

Simple Educational Intervention to Improve the Recovery from Acute Whiplash: Results of a Randomized, Controlled Trial

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Abstract

Objectives: To determine if an educational intervention in the acute stage of whiplash injury may improve the recovery rate. **Methods:** Consecutive subjects were randomized to one of two treatment groups: educational intervention or usual care. The intervention group received an educational pamphlet based on the current evidence. The control group did not receive these materials but received usual emergency department care and a standard nondirected discharge information sheet. Both groups underwent follow-up by telephone interview at two weeks and three months. The primary outcome measure of recovery was the patient's response to the question, "How well do you feel you are recovering from your injuries?" **Results:** A total of 112 subjects agreed to participate. Age, gender, precollision employment level and health, initial symptoms, collision parameters, and emergency treatments were similar between the groups. At two weeks postcollision, 7.3% in the

treatment group reported recovery compared with 8.8% in the control group (absolute risk difference, -1.5%; 95% confidence interval = -12.6% to 9.7%). At three months postcollision, 21.8% in the treatment group reported complete recovery compared with 21.0% in the control group (absolute risk difference, 0.8%; 95% confidence interval = -14.4% to 16.0%). At three months, there were no clinically or statistically significant differences between groups in severity of remaining symptoms, limitations in daily activities, therapy use, medications used, lost time from work, or litigation. **Conclusions:** An evidence-based educational pamphlet provided to patients at discharge from the emergency department is no more effective than usual care for patients with grade 1 or 2 whiplash-associated disorder. **Key words:** whiplash; neck sprain; chronic pain; motor vehicle collisions; therapy. *ACADEMIC EMERGENCY MEDICINE* 2005; 12:699-706.

The term "whiplash-associated disorder" (WAD) was coined by the Quebec Task Force to indicate a range of clinical manifestations that describe the acute symptoms typically arising from the setting of a motor vehicle collision.¹ Grade 1 (neck stiffness or pain with normal neck range and no point tenderness) and grade 2 WAD (neck stiffness or pain with restricted

range and/or point tenderness) typify what has been commonly labeled as "whiplash injury" or "soft tissue" injury, and these cases account for most patients (90%) encountered by primary care and emergency physicians following motor vehicle collisions (whereas grade 3 is diagnosed when objective neurologic signs are associated with injury and grade 4 when fracture/dislocation is present).¹ The health burden of WAD is significant for both the individual and society, the latter in terms of direct costs of care and the indirect cost of whiplash-associated disability. Studies in Canada,^{2,3} Sweden,⁴ the United States,⁵ the United Kingdom,^{6,7} Ireland,⁸ and Norway⁹ have shown that as many as 50% of victims of whiplash injury (grade 1 or 2 WAD) will still be experiencing chronic neck pain and disability six months later. While litigation costs are significant, much of the cost of WAD can also be attributed to the investigation, assessment, and attempted treatment of chronic pain. It is known, for example, that while only 12% of patients with whiplash remained in chronic pain one year after their collision, these 12% accounted for 47% of costs of all whiplash injuries in terms of treatment and lost wages.¹⁰ Approaches that prevent the

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progression from a transient, acute injury to chronic pain would be of major importance to the injured individual and to society.

Many therapies have been attempted, including drugs (e.g., narcotics, nonsteroidal anti-inflammatory medications, muscle relaxants, and so on), physical therapy (physiotherapy, massage, chiropractic), rest (e.g., neck supports/braces, bed rest, inactivity), and psychological therapy.^{1,11} Unfortunately, most therapies are either ineffective or have not been adequately studied.^{1,11} The need for careful evaluation of therapies was an emphasis of the message from the Quebec Task Force on WAD, particularly noting the lack of good-quality studies on early treatment interventions in the prevention of chronic pain.¹

In an observational study in the United Kingdom, McClune et al.¹² described the change in patient beliefs through the use of *The Whiplash Book*, a booklet containing a set of unambiguous, evidence-based, patient-centered messages that challenge unhelpful beliefs about whiplash and promote active recovery. Comparing a sample of patients with WAD attending accident and emergency or manipulative practice with nonrandomized uninjured controls, they showed that this book produced improvement in beliefs about whiplash. On the basis of these findings, they recommended that this approach be investigated for its effect on clinically important outcomes.

With this knowledge, and with the evidence from treatment studies,^{1,11,13-15} we designed a one-page pamphlet aimed at patients presenting to the emergency department (ED) after a motor vehicle collision. The pamphlet was designed to summarize the dos and don'ts following WAD injuries, based on *The Whiplash Book*. We then undertook a study to examine whether distribution of this educational pamphlet to individuals experiencing a grade 1 or 2 whiplash injury following ED discharge improves outcomes at three months.

METHODS

Study Design. This study was a randomized, concealed-allocation, controlled clinical trial of an educational intervention versus usual care. This study was approved by the Research Ethics Board of the University of Alberta.

Study Setting and Population. The study took place in an ED setting of a single teaching hospital in a major metropolitan region. Patients with grade 1 or 2 WAD were included if they were seated within the interior of a car, truck, or van in a collision (any of rear, frontal, or side impact), had no or less than 5 minutes of loss of consciousness, were 18 years of age or older, and presented within 72 hours of their collision. Patients were excluded if they demonstrated grade 3 or 4 WAD, refused to give consent, had

no fixed address, were unable to communicate in English, were admitted to the hospital, or were not from within the Capital Health region. Using concealed allocation, consenting patients were then randomized via computer-generated random numbers into two groups, using variable block sizes to avoid potential seasonal variation.

Study Protocol. Patients with whiplash presenting in 2003 with grade 1 or 2 WAD (defined by the Quebec Task Force as the presence of neck pain, headache, or back pain with no objective neurologic signs or fracture/dislocation)¹ were identified during their assessment in the ED. Subjects were referred by the treating emergency physician to research staff for participation in the study. The emergency physicians assessed these patients for major injuries, and the research nurses enrolled them in the study. The setting minimized physician-based bias. Because the emergency physician essentially tells patients that they do not have a neck or back fracture and then refers them to their family physician for follow-up (i.e., there is little opportunity for educational intervention otherwise), mixtures of educational advice that may have added to or detracted from the information given to the intervention or control group are avoided. In this study, the physicians never saw the intervention delivered by the research nurse and were unaware of the study intervention differences. We obtained informed written consent to provide the educational materials and to follow up participants by telephone interview at two weeks and three months postinjury.

Patients in both groups were assessed by a full-time emergency physician; investigations and treatment were not standardized in the protocol. Cervical and other radiographs were ordered at the discretion of the emergency physician.

Control Group. At discharge, the control group received usual, standard ED care, which included an information sheet. The information sheet was "generic" and discussed the definition of "neck sprain" or "whiplash," the symptoms, possible treatments, and what signs should prompt a return to the hospital. The generic information sheet was a part of usual care, but it does not offer any evidence-based advice or direction per se on what the patient with whiplash should or should not do in terms of treatment.

Intervention Group. At discharge, the intervention group received in a similar envelope a one-page evidence-based whiplash prevention pamphlet (available as an online Data Supplement at <http://www.aemj.org/cgi/content/full/12/8/699/DC1>). The pamphlet was based on *The Whiplash Book*¹² and on the current evidence, relating to the need for explanation and reassurance, as well as the importance of mobilization

and continuation of normal activities. These are summarized as a list of ten pieces of advice. This advice encompasses all the major points of *The Whiplash Book* but does not expand on them. These ten pieces of advice are consistent with available literature reviews on treatment of whiplash.^{1,11} We chose to use the information contained in *The Whiplash Book* for a number of reasons: 1) the relatively low cost of the intervention, 2) the provision of a standardized intervention, and 3) the fact that the information format could be referred to by the patient at a later time and/or shown to friends and physicians. *The Whiplash Book* itself was not used because it is 26 pages long, uses higher-level language than is reasonable for most ED audiences, and could be summarized in pamphlet format.

Measurements. Demographic information, pre-morbid health, employment status, collision parameters, initial treatment and investigations, and initial symptoms were recorded by the research nurse using standardized forms. A research nurse completed the forms using a standardized telephone interview to assess outcomes at two weeks and three months in both groups. The primary outcome measure of recovery was the patient's response to the question, "How well do you feel you are recovering from your injuries?" The possible responses ranged from "all better" to "much worse," and the subjects responding with "all better" were defined as recovered. The question was posed by the research nurse with direct reference to the patient's whiplash injury. Additional outcomes included the severity of various symptoms classified as mild, moderate, and severe; the need to modify leisure activities; limitation of daily activities (none, slight, moderate, and severe); employment status (off work and missed work); litigation status; and resource use.

Blinding. The study subjects receiving the pamphlets were not blinded to their intervention; however, they were instructed not to reveal their study group status to the research assistant conducting the follow-up telephone interviews. Neither group was made aware of the use of an enhanced intervention in this study. To minimize the potential impact of the trial and its intervention on practice patterns, the attending physicians providing initial care in the ED were minimally exposed to the ongoing trial and did not have knowledge of each patient's potential participation. The research assistants conducting the follow-up telephone interviews were blinded to treatment allocation.

Data Analysis. Descriptive statistics were generated, including percentages and their associated 95% confidence intervals (95% CI) for dichotomous variables and means and standard deviations or medians and interquartile ranges for continuous variables. A

Pearson chi-square test was used to test differences in the primary outcome between intervention and control groups. For comparisons of baseline characteristics and analyses of secondary outcomes, the Student's t-test or the Mann-Whitney U test was performed on differences in continuous variables. For binary and continuous variables, 95% CI for the difference between the control and intervention groups were calculated.

Sample Size Calculation. Based on a review of the literature, we expected that usual care would be associated with a 20% rate of complete recovery by three months. For the proposed intervention to be clinically meaningful and adopted widely, we assumed at least a 30% absolute increase in the rate of recovery over usual care (i.e., an increase in proportion recovered from 20% usually to 50% in the intervention group). Using the formula for a two-sided chi-square test with a continuity correction with the parameters of $\alpha = 0.05$, $\beta = 0.20$, a control recovery rate of 20%, and an absolute effect size of 30%, we calculated that at least 45 patients per group (total sample size of 90) would be needed. To allow for losses to follow-up, the sample size was increased by 20%. The study was terminated when 100 patients had complete three-month follow-up data.

RESULTS

Recruitment. During the period of recruitment, 631 potentially eligible patients involved in motor vehicle collisions presented to the ED. Of these, 449 were excluded (114 were excluded because they could not be entered into the study within 72 hours of their collision, and 335 others were excluded in almost all cases because they were not in a collision with injuries limited to grade 1 or 2 WAD). The remaining 182 patients were eligible to enter into the study; of these, 112 (62%) agreed to participate (70 refusals). These subjects were randomized into either the intervention group ($n = 55$) or the control group ($n = 57$). A total of six subjects were lost to three-month follow-up in the treatment group and four subjects were lost in the control group (see Figure 1).

Patient Groups. Demographic characteristics, employment status, pre-morbid conditions, collision parameters, and initial symptoms (within the first three days postcollision) are shown in Table 1. There were no important differences between the two groups on any of these measures. The initial symptoms are in keeping with other studies of patients with grade 1 or 2 WAD.^{2,3,9,14,15}

Cointerventions. The cointerventions and other resources reportedly used by subjects at two weeks and three months postcollision, including items such as health care practitioner utilization, use of medications,

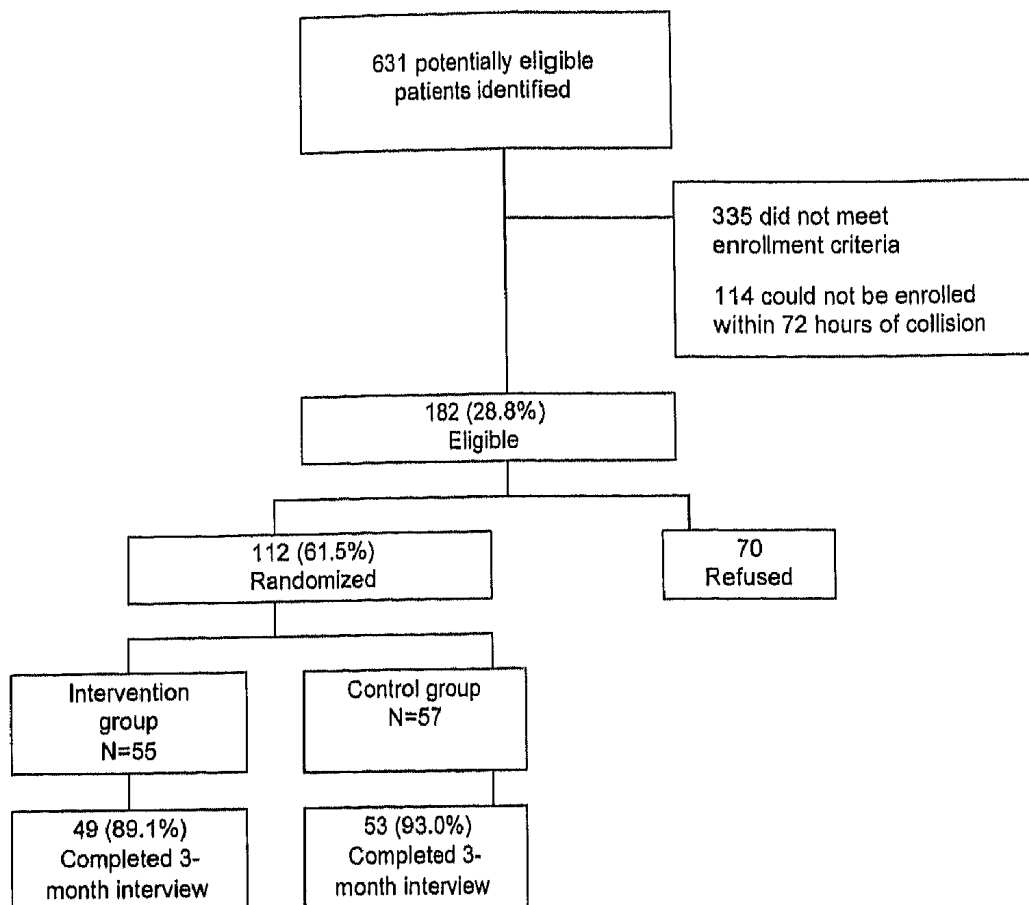


Figure 1. Recruitment flowchart.

initiating injury claims, taking time off work, and hiring a lawyer, were similar between the two groups (Table 2). There were no statistically significant differences between the intervention and control groups. Although there were trends ($p = 0.08$, for example, for the intervention group to have been more likely to have hired a lawyer), this difference was not statistically significant, especially when considering that no correction has been made for multiple comparisons, a maneuver that would merely increase the p -values further. There were also no differences in the initial ED radiographic utilization or prescription drug treatment between the two groups (data not shown).

Compliance Reading Pamphlets. At both follow-up periods, patients in both groups were contacted to evaluate their use and impressions of the pamphlet. Of patients available for follow-up at two weeks, 79.6% of patients (43 of 54) randomized to the intervention group reported reading all or a portion of the pamphlet compared with 85.5% (47 of 55) in the control group who had read all or part of their pamphlet ($p = 0.42$). There was no significant difference in the proportion of patients with recovery at three months for patients who had read the materials provided compared with those who had not ($p = 0.20$). However, there was a significant difference in the proportion of patients with "quite a bit of improvement" at three months in both groups for

patients who had read the materials compared with those who had not ($p = 0.04$).

Outcomes. The primary outcome measure was the proportion of subjects in each group who reported complete recovery. At two weeks postcollision, 7.3% in the treatment group reported recovery, compared with 8.8% in the control group (absolute risk difference, 21.5%; 95% CI = -12.6% to 9.7%). At three months, 12 of the 55 patients (21.8%) randomized to the intervention group reported complete recovery compared with 12 of the 57 patients (21.0%) randomized to the control group. There were no statistically significant or clinically important differences between the groups in recovery status (including symptom severity, limitations in daily activities, and employment status) at three months (Table 3). Combining the responses "all better" and "quite a bit of improvement" as a measure of what most people would consider clinically important recovery did not result in statistically significant or clinically important differences between groups. In a sensitivity analysis that excluded patients who were lost to follow-up (i.e., no three-month follow-up interview), the differences remained unchanged ($p = 0.83$).

DISCUSSION

This single-center, randomized, controlled trial examined the effectiveness of a written educational inter-

TABLE 1. Characteristics of Intervention (Education) and Control Groups at Baseline

	Intervention (n = 55)	Control (n = 57)	Between-group Difference (95% CI)
Mean age, yr (SD)	36.0 (14.5)	41.2 (15.4)	(-10.9, 0.4)
No. of male patients (%)	27 (49.1)	24 (42.1)	(-13.2, 27.2)
Mean body mass (SD)	26.0 (5.2)	26.1 (5.3)	(-2.0, 1.9)
Smoking status, n (%)			
Current	12 (21.8)		
Former	15 (27.3)		
Never	28 (50.9)		
Never consumes alcohol, n (%)	13 (23.6)	16 (28.1)	(-22.4, 13.5)
Marital status, n (%)			
Married/common law	26 (47.3)		
Single	24 (43.6)		
Other	5 (9.1)		
Employed outside the home, n (%)	46 (83.6)	42 (73.7)	(-6.9, 26.8)
General health before collision, n (%)			
Excellent	18 (32.7)		
Very good	28 (50.9)		
Good	7 (12.7)		
Fair	1 (1.8)		
Poor	1 (1.8)		
Previous whiplash injury, n (%)	17 (30.9)	11 (19.3)	(-6.1, 29.3)
Previous back injury, n (%)	15 (27.3)	16 (28.1)	(-17.9, 15.8)
Previous neck injury, n (%)	17 (30.9)	14 (24.6)	(-12.0, 24.7)
Usual physical activity, n (%)			
Never/rarely	0 (0)		
Occasional	5 (9.1)		
1-3 times/wk	11 (20.0)		
4-7 times/wk	39 (70.9)		
Any prior medication, n (%)	42 (76.4)	33 (57.9)	(-0.3, 37.3)
Opiate/narcotic	10 (18.2)		
Anti-inflammatory	14 (25.5)		
Muscle relaxant	7 (12.7)		
Position in vehicle			
Driver	43 (78.2)		
Front passenger	11 (20.0)		
Rear passenger	1 (1.8)		
Seat belt	54 (98.2)	56 (98.3)	(-4.9, 4.8)
Airbags deployed	7 (12.7)	6 (10.5)	(-11.5, 15.9)
Head rest	51 (92.7)	52 (91.2)	(-8.6, 11.6)
Previous collision including visit to the ED	20 (36.4)	16 (28.1)	(-10.7, 27.3)
≥2 collisions	3/20 (15.0)		
Arrived by emergency medical services	37 (67.3)	30 (52.6)	(-5.1, 34.4)
Lost consciousness	1 (1.8)	2 (3.5)	(-7.6, 4.7)
C-spine immobilization	33 (60.0)	29 (50.9)	(-11, 29.2)
Symptoms			
Neck pain	54 (98.2)	57 (100.0)	(-4.2, 7.6)
Severity, mean (SD)	5.6 (2.1)	5.5 (2.2)	
Shoulder pain	41 (74.6)	38 (66.7)	(-10.7, 26.5)
Severity, mean (SD)	5.0 (2.1)	5.3 (2.3)	
Low back pain	25 (45.5)	31 (54.4)	(-29.2, 11.3)
Severity, mean (SD)	6.5 (2.2)	5.2 (2.7)	
Headache	43 (78.2)	47 (82.5)	(-20.8, 12.2)
Severity, mean (SD)	6.2 (2.7)	5.9 (2.5)	
Numbness	15 (27.3)	12 (21.0)	(-11.4, 28.8)
Severity, mean (SD)	3.4 (1.8)	5.1 (2.7)	

vention for preventing persistent neck symptoms following assessment and treatment in an ED for WAD. The results of this trial suggest no greater improvement among patients who received the enhanced evidence-based written information compared with those who received a generic whiplash information pamphlet. The magnitude of the observed differ-

ence did not remotely approximate the a priori definition of minimal clinically important difference, and our results are robustly negative. The main secondary outcomes (severity of various symptoms, need to modify leisure activities, limitation of daily activities, employment status, litigation status, and resource use) were also similar between the groups.

TABLE 2. Resource and Other Cointervention Utilization at 2 Weeks and 3 Months

	Intervention (2 wk) (n = 54)	Control (2 wk) (n = 55)	95% CI	Intervention (3 mo) (n = 49)	Control (3 mo) (n = 53)	Between-group Difference (95% CI)
Seen physician	39 (72.2)	38 (69.1)	(-15.8, 22.1)	41 (83.7)	42 (79.3)	(-12.6, 21.4)
Seen chiropractor	8 (14.8)	9 (16.4)	(-15.2, 12.1)	10 (20.4)	13 (24.5)	(-22.2, 14)
Seen physiotherapist	16 (29.6)	14 (25.5)	(-14.4, 22.8)	28 (57.1)	26 (49.1)	(-13.2, 29.4)
Seen massage therapist	4 (7.4)	8 (14.6)	(-20.6, 0.6)	16 (32.7)	13 (24.5)	(-11.3, 27.6)
Still taking ED medications	14 (26.9)	19 (34.6)	(-27.6, 10.4)	10 (20.4)	16 (11.3)	(-28.5, 8.9)
Injury claim	31 (57.4)	24 (43.6)	(-6.7, 34.2)	29 (59.2)	25 (47.2)	(-9.2, 33.2)
Hired a lawyer	17 (31.5)	10 (18.2)	(-4.6, 31.1)	21 (42.9)	14 (26.4)	(-3.8, 36.7)

All values are expressed as n (%).

While it is true that various patient-decision aids may alter knowledge or beliefs in general,¹⁶ and that educational materials may alter the belief systems of whiplash victims,¹² it is not yet evident that such

changes in knowledge or beliefs actually alter clinical outcomes. The current study does not support the effectiveness of a simple information pamphlet in the ED setting, even though it was based on a previously

TABLE 3. Outcome Measures in Intervention (Education) and Control Groups at 3 Months Postcollision

	Intervention (n = 49)	Control (n = 53)	Between-group Difference (95% CI)
Recovery			
All better	12 (24.5)	12 (22.6)	(-27.2, 13.8)
Quite a bit of improvement	18 (36.7)	27 (45.3)	
Some improvement	14 (28.6)	11 (20.8)	
No improvement	2 (4.1)	2 (3.8)	
A little worse	2 (4.1)	0	
Much worse	1 (2.0)	4 (7.6)	
Any pain	41 (83.7)	44 (83.0)	(-13.8, 15.1)
Minor	9 (22.0)	12 (27.3)	
Moderate	25 (61.0)	28 (63.4)	
Severe	7 (17.1)	4 (9.1)	
Neck pain	33 (67.4)	30 (56.0)	(-10.0, 31.4)
Minor	7 (21.2)		
Moderate	20 (60.6)		
Severe	6 (18.2)		
Shoulder pain	25 (51.0)	30 (56.6)	(-26.9, 15.7)
Minor	10 (40.0)		
Moderate	11 (44.0)		
Severe	4 (16.0)		
Low back pain	30 (61.2)	26 (49.1)	(-9.0, 33.2)
Minor	11 (36.7)		
Moderate	14 (46.7)		
Severe	5 (16.7)		
Headaches	28 (57.1)	24 (45.3)	(-9.3, 33.1)
Minor	7 (25.0)		
Moderate	10 (35.7)		
Severe	11 (39.3)		
Numbness/tingling	12 (24.5)	16 (30.2)	(-24.9, 13.5)
Minor	5 (41.7)		
Moderate	5 (41.7)		
Severe	2 (16.7)		
Modified leisure activities	29 (59.2)	30 (56.6)	(-18.6, 23.7)
None	21 (42.9)	23 (43.4)	
Slight	17 (34.7)	16 (30.2)	
Moderate	10 (20.4)	12 (22.6)	
Severe	1 (2.0)	2 (3.8)	
Employed	42 (85.7)	42 (79.3)	
Off work (days)	5 (11.9)	4 (9.5)	(-10.8, 15.6)
Median (IQR)	60 (60-90)	51 (14-100)	
Missed work (days)	35 (83.3)	30 (71.4)	(-8.2, 32.0)
Median (IQR)	7 (3-25)	10 (2-21)	

IQR = Interquartile range.

validated source,¹² focused on a set of clear messages, and provided simple and "common sense" advice. The two randomized groups were well matched in sociodemographics, and the subjects are typical of patients attending most tertiary care EDs, given the reasonably (112 of 182; 61%) high rate of recruitment and high rate of follow-up. Furthermore, the socio-demographic profile of our cohort is virtually identical to that found in other large Canadian cohorts of patients with whiplash.²

Within the power limits of the sample size, we were unlikely to have missed any major impact. Furthermore, the estimate of effect does not remotely approximate our minimal clinically important difference. More to the point, almost all of the secondary outcomes, such as days lost from work and litigation status, favored the control group. Our educational intervention was associated with no effect on our primary outcomes and the suggestion of potential harm with respect to important secondary outcomes.

LIMITATIONS

There may be many reasons why the intervention was not effective. First, there may not have been any alteration in the belief system of subjects with this brief pamphlet, and this was something we did not test. Although the main messages of our pamphlet are very similar to *The Whiplash Book*, the longer and more detailed book offers more discussion and statements to reinforce these main messages. On the other hand, McClune et al.,¹² when they tested *The Whiplash Book* itself, found an "effect" on beliefs and were not specifically testing injury outcomes. It may be that more intensive education is needed; however, rather than utilize a more intensive educational program, the aim of this study was to begin with a "minimal" approach to see if any effect exists and build from there in a series of planned studies of increasingly intensive and more costly educational programs. Third, the pamphlet messages focus mainly on emphasizing active coping messages (i.e., stay active, maintain good posture). Some recent evidence suggests that the development of disabling neck/low back pain is strongly associated with an increased use of passive coping strategies (e.g., reliance on medications for symptom relief), regardless of levels of active coping.¹⁷ That is, even if an injured person remains active and engages in physical exercise, the concomitant tendency to hold passive strategies such as relying heavily on pain medications, frequently focusing on and discussing their pain with others, and canceling social activities negates the beneficial effects of the active coping.¹⁷

Another limitation to educational literature interventions is that it is difficult to verify compliance. Even with practitioner-led educational interventions, compliance with advice is an issue. In addition, we

used an ordinal scale of recovery statements as an outcome measure. In future studies, it may be possible to detect the effect of this kind of intervention by using health questionnaires that provide interval data, such as the Short-Form 36 generic quality of health measure. Finally, it may be that the intervention is not sufficiently robust to counter the provincial litigation system in Alberta. Of subjects who hired a lawyer, approximately half did so within two weeks after the collision. Cassidy et al. have shown that the characteristics of the prevailing litigation system may significantly reduce recovery rates from whiplash-related injuries.^{2,18}

One may ask how likely it is that our sample is representative of patients with whiplash in general. Although the three-month recovery rate of 25% (as we defined recovery) seems low, this is consistent with that found in a large population-based study in the neighboring province of Saskatchewan.² Thus, it is unlikely that we merely selected a biased sample of patients with an outcome much worse than expected. This study emphasizes the need to subject all interventions, even very simple ones, to formal testing in randomized trials before widespread dissemination and adoption. It may be that educational interventions need to be more intensive than the use of a simple pamphlet to benefit whiplash recovery.

CONCLUSIONS

In conclusion, our study certainly demonstrates that seemingly logical, simple, and well-intentioned interventions may be no better than usual care in improving outcomes related to whiplash injuries and, depending on how recovery is defined, may even be associated with trends toward harm.

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