 times as great as

**Table 3. Pain Scores at the Three Follow-up Points for the Two Groups**

| | Experimental | | Control | |
|---|---|---|---|---|
| | Mean (SD) | n | Mean (SD) | n |
| Baseline | | | | |
| Pain at worst | 71.5 (19.2) | 83 | 68.7 (18.5) | 79 |
| Pain at best | 15.8 (17.5) | | 15.6 (18.7) | |
| 2 weeks | | | | |
| Pain at worst | 53.9 (27.2) | 66 | 53.9 (26.3) | 60 |
| Pain at best | 9.7 (12.2) | | 12.9 (5.2) | |
| 3 months | | | | |
| Pain at worst | 49.2 (29.7) | 62 | 50.1 (28.5) | 55 |
| Pain at best | 8.7 (14.4) | | 8.8 (5.2) | |
| 1 year | | | | |
| Pain at worst | 50.9 (29.6) | 66 | 50.8 (27.8) | 60 |
| Pain at best | 10.1 (16.6) | | 10.6 (17.8) | |

Note: All differences between group means are statistically nonsignificant.

**Table 4. Analysis of Clinically Important Improvements for the 103 Patients With Complete Data for FABphys at 2 weeks and RDQ at 3 months**

| Group | Number With High Initial FABphys (median split, >14 points) | Number With High Initial FABphys Showing Clinically Important Improvements in FABphys at 2 Weeks AND in RDQ at 3 Months |
|---|---|---|
| Experimental (n = 53) | 31 | 18 |
| Control (n = 50) | 26 | 6 |

Note: Relative risk = 2.52; 95% confidence interval = 1.17–5.40.

that for one receiving the control treatment. The level of statistical significance was set at 5%. Clinically important improvement in the main outcome measures was defined as greater than four points for FABphys scores[40] and three points or more for RDQ scores.[17]

## Results

In the first stage of analysis, using mean values, patients receiving the experimental booklet showed a statistically significant improvement in beliefs about activity (FABphys) across time, whereas those receiving the control booklet showed no clear trend for improvement (Figure 1). The difference between the two groups was statistically significant at all three follow-up points ($P = 0.02$ at 2 weeks and at 3 months and $P = 0.05$ at 1 year). Beliefs about the inevitable consequences of back trouble (BBQ) were improved by 2 weeks and maintained at 1 year in patients receiving the experimental booklet (mean BBQ scores: baseline, 27.1; 2 weeks, 30.6; 1 year, 29.9; $P < 0.001$). Patients receiving the control booklet showed no statistically significant change throughout.

Disability (measured by RDQ) showed a significant improvement across each time period (Figure 2). Disability improved more in the experimental group than in the control group at all three follow-up points, but the differences in the means were not statistically significant.

Mean values for pain (Table 3) improved across time in the experimental and control groups. "Pain at worst" and "pain at best" showed a statistically significant improvement from baseline to the assessment at 2 weeks and from the assessment at 2 weeks to that at 3 months ($P < 0.03$), but not from the assessment at 3 months to that at 1 year. There were no statistically significant differences in pain between the experimental and control groups.

The second stage of the analysis considered clinically important improvements in beliefs (FABphys) and disability (RDQ) in individual patients. Table 4 shows, for those patients with a high initial FABphys score (median split, > 14 points), that the experimental booklet was 2.5 times more likely than the control booklet to result in clinically important improvement in FABphys at 2 weeks followed by clinically important improvement in RDQ at 3 months.

Patients in the experimental and control groups were compared by considering RRs, with the numbers available varying slightly for each analysis. Tables 5–7 show the statistically significant RRs with their 95% confidence intervals. Patients receiving the experimental booklet were more likely to have a clinically important improvement in FABphys at 2 weeks, at 3 months, and at 1 year than patients receiving the control booklet (RR: 2.72, 1.53, and 1.47, respectively). Patients who had a clinically important improvement in FABphys at 2 weeks and at 3 months were more likely to show a clinically important improvement in RDQ at 3 months (RR, 1.35 and 1.50, respectively). Considering hypothesis #4, those patients with a high baseline FABphys who received the experimental booklet were more likely to show a clinically important improvement in RDQ at 2 weeks than those receiving the control booklet (RR, 1.58).

For a sensitivity analysis, it was assumed that all patients who dropped out had no clinically important improvement in FABphys or RDQ. The results were robust: RRs generally fell by approximately 0.10, but the pattern of results was not unduly disturbed. Age and gender were tested as covariates, with no statistically significant effects.

The distribution of the clinical record data on certified work loss and further health care use was so skewed that it was not possible to demonstrate any significant differences between the two groups. Certified absence from work was low in this sample; 81% of working patients did not have any certified absence from work, and fewer than 9% were certified for more than 10 days. The mean work loss for the experimental group was 2.3 days, and that for the controls was 3.0 days. Similarly, most episodes of care were short; 60% of patients had no return visits to the doctor, and only 9% returned more than

**Table 5. Clinically Important Improvement in FABphys (>4-Point Reduction) Over Time, for the Experimental and Control Groups**

| Time | Experimental | Control | n | RR | 95% CI |
|---|---|---|---|---|---|
| 2 weeks | 36/65 | 12/59 | 124 | 2.72 | 1.57, 4.72 |
| 3 months | 38/61 | 22/54 | 115 | 1.53 | 1.05, 2.23 |
| 1 year | 39/63 | 24/57 | 120 | 1.47 | 1.02, 2.11 |

RR = relative risk; CI = confidence interval.
Note: The counts used to correlate the RRs are shown as ratios.

**Table 6. Clinically Important Reductions in RDQ at 3 Months Associated With Clinically Important Reductions in FABphys at 2 Weeks and 3 Months**

| | Reduction in RDQ ≥3 Points, at 3 Months | | | | |
|---|---|---|---|---|---|
| Reduction in FABphys >4 points | Yes | No | n | RR | 95% CI |
| 2 weeks | 30/65 | 10/38 | 103 | 1.35 | 1.02, 1.79 |
| 3 months | 46/74 | 13/39 | 113 | 1.50 | 1.12, 2.01 |

RR = relative risk; CI = confidence interval.

twice. Forty percent of patients received medication at the initial consultation, whereas only 28% were prescribed further medication.

## ■ Discussion

There is an extensive theoretical and evidence base for modern management approaches to back pain, but so far as the current authors are aware, this is the first empirical evidence that a simple educational intervention in routine primary care can have a positive effect on patient beliefs and outcomes. *The Back Book* is completely different from virtually all previous educational material for patients with back pain. It departs from traditional orthopedic and physiotherapy information and advice and instead focuses on patients' beliefs and on what they themselves should do about their back pain. It was specifically designed to complement and support evidence-based, management strategies in current clinical guidelines.

This was a very weak intervention. Patients were simply handed a small booklet; no other attempt was made to influence their treatment. Still, this intervention demonstrated a positive shift in beliefs, which led to a reduction in self-reported disability in the targeted group of patients. The nature of the intervention was not expected to have any effect on pain, and this proved to be the case. The review of clinical records showed that analgesic use was generally limited, and there was no difference between the groups.

*The Back Book* is not designed for use in isolation; the trial design sought to apply the most rigorous possible test of its impact. Educational experts advise that a coordinated approach, in which physicians and therapists all give the same information and advice and use educational material to reinforce that message, is likely to have a more powerful effect.[19] Such an integrated management package for back pain, which involves training the family doctors and their staff in an "active management" approach supplemented by prescription of the *Back Book*, is currently being implemented in the UK BEAM trial (www.york.ac.uk/org/ukbeam/ukbeam).

The major weakness of the current study is that, because most of the patients did well, returned to work, and did not seek further health care, the trial did not have sufficient statistical power to test any effect on work loss or subsequent care. It was therefore not possible to demonstrate the final part of hypothesis #3: that appropriate information and advice could reduce work loss and health care use. Although this hypothesis needs to be investigated further, the current results did show a trend on work loss. Also, an RCT of one predecessor to this booklet showed a reduction in extended absence in workers,[34] and an RCT of another predecessor showed a reduction in further GP consultations in patients.[29] In view of the multiple social and other influences on work loss, the authors of the current study suggest that a booklet in isolation is unlikely to have much impact on work absence, and that only a complete management strategy as described above is likely to have any significant impact.

The strength of this study is that the RCT, as well as the booklet development, was in routine primary care. The recruitment and follow-up rates are high for a trial with a mailed follow-up questionnaire involving no direct contact between patients and the research team. It is therefore likely that the results can be generalized, at least in the U.K. This was a very simple, practicable intervention, which is acceptable to patients and likely to improve patient satisfaction. Although there has not been any formal cost analysis, this intervention's simplicity and demonstrated effectiveness suggest that it is likely to be cost-effective. The authors conclude that *The Back Book* may be a useful adjunct to the management of low back pain in primary care. In view of possible cultural differences in knowledge and perceptions of back pain and in attitudes about its management, however, *The Back Book* needs to be tested in other countries. The authors are aware of such investigations taking place in Australia, Canada, Germany, and Finland.

**Table 7. For Patients With an Initial FABphys Score >14 Points, the Clinically Important Reductions in RDQ at 2 Weeks, for Experimental and Control Groups**

| Reduction in RDQ ≥3 points | Experimental | Control | n | RR | 95% CI |
|---|---|---|---|---|---|
| 2 weeks | 28/41 | 13/30 | 71 | 1.58 | 1.00, 2.49 |

RR = relative risk; CI = confidence interval.

This trial raises a more fundamental question about trial design and methods of analysis. Most RCTs are designed and analyzed to detect statistically significant differences in the mean scores of various outcome measures in the experimental and control groups. The problem is that such mean scores completely obscure the individual diversity of large groups of patients. The primary care research community[9] has stressed the importance of looking at subgroups of patients with back pain, and it also may be more relevant to place greater emphasis on clinically important rather than purely statistically significant changes in the outcome measures. This may best be achieved by analyzing the course of individual patients. That was the approach used in the current trial, which produced a clearer picture of clinically important, statistically significant effects of the intervention (Tables 4 and 5). The major proviso is that the trial design and analysis must be based on theoretical *a priori* hypotheses, not *post hoc* statistical trawling of the data, and that depends on scientific integrity.

In conclusion, this study provides empirical evidence about the sort of information and advice that should be given to patients with back pain (Table 1), and confirms that such information and advice may be a potent element of the health care intervention. There is, however, room for refinement of the message and its overall delivery. In this trial, *The Back Book* had a measurable impact on self-reported disability in activities of daily living, but there are only suggestive hints about more objective outcomes. Nevertheless, the most important clinical message from this study is that carefully selected and presented information and advice about back pain, in line with current management guidelines, can have a positive effect on patients' beliefs and clinical outcomes.

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