

The *Back Home* Trial

General Practitioner-Supported Leaflets May Change Back Pain Behavior

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Study Design. A single-blind randomized controlled trial of a leaflet developed for people with acute low back pain was compared with the usual general practitioner management of back pain.

Objective. To test the effectiveness of a patient information leaflet on knowledge, attitude, behavior, and function.

Summary of Background Data. Despite the commonality of back pain in general practice, little evidence on the effectiveness of simple interventions such as leaflets and advice on self-management has been reported. On the basis of a five-stage needs analysis, a simple leaflet was developed that considered the views of patients and health professionals.

Methods. For this study, 64 patients with acute back pain were assigned to the leaflet or control group. The participants were visited at home after 2 days, 2 weeks, then 3, 6, and 12 months, where they completed a range of self-report measures. Behavioral aspects were discreetly recorded by a "blinded" researcher. Primary outcomes were knowledge, attitude, behavior, and function.

Results. In all, 272 home visits were undertaken. The findings show that at 2 weeks, knowledge about sitting posture was greater in the leaflet group ($P = 0.006$), which transferred to a behavioral difference (sitting with lumbar lordosis support) when participants were unaware that they were being observed ($P = 0.009$). This difference remained significant at 3 months. Patients in the leaflet group also were better at maintaining a wide base of support when lifting a light object than the control subjects throughout all five assessments. There were no significant differences in the functional outcomes tested.

Conclusions. This trial demonstrates that written advice for patients can be a contributory factor in the initial general practitioner consultation because it may change aspects of knowledge and behavior. This has implications

for the management of acute back pain, with potential health gain. [Key words: advice, back pain, leaflet, primary care, randomized controlled trial] **Spine 2002;27:1821-1828**

Back pain, commonly seen in general practice, is costly to the individual, health care providers, and society as a whole. The search continues for strategies to lessen this financial burden, but at this writing, little evidence has been reported on the effectiveness of simple, self-help interventions such as information leaflets.

Cherkin et al⁷ argued that "because back pain is typically a recurrent problem that improves with time regardless of treatment, effectively teaching patients to take more responsibility for their own care remains a high priority." Nordin claimed that when patients with nonspecific low back pain are given information, they are more satisfied at the first visit and require less health care.²³ Therefore, it is evident that information and advice given by health professionals to patients may be a potent element of the health care intervention.³

In an accident and emergency setting, Jones et al¹⁴ reported that an educational intervention supplemented by a telephone call increased compliance in patients with low back pain who were in need of follow-up care. Indeed, all primary health care professionals, particularly general practitioners (GPs), are well placed to exert considerable influence on whether patients feel able to take an active role in their own health care, an empowering process.

The most obvious reason why individuals visit their GP is because they believe they have a health problem.¹¹ As Cameron et al⁵ stated: "The opportunity to disclose one's concerns, to receive reassurances that one's symptoms are benign, and to receive treatments makes seeking medical care a comforting choice." In relation to low back pain, Bush et al⁴ reported that patients consulted their physician to obtain information and reassurance. How then can health professionals maximize their role in providing this information and reassurance?

One possibility involves using leaflets, which can act as a reminder after a medical consultation because, according to Livesley and Rider,¹⁶ "much that is said is forgotten." Other proposed benefits of leaflets include alleviation of anxiety,¹⁸ promotion of psychological benefit,¹⁸ and reduction of medicolegal problems that occur with dissatisfied patients.¹⁶ A leaflet allows people to absorb the content at a time and place appropriate to

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themselves, and can be used to provide an opportunity for people to identify their health beliefs.

Such advantages are not universally reported. Hazard et al¹⁰ reported no effect at 3 or 6 months in terms of pain, health status, and health care use in people reporting back pain when an educational pamphlet was mailed in an occupational setting. It also is important that leaflets are not seen as a substitute for good communication between the physician and the patient.⁹ As Hadler⁸ said, "Does not everyone in pain deserve the empathy and human contact that can never occur in any educational booklet?"

Not only the content and presentation of leaflets are important, but also the manner in which the leaflet is issued. Harland et al⁹ argued that because doctors are viewed by patients as the primary source for information, leaflets may be best delivered by the doctors themselves during the consultation to achieve the most impact. Verbal reinforcement also may be essential.¹⁶

Regarding back pain, there have been several studies of educational interventions. Roland and Dixon²⁵ reported that patients who received an information booklet (in a controlled trial) saw their GP on fewer occasions in the ensuing year than the control group that did not receive the booklet. Knowledge scores also were higher in the booklet group, but no differences were reported between the two groups in terms of absence from work. Unfortunately, the outcome measures did not include symptomatology or back protection behaviors, and allocation (based on date of birth) was not concealed.

Burton et al³ showed, in a double-blind randomized controlled trial, that carefully selected and presented information and advice about back pain can have a positive effect on patients' beliefs, particularly "fear-avoidance beliefs about physical activity and beliefs about the inevitable consequences of back trouble." Patients who received the "novel patient educational booklet" also demonstrated a trend toward improved function.

More recently, Little et al¹⁵ reported that doctors can increase patients' satisfaction and moderately improve functional outcomes in the period immediately after the consultation, when back pain is worst, by using simple interventions such as endorsing a self-management booklet or giving advice to take exercise. However, although this study reported improvements in satisfaction, knowledge and pain/function, there is little information as to how this might have happened and whether the behavior of patients was altered.

Changing behavior is more difficult than changing beliefs or improving information levels. Arthur¹ cites two studies reporting behavioral changes and increased knowledge levels. One study evaluated a GP practice leaflet, and the other an osteoporosis education program. What remains unproved is whether educational leaflets can change behavior in people with back pain. We describe the process of developing a new educational leaflet and report the primary outcomes from a randomized

Table 1. Leaflet Development Stage 2: Results of the Total Scores From 13 Interviews

	Stage 2 Total Score*
How to lift things	33
What treatment is available	33
Where to get help/further advice	33
Getting back to work	31
What exercises to do	30
How to position myself (e.g., lying, sitting)	29
What can I do to get/keep myself fit	29
How soon is my back pain likely to settle	28
How to sleep or rest comfortably	27
How to control pain using self-help measures (e.g., hot water bottles)	27
How the back works	26
How to modify my life to prevent my back pain from coming back	25
How to drive	24
What are some causes of low back pain	24
How to modify my bedding and pillows to help my pain	23
What makes up the spine	22
How to get washed or dressed easily	21
How to control my pain by using tablets	21
Getting back to social and leisure activities	21
Getting back to physical relationships	21
How to get about	17
How to do my daily tasks	17
How to cough and sneeze	17
How to manage the shopping	16
Getting back to sports	16
Getting back to gardening	16
Getting back to DIY	15

* 5-point Likert scale: 3 (essential), 2 (very important), 1 (important), 0 (not very important or not relevant). The maximum score attainable is 39. DIY = "Do it yourself."

controlled trial that evaluated the effectiveness of this leaflet on knowledge, attitude, behavior, and function in people with acute low back pain.

■ Methods

Development of the Back Home Leaflet. A needs analysis of patients who had recently experienced acute low back pain was undertaken to determine the content of the leaflet.

Stage 1. A brief questionnaire was given to patients ($n = 7$) on their first visit to the GP with an episode of acute back pain, asking them to identify topics about which they would most like advice from their physician. The 27 topics identified are listed in Table 1.

Stage 2. Semistructured interviews were undertaken ($n = 13$), with people who experienced recent back pain attending an outpatient physiotherapy department. During the interview, the patients were asked to rate the 27 topics identified in Stage 1, using a Likert scale. The preferences found were used to order the topics presented in Table 1. In the evaluation of the responses, the patients experiencing their first episode of back pain ($n = 5$) were analyzed as a subgroup to ensure that their needs were specifically addressed.

Stage 3. The list of topics and the Likert scale from Stage 2 then were given to patients attending a back school ($n = 9$) who had experienced back pain for several weeks, and thus could reflect over a longer time span. Interestingly, their responses were more passive than those from the patients in Stage 2. They

considered “what treatment is available” as most important, whereas “how to control my pain using self-help measures” ranked only 22nd (compare with the order in Table 1).

Stage 4. Opinions were sought from senior chartered physiotherapists ($n = 12$), who were keen to include details of simple anatomy to explain “what makes up the spine.” The patients had ranked this sixth in Stage 2. Another area of controversy involved giving advice on specific back exercises. After much debate, the consensus was to omit details of exercises, because professionals were reluctant to recommend specific back exercises without first assessing patients. This conflicted with the patients’ agenda. “What exercises to do” ranked fifth in Stage 2 and third for the subgroup experiencing acute back pain for the first time. Further opinions on the content of the leaflet were sought from a rheumatologist and a GP research fellow, who discussed the potential content with other GP colleagues.

Stage 5. The draft leaflet, termed *Back Home*, was produced and evaluated, using a questionnaire, by patients attending back schools ($n = 10$).

With the agenda established from potential recipients of the leaflet and from the health professionals who might issue it, the evidence base for the content was reviewed.²⁴ Much of the advice on positioning (including sitting) and manual handling was based on Nachemson’s^{21,22} work on lumbar disc pressure measurements and basic biomechanics. Specific to sitting, the more the lumbar spine was moved toward lordosis, the less disc pressure Nachemson detected.²¹ The aim of using a lumbar roll, for example, is to help maintain this lordosis. In addition to ergonomic advice aimed at encouraging personal control and decreasing levels of pain, the rationale for using ice and heat, specifically for pain relief, has been described.^{13,17}

The final *Back Home* leaflet comprises 12 DL-size (21×10 cm) pages of green monotone print on ivory paper. The cover contains the positive messages “you can ease your pain” and “most people do get better within 4 weeks.” There are interactive aspects, encouraging patients to list the movements or positions that increase their pain. Patients are asked to identify positions in which they are most comfortable, with suggestions including crook lying, sitting in a straight chair and using a pad to support the lumbar spine, or lying supine with the legs supported, for example, on a chair or sofa.

The leaflet also includes simple anatomy, advice on the limited use of radiographs, simple messages about mattresses, and information on analgesia, the need to minimize bed rest, and the importance of keeping mobile. There are practical tips for getting in and out of bed, standing, sitting, getting washed and dressed, driving, bracing for coughing and sneezing, and lifting. In addition, there is instruction in self-help measures such as applying ice or heat and advice about general exercise, encouraging activities such as walking, swimming, yoga, and relaxation. Sources of further reading and helpful addresses are included on the back cover. Gunning’s Fog Index, describing the readability of the leaflet rates the reading level at 6.5, within the range recommended for health education leaflets (Grades 5–9).⁶

Trial of the Leaflet. A single-blind, randomized controlled trial was undertaken in southern England to evaluate the leaflet. The area included the city of Southampton and adjacent, largely rural, New Forest. Ethical approval was granted from

the Southampton and South West Hants Health Authority Ethics Committee.

All the GPs in New Forest and west of Southampton were contacted, and 51 consented to participate from 26 practices. The participating practices were randomly allocated to either the control or experimental group within pairs of practices matched for location (to control for socioeconomic area) and number of participating GPs in the practice (range, 1–9). Randomization, used in each pair, was accomplished with computer-generated random numbers. The allocation was concealed from the researcher until the completion of data collection.

The participants were experiencing acute back pain, defined as pain in an area bounded by the 12th thoracic vertebra and 12th ribs superiorly, the gluteal folds inferiorly, and the contours of the trunk laterally. The inclusion criteria for the trial required written consent, an age of 16 to 60 years (to exclude children and minimize the risk of symptoms secondary to osteoporosis), no low back pain in the previous 6 months (to identify the current symptoms as a new episode), back pain severe enough to warrant at least 3 days off work or an equivalent (to exclude people with mild symptoms), and ability to read and understand English. The trial excluded people who presented with any “red flag” signs or symptoms, had received previous formal instruction in back pain management (because they could have been influenced by this education), sought treatment from private practitioners such as physiotherapists, chiropractors, or osteopaths before the second assessment (at 2 weeks), were pregnant or postpartum, or were involved in litigation.

Intervention. The GPs in the control group continued with their usual management and advice for patients with acute back pain. The GPs in the experimental group also gave the patient a copy of the *Back Home* leaflet, verbally reinforcing the content by making the following standardized empowering statement to reflect clinical practice and maximize any potential benefit of the leaflet: “This leaflet, called *Back Home*, gives you practical hints about how you can help to ease your back pain. Please read the leaflet carefully and use as many of the ideas as you can. This leaflet is important. It will allow you to be in control of your back pain.” There were two boxes for the GPs to tick, indicating whether they had read the statement to the patient or not.

Once the patient had consented to enter the trial, the GP telephoned an answer phone to record the person’s name and contact details, ensuring that the first assessment could occur within 2 working days of the GP consultation. Throughout the trial, a telephone advice line was available for any GPs in the experimental group to use if patients asked any questions arising from information in the leaflet that the GP did not feel able to answer. This service was never used.

Outcome Measures. The participants were followed up at home on five occasions: within 2 working days, then after 2 weeks, 3 months, 6 months, and 1 year. Assessment comprised a battery of self-report questionnaires (Table 2). The same researcher carried out all the data collection. The primary outcomes of the trial were knowledge, attitude, observable behavior, and function. Preexisting questionnaires were used wherever possible, and the order in which the outcome measures were administered was randomized. Pilot work had previously been undertaken with 20 patients to test the practicality of the outcome measures, especially those that had been developed or revised.²⁴

Table 2. Outcome Measures Used in the *Back Home* Trial

	Assessment				
	1 2 Days	2 2 Weeks	3 3 Months	4 6 Months	5 12 Months
Self-report					
Anxiety ¹⁹	✓	✓	✓	✓	✓
Demographic details*	✓	—	—	—	—
Attitude*	—	✓	—	—	—
Back-to-work data*	—	✓	✓	✓	✓
Function ²⁷	✓	✓	✓	✓	✓
Knowledge ^{after 12}	—	✓	—	—	—
Management/treatment*	—	✓	✓	✓	✓
Multidimensional health locus of control (A) ²⁹ & (C) ³⁰	✓	✓	✓	✓	✓
Pain I ^{after 20}	✓	—	—	—	—
Pain II ^{after 20}	—	✓	✓	✓	✓
Perceived control ^{after 2}	✓	✓	✓	✓	✓
Satisfaction I*	✓	—	—	—	—
Satisfaction II*	—	✓	✓	✓	✓
Pain diary ^{after 20}	Completed between assessments 1 & 2		—	—	—
By researcher					
Home assessment I*	✓	—	—	—	—
Home assessment II*	—	✓	—	—	—
Observable behavior*	✓	✓	✓	✓	✓

* Denotes the questionnaires developed by the research team because appropriate questionnaires were not available.
after = based on

Knowledge. The knowledge outcome measure was based on the earlier Back Quiz¹² and revised to reflect specific information provided in the *Back Home* leaflet. This measure contained nine multiple-choice questions, each with a choice of five possible answers plus a category for “don’t know.” Knowledge could be assessed only once in this trial, because if it had been measured as a baseline variable, it might have influenced the participants in acquiring additional information, thus contaminating any impact of the leaflet.

Attitude. Six questions were included about patients’ attitudes toward their back pain. One of these questions (“Do you think you can manage your back pain on your own?”), with three answer choices, “yes,” “no,” and “don’t know,” was selected in advance as a primary outcome and analyzed as “yes” versus “no”/“don’t know.”

Observable Behavior. The observable behavior outcome involved simple, dichotomous observations of the patient undertaking four activities and recording “yes,” “no,” or “did not undertake the activity.” The observations were as follows:

If they were in bed, did they get up through side-lying?

If they were sitting, did they make any attempt to support their lumbar lordosis (with a pillow or cushion).

How did they get up from the sitting position? Did they make any attempt to move to the front of the chair first?

In lifting or picking a light object up from the floor, (a) did they attempt to bend their knees, and (b) did they have a suitably wide base of support, defined as having their feet greater than or equal to the distance of their shoulders?

These activities had been highly rated in the needs analysis for development of the leaflet because they were functional and could be readily and discreetly observed. Pilot work was undertaken with this outcome.²⁴ Only

one person actually was in bed for the second assessment, so the first activity was omitted from the analysis.

Function. Function was assessed using the Aberdeen Low Back Pain Scale,²⁷ a 19-item scale designed for use in the community. The scale contains questions on pain distribution and function, with 3 to 6 possible answers. It was anticipated that this scale would be more sensitive in detecting smaller changes than dichotomous scales such as the Roland Morris Disability Questionnaire.²⁶

Statistical Analysis. In this trial, knowledge and attitude were measured only at 2 weeks, whereas behavior and function were assessed at five points during the year-long monitoring of patients. All knowledge, attitude, and behavior observations were treated as binary items, with “don’t know” and “not applicable” responses excluded. Odds ratios, associated 95% confidence intervals, and Pearson χ^2 statistics are presented where numbers allowed. Otherwise, exact tests based on a patient level analysis are reported. In part, because of uneven recruitment, with a few GPs recruiting most of the participants and many recruiting none, there were differences between the groups at baseline regarding the highest level of education achieved and whether the occupation of the participants involved manual work, whether previous episodes of back pain had occurred, and whether the participant engaged in regular exercise before the current episode of back pain (Table 3). With the exception of the highest level of education achieved, it might be anticipated that these differences would favor the control group.

We also compared the binary outcomes achieving significance in unadjusted comparisons in logistic regression models, and controlled for these factors. Accounting for baseline differences generally increased the significance of results. However, estimated odds ratios became extremely large, suggesting that

Table 3. Baseline Characteristics in the Trial of Information Leaflets for Back Pain

Variable	Leaflet (n = 35) n (%)	Control (n = 28) n (%)
Mean age (years)	39.2 ± 10.9	39.3 ± 9.7
Min-max	16-58	22-56
Gender		
Female	13 (37)	9 (32)
Male	22 (63)	19 (68)
Social class*		
I	0	3/27 (11)
II	3 (9)	4/27 (15)
III	12 (34)	13/27 (48)
IV	16 (46)	4/27 (15)
V	4 (11)	2/27 (7)
Unclassifiable	0	1/27 (4)
Manual*	24 (69)	11/27 (41)
Previous back pain	31 (89)	16 (57)
Those with previous back pain who consulted their GP	27/31 (87)	11/16 (69)
Low educational achievement (0-level/CSE/GCSE or lower)	32 (92)	15 (54)
In paid employment	28 (80)	24 (86)
Smoking		
Never	6 (17)	9 (32)
Yes	22 (63)	13 (46)
Used to	7 (20)	6 (21)
Involved in regular sports or active hobbies	8 (23)	12 (43)

* One participant with missing values in the control group.
CSE = Certificate of secondary education; GCSE = General certificate of secondary education.

the numbers available were insufficient to fit models reliably. For this reason, and because baseline difference tended to favor the control group, controlled results are not generally reported. In two cases, the estimated odds ratios were reduced, and the association no longer achieved significance. For these cases only, controlled results are reported.

We also undertook logistic regression, including clustering at the practice level in Stata, for the binary outcomes achieving significance in unadjusted standard logistic regression. The confidence intervals (CI) around estimated odds ratios usually were more narrow, indicating a lack of intrapractice correlation for the outcomes in question. Again, the results are reported only for the one outcome in which the confidence inter-

val became wider and significance was lost. Functional scores were compared between groups using Mann-Whitney *U* tests, and leaflet-control differences in the mean score were presented with 95% confidence intervals.

■ Results

The 64 people who entered the trial were randomized over a 2½-year period, and 272 home visits were undertaken. One patient left the trial for personal reasons before the second assessment. The median number of days (and 90th percentile) between the first assessment and those scheduled to take place after 2 weeks, then after 3, 6, and 12 months were in fact 14 (16), 86 (95), 183 (200), and 373 (391), respectively.

The demographic details describing the 64 patients are shown in Table 3. The results of the primary analyses are shown in Tables 4 to 6.

Knowledge

At 2 weeks, two of the nine knowledge questions were significant at the 5% level, as shown in Table 4. These questions specifically related to sitting posture and identifying the easiest position for putting on socks or tights. After accounting for baseline differences, the odds ratio associated with the “easiest position to put on socks/tights” was increased to 5.13 (95% CI, 0.91–28.75) with a higher *P* value (*P* = 0.043).

Attitude

At 2 weeks, when patients were asked “Do you think you can manage your back pain on your own?” there was no significant difference between the leaflet and control groups.

Observable Behavior

The results from observing behaviors are shown in Table 5. It can be seen that sitting with the lumbar lordosis supported was statistically significant at the 5% level at 2 days, 2 weeks, and 3 months, as was maintaining a wide base of support during lifting, which remained significant throughout all the assessments. Controlling for baseline differences resulted in a reduction of the odds

Table 4. Patients Reporting Correct Answers in the Knowledge Outcome Measure at 2 Weeks and Responding “Yes” to the Attitude Question

	Leaflet n (%)	Control n (%)	Leaflet Control	OR (95% CI)	<i>P</i>
Most common cause of back pain	9/32 (28)	4/26 (15)	2.15	(0.58–8.02)	0.247*
Least stressful position	11/32 (34)	11/26 (42)	0.71	(0.25–2.08)	0.536*
Most likely to worsen pain	18/31 (58)	15/26 (58)	1.02	(0.35–2.92)	0.977*
Easiest position for putting on socks/tights	13/32 (41)	4/26 (15)	3.76	(1.05–13.50)	0.036*
Application time for ice pack	4/32 (13)	1/26 (4)	3.57	(0.37–34.11)	0.367†
Frequency of position changing	14/32 (44)	9/26 (35)	1.47	(0.51–4.27)	0.479*
Tissue affected by heat pack	20/32 (63)	19/26 (73)	0.61	(0.20–1.89)	0.393*
Best sitting position	19/32 (59)	6/26 (23)	4.87	(1.54–15.44)	0.006*
Best form of exercise	31/32 (97)	22/26 (85)	5.64	(0.59–53.93)	0.163†
Do you think you can manage your back pain on your own?	15/32 (47)	14/26 (54)	0.76	(0.27–2.14)	0.597*

* Asymptotic χ^2 test.

† Exact χ^2 test.

OR = odds ratio; CI, confidence interval.

Table 5. Observed Behavior at Each Follow-up Visit

Observation	Follow-up	Leaflet n (%)	Control n (%)	Leaflet Control	OR (95% CI)	P
Did they attempt to support the lumbar lordosis?	2 Days	14/31 (45)	4/27 (15)	4.74	(1.32–16.96)	0.013*
	2 Weeks	13/30 (43)	3/26 (12)	5.86	(1.44–23.85)	0.009*
	3 Months	12/30 (40)	3/25 (12)	4.89	(1.19–20.03)	0.020*
	6 Months	6/25 (24)	5/22 (23)	1.07	(0.28–4.16)	0.918*
	1 Year	10/25 (40)	4/20 (20)	2.67	(0.69–10.36)	0.150*
Did they move to the front of the chair first?	2 Days	29/32 (91)	21/28 (75)	3.22	(0.75–13.94)	0.105†
	2 Weeks	27/30 (90)	21/26 (81)	2.14	(0.46–10.00)	0.451†
	3 Months	28/29 (97)	22/24 (92)	2.55	(0.22–29.93)	0.584†
	6 Months	23/24 (96)	20/22 (91)	2.30	(0.19–27.30)	0.600†
	1 Year	23/24 (96)	19/21 (91)	2.42	(0.20–28.80)	0.592†
Did they attempt to bend their knees?	2 Days	19/20 (95)	14/15 (93)	1.36	(0.08–23.62)	1.000†
	2 Weeks	30/30 (100)	23/25 (92)	—	—	0.202†
	3 Months	30/30 (100)	23/25 (92)	—	—	0.202†
	6 Months	25/26 (96)	21/22 (96)	1.19	(0.07–20.21)	1.000†
	1 Year	22/23 (96)	20/21 (95)	1.10	(0.06–18.77)	1.000†
Did they have a suitably wide base?	2 Days	18/20 (90)	3/15 (20)	36.0	(5.21–248.66)	0.000*
	2 Weeks	22/30 (73)	3/25 (12)	20.17	(4.72–86.19)	0.000*
	3 Months	21/29 (72)	7/25 (28)	6.75	(2.05–22.27)	0.001*
	6 Months	19/26 (73)	9/22 (41)	3.92	(1.17–13.20)	0.024*
	1 Year	16/23 (70)	7/21 (33)	4.57	(1.28–16.27)	0.016*

* Asymptotic χ^2 test.† Exact χ^2 test.

OR = odds ratio (not calculated when rates are 0% or 100%); CI, confidence interval.

ratio for “Did they support the lumbar lordosis?” at 3 months to 3.41 (95% CI, 0.67–17.38), with *P* value of 0.119. Taking account of clustering at the GP practice level increased the confidence interval associated with the odds ratio for “Did they have a suitably wide base of support?” at 1 year to 0.97–21.45.

Function

There were no statistically significant differences in the Aberdeen Low Back Pain Scale between the control and leaflet groups in their functional outcome.

Discussion

In developing the content of the *Back Home* leaflet, it was apparent that the priorities of patients and health

professionals differed, especially about exercises and spinal anatomy. Therefore, in developing any educational materials, it is paramount to canvass the views of potential users, in this case, people with acute low back pain. We suggest that it is particularly important to ascertain the needs of the subgroup of people experiencing their first episode of back pain to ensure that their needs are addressed.

A total of 35 primary outcomes were specified in advance: 9 assessing knowledge, 1 assessing attitude, 20 assessing behavior, and 5 assessing function. This number of comparisons would be expected to result in two significant findings at the 5% level through chance alone. In fact, 10 comparisons were significant in unadjusted analyses, five at the 1% level, suggesting real differences between the patients who received the leaflet and those who did not. Eight comparisons remain significant after control was used for baseline differences or clustering at the GP practice level.

We demonstrated differences in specific areas of knowledge, which then were reflected in a change of behavior. Care was taken to ensure that patients were unaware that their behavior was being observed. It must be remembered that these results were achieved with a very simple intervention, given at the initial GP consultation, with minimal resource or training implications.

The patients in this trial were monitored from within 2 days of their initial GP consultation until 12 months afterward. The leaflet was given at the first appointment when patients were still experiencing considerable pain and distress. Since it is possible that at this point their cognition could have been impaired, because of pain and medication, the leaflet was designed to be very basic, giving only simple, practical advice. In the current trial it was is-

Table 6. Percentage Functional Scores

	Leaflet*	Control*	Leaflet–control mean difference (95% CI)	P†
2 Working days	42.7 ± 11.9 18.1–69.6 (n = 35)	42.6 ± 13.6 16.7–77.8 (n = 28)	0.1 (–6.5–6.3)	0.678
2 Weeks	37.7 ± 14.8 15.9–73.9 (n = 32)	35.6 ± 15.9 5.6–73.6 (n = 26)	2.0 (–6.1–10.1)	0.766
3 Months	14.6 ± 17.6 0.0–62.3 (n = 32)	14.4 ± 17.6 0.0–56.9 (n = 25)	0.2 (–9.2–9.6)	0.878
6 Months	14.7 ± 16.1 0.0–69.6 (n = 26)	8.6 ± 10.1 0.0–33.3 (n = 23)	6.1 (–1.8–13.9)	0.180
1 Year	11.0 ± 14.2 0.0–60.9 (n = 25)	8.1 ± 9.6 0.0–30.6 (n = 23)	2.9 (–4.2–10.0)	0.363

* Figures are mean ± standard deviation, min–max.

† Mann Whitney *U* test.

CI, confidence interval.

sued with verbal reinforcement by the GP, as recommended by Livesley and Rider¹⁶ to maximize its impact. This process also mirrors clinical practice, in which educational materials probably are given with reinforcement.

The major strength of this intervention was its simplicity. This elementary, practical leaflet was designed to be used in primary care. It focuses on managing acute low back pain and is cheap to produce. It does not require complex training by the health professional issuing it, but merely active support and reinforcement. Despite its simplicity, it brought about changes in knowledge and behavior in people with acute low back pain.

Interestingly, the observed use of lumbar supports such as a pillow or cushion during sitting remained statistically significant for the first 3 months. However, at 6 months, this difference was no longer evident, suggesting that patients used this strategy during the acute phase of their back pain episode. They may not continue this behavior as a prophylactic measure over the long term.

Secondary outcomes measured in this trial also have shown the *Back Home* leaflet to be associated with clinically important differences in perceptions of control, anxiety, and satisfaction.²⁴ Patients who received the leaflet perceived themselves as more able to control their low back pain than those in the control group. In addition, they reported lower levels of anxiety and higher levels of satisfaction with the information they received and the way their back pain was being managed.²⁴

Some problems were encountered in the trial. The recruitment of patients by GPs (64 patients from 51 GPs in 2½ years) was slower and more uneven than we had planned, and this may account for the imbalance in the baseline characteristics. Additional work with participating GPs showed that “pressure of work” and “difficulties remembering to enter patients” as the main reasons for the poor recruitment.²⁴ Randomization occurred at the level of the GP practice, so the allocation could not be concealed when GPs recruited patients into the trial. Although this had certain advantages, in that GPs could verbally reinforce the leaflet (using a standardized empowering statement), and in that it probably reduced contamination from patients possibly seeing different GPs within the same practice throughout the duration of the trial or talking to other patients who had been given a leaflet, it may have been responsible for the poor recruitment in control practices, with two GPs in this group withdrawing because the trial “did not provide any help to the patients at the time when they needed help.” For practical reasons, randomizing at the patient level may be a better option in this type of trial.

The demographic details outlined in Table 3 show that the social class of the leaflet group was lower than that of the control group, and that there were more manual workers in the leaflet group. These differences may have reduced any potential impact gained from the leaflet, with the result that the current findings, if anything, underestimated the true benefit. The other main difference between the groups was the greater number of pa-

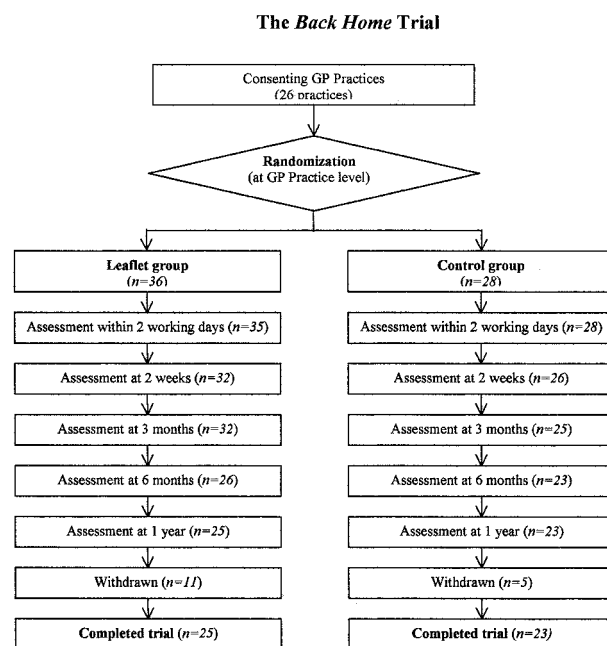


Figure 1. The *Back Home* trial.

tients in the leaflet group who had experienced previous episodes of low back pain. This may have affected patients’ previous knowledge, such that they had learned how to manage their pain from previous experience. Attempts were made to minimize this problem by excluding patients who had received formal instruction in back care as well as patients who had experienced low back pain within the previous 6 months. The baseline differences were addressed in the analysis, and the most conservative results are presented.

The leaflet did not affect function as measured by the Aberdeen Low Back Pain Scale.²⁷ Perhaps the reason for this was that the function scores changed most between 2 weeks and 3 months and an intermediary measurement, at 6 weeks, for example, may have been more sensitive. Furthermore, the leaflet could perhaps have been more strongly relevant to the participants’ individual lifestyles. One reported research finding is that education is more successful when people are taught how to incorporate learned health behavior into their daily routines.²⁸ This could be achieved either by the health professional taking time to personalise the content at the initial consultation, which is unrealistic in the context of a GP surgery, or by increasing the interactive content of the leaflet. Further work is needed to determine the effect of personalising information in leaflets on a population with low back pain.

In conclusion, Burton et al³ have previously claimed that “information and advice may be a potent element of the health care intervention.” The *Back Home* trial has shown that a simple leaflet may be a useful adjunct to management strategies that is particularly well suited to primary care. Although recruitment to the *Back Home* trial proved to be difficult, the results suggest that GP-

supported leaflets may change aspects of behavior in people with acute low back pain.

■ Key Points

- Leaflets given to patients with acute low back pain in an initial GP consultation may change aspects of behavior and knowledge.
- Simple leaflets may be a useful adjunct to management strategies for patients with acute low back pain.
- Patient information leaflets are well suited to primary care.

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