

Active Involvement and Intervention in Patients Exposed to Whiplash Trauma in Automobile Crashes Reduces Costs

A Randomized, Controlled Clinical Trial and Health Economic Evaluation

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Study Design. To examine and compare the costs and consequences in a partial economic evaluation of two competing interventions in patients exposed to whiplash trauma in automobile crashes. The interventions were an active involvement and intervention using early mobilization and a standard intervention of rest, recommended short-term immobilization in a cervical collar and a cautious, gradual self-exercise program according to a leaflet. The study was randomized and controlled.

Objectives. The aim of the study was to compare the costs of an active involvement and intervention *versus* a standard intervention and to relate them to the clinical benefits in patients exposed to whiplash trauma in automobile crashes to facilitate decision-making regarding intervention and resource allocation.

Summary of Background Data. There is very little known about the health economic aspects of various interventions in the target treatment group of patients.

Methods. Based on a prospective, randomized, clinical trial, data on clinical effectiveness and resources used for the active involvement and intervention and standard intervention were collected for a comparative analysis of the costs related to physical therapy treatment and sick leave. A cost-consequence analysis consisting of a modified cost-effectiveness analysis was used.

Results. The costs were significantly lower after 6 and 36 months with an active involvement and intervention as compared with the standard intervention. The active involvement and intervention were significantly superior in reducing experienced pain and reducing sick leave.

Conclusions. For patients exposed to whiplash trauma in a motor vehicle collision, an active involvement and intervention were both less costly and more effective than a standard intervention.

Key words: whiplash injuries, whiplash-associated disorders, physical therapy, cost-consequence analysis. **Spine 2006;31:1799–1804**

the last 30 years in the western world alone. These injuries are extremely costly to society; and according to the World Health Organisation (WHO), traffic injuries constitute approximately 1% of the combined gross national products of the nations of the western world.¹

Whiplash-associated disorders (WADs) occur commonly after road traffic accidents. The Abbreviated Injury Scale (AIS) is an anatomic scoring system first introduced in 1969 and has been considered a reasonably accurate way of ranking the severity of injury. Injuries are ranked on a scale from 1 to 6 from “minor” (AIS 1) to “virtually unsurvivable injury” (AIS 6). The AIS 1 neck injuries² included in WADs have become the most common traffic injury with an estimated incidence of 100 per 100,000 inhabitants in Sweden.^{3,4} Costs for medical care and disability and the consequences in terms of suffering of patients with WAD are significant, affecting patient, family, employers, and society in general,⁵ although cost-of-illness studies for WAD present difficulties due to the uncertainty of the diagnosis. Deriving the division of costs is also difficult when WAD occurs along with other injuries. The costs to society for WAD in Sweden has been roughly estimated at nearly 2 billion Swedish Crowns (SEK) (\$251,000,000) yearly with the bulk of these costs, 1.5 billion SEK, 2001 (\$18,800,000) in lost output.⁶ It is estimated that whiplash injuries cost Europe €10 billion yearly (\$12,100,000,000).⁷

Slow and costly recovery can and should be avoided by using effective treatment methods. There is some evidence for the efficacy of an early, active involvement and intervention for patients with WAD,^{8–11} but no economic evaluation has been made. Drummond defines economic evaluation as “the comparative analysis of alternative courses of action in terms of their costs and consequences.”¹²

A study in Germany similar to the Rosenfeld study but with only a 2- and 12-week follow-up concluded that considerable reduction of costs are possible if appropriate treatments are used in patients with WAD.¹³ However, no statistical analyses were presented in that study for differences in either sick-leave or costs, thus invalidating this conclusion.

The aim of the present study was to compare the costs of an active involvement and intervention *versus* a standard intervention and relate them to the clinical effects in patients exposed to whiplash trauma in automobile crashes to facilitate decision-making regarding intervention and resource allocation of these patients.

Road traffic injuries are a major public health problem, with 5.5 million deaths and 230 million injured during

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■ Methods

Selection of Patients. From March 1995 to March 1996, 102 consecutive patients exposed to whiplash trauma in automobile crashes seeking health care were asked to participate in the study. The patients were referred to the study from the southern half of Elfsborg municipality in the southwestern part of Sweden. Patients were recruited from 29 primary care units and emergency rooms in three hospitals in western Sweden.

The study was single-blinded. Different personnel performed randomization, data collection, and intervention. The personnel gathering data were unaware of intervention assignment and those randomizing patients were unaware of the outcome of initial measurements. The Ethics Committee, Göteborg University, approved the study.

Criteria for inclusion were exposure to whiplash trauma in automobile crashes caused by rapid movements of the head resulting from acceleration forces in any vector. Patients with cervical fractures or dislocations, neurologic deficit, head injury, previously known symptomatic chronic neck problems, alcohol abuse, dementia, serious mental diseases, or diseases that could be expected to lead to death before the study's completion were not included. Patients that could be randomized within 96 hours after collision were referred to the study. Sample size of 100 patients was considered sufficient using the two-factor design (see Discussion).

Randomization of Patients. A complete randomization method was used to create four unmatched groups of approximately equal size.

Following initial measurements, patients were randomized to one of four intervention groups: active involvement and intervention initiated within 96 hours following collision (Group 1), standard intervention initiated within 96 hours (Group 2), active involvement and intervention initiated with a delay of 14 days after collision (Group 3), and standard intervention initiated with a delay of 14 days (Group 4).

Delay of the treatments, created subgroups (Groups 3 and 4) for the active involvement and intervention and standard intervention patients, and were used to test the impact of the timing of initiating treatment. Sequentially numbered, opaque, sealed envelopes were used to conceal study group assignments.

Active Involvement and Intervention. The active involvement and intervention (AII) is an active exercise protocol incorporating the idea of early and repeated movement based largely on Salter's work on continuous passive motion¹⁴ and components consistent with McKenzie's principles.^{10,15} The McKenzie system classifies spinal-related disorders on the basis of the mechanical (such as range of motion) and symptomatic (such as pain) responses to repeated movements, positions, and activities derived from the history and assessment. Treatment is predicated on these responses and emphasizes self-care. The active intervention and involvement thus consisted of two phases: 1) an initial phase including information, postural control, and cervical rotation exercises; and 2) a second phase, if symptoms were unresolved, of evaluation and treatment according to McKenzie principles.

Healthcare resources were used for this intervention using physical therapy. There were also societal costs in the form of loss of production for treatment.

Standard Intervention. Standard intervention (SI) consisted of written information in a leaflet on injury mechanisms, advice on suitable activities, and postural correction. This leaflet was used by the Neck Injury Unit, Orthopedic Clinic, Sahlgrenska University Hospital, Göteborg, Sweden.

Further details of the AII and SI have been presented in an earlier publication.¹⁰

Measurements. The main outcomes of the clinical study were change in pain intensity measured by a Visual Analogue Scale (VAS) of sensory intensity and affective magnitude, change in cervical range of motion, and number of sick leave days last 6 months. All measures were recorded at baseline, 6 months, and 3 years.

The VAS has been a commonly used scale in pain assessment.¹⁶ A 10-cm horizontal line with word anchors at each end, "no pain" and "maximum pain," was used. Patients indicated their experienced pain level by a mark on the line measured and recorded for each patient. The person was asked to make a mark on the line to represent pain intensity. This mark was converted to distance in centimeters from the "no pain" anchor to give a pain score that ranged from 0 to 10 cm.

Cervical range of motion was assessed by a medical laboratory technologist, registered nurse, or physiotherapist using a cervical measurement system.¹⁷ The personnel were instructed in the measurement technique according to the manufacturer to assure standardization.

At 6 months and 3 years, patients were asked to report the extent of full-time or part-time sick leave due to pain from shoulders, head, or neck due to the whiplash trauma in connection with the accident during the previous half-year. Self-reported sick leave has been shown to be a reliable method of recording sick leave.¹⁸

Health Economic Evaluation

Resource Consumption. Visits to the physiotherapist were recorded. Only healthcare resources consumed in relation to physiotherapy treatment were considered, while visits to other healthcare providers such as general practitioners or specialists were not included. Furthermore, total sick leave was calculated by adding part-time and full-time sick leave at the 6-month and 3-year follow-ups.

Cost-Consequence Analysis. A partial economic evaluation considering costs and consequences has been used in a cost-consequence analysis. The cost-consequence analysis consisted of a modified cost-effectiveness analysis where the costs for the competing interventions are first compared in a simplified cost analysis and later related to the benefits (outcomes) without using a cost-effectiveness ratio due to the use of several outcome variables.

All costs are in Swedish Crowns (SEK) and in United States Dollars (USD) based on the current exchange rate. Physical therapy treatment costs in the AII group were calculated by adding the patient fee of 80 SEK (\$10) to the government insurance agency subsidy costs of 222 SEK (\$28), giving a total of 302 SEK (\$38) per treatment session. This was multiplied by the average number of physical therapy treatment sessions of 3.95, giving a total treatment cost of 1,193 SEK (\$149) per patient in the AII group. We then estimated an average loss of production in connection with the treatment session at 3/8 of a day. Thus, estimated costs for production loss were 1,024 SEK

Table 1. Baseline Values

	Group 1	Group 2	Group 3	Group 4
Intervention	Active	Standard	Active	Standard
Intervention initiated	<96 hr	<96 hr	>2 wk	>2 wk
No.	21	23	22	22
Mean (SD) age (yr)	39 (16)	33 (11)	32 (12)	38 (14)
Sex (male/female)	8/13	8/15	8/14	5/17
Initial pain intensity*	37 (24,64); 43 (24.4)	30 (12,55); 34 (23.8)	35 (16,52); 40 (25.8)	39 (19,52); 42 (29.1)
Flexion in the cervical spine [mean (SD)]	40.4 (17)	44.5 (14)	49.8 (13)	41.3 (17)
Extension in the cervical spine [mean (SD)]	50.0 (17)	51.4 (16)	49.1 (16)	48.1 (18)
Flexion and extension in the cervical spine [mean (SD)]	90.4 (30)	95.9 (24)	98.9 (23)	89.4 (32)
Total lateral flexion in the cervical spine [mean (SD)]	65.2 (22)	66.2 (14)	64.2 (11)	53.7 (17)
Total rotation in the cervical spine [mean (SD)]	114 (38)	119 (21)	121 (24)	101 (31)
Total CROM in the cervical spine† [mean (SD)]	270 (81)	282 (50)	285 (49)	244 (75)

CROM = cervical range of motion.

*Visual Analogue Scale (VAS) indicating levels of pain intensity: length 0 to 100 mm. Higher values indicate higher pain intensity. First value is median value in VAS (25th and 75th percentile). Second value is mean value (SD).

†Lateral flexion, extension-flexion, and rotation were combined (SD).

(\$128) per day,¹⁹ adding up to 1,577 SEK (\$197) per patient in the All group. The source of the treatment costs was the Swedish Council on Technology Assessment in Health Care, Report 102, October 1999.

Costs were estimated both from the perspective of the healthcare system and from the societal perspective.

Statistical Analysis. Analysis was by intention to treat. The costs for each patient were compared in a two-factor analysis. Differences in initial measurements between the four groups

(Table 1) were analyzed with one-way analysis of variance (ANOVA) for continuous variables with equal variance between groups. Differences in variance between groups were tested using Bartlett's test for homogeneity of variance. χ^2 was used for dichotomous variables such as gender.

At the 6-month (Table 2) and 3-year (Table 3) follow-ups, change in pain intensity, the extent of reported sick leave during the previous half-year, and costs (Tables 2, 3) were compared between groups with a two-way ANOVA. Friedmann's test was used for skewed data.

Table 2. Six-Month Follow-Up

	Group 1	Group 2	Group 3	Group 4
Intervention	Active	Standard	Active	Standard
Intervention initiated	<96 hr	<96 hr	>2 wk	>2 wk
No.	21	23	22	22
Change in pain intensity*	-27 (-14, -46); -29.6 (24)	-6 (24, -16); 0.74 (30)	-11 (-5, -27); -15 (19)	-8.5 (-2, -13); -7.1 (22)
Low pain at follow-up†	52% (11/21)	30% (7/23)	36% (8/22)	9% (2/22)
Sick leave days for all patients‡	15.1 (42)	10.3 (22)	11.5 (38)	28.9 (51)
Sick leave days for patients 16-65 years of age	16.7 (44.8)	10.3 (22.2)	12.1 (39.1)	28.9 (50.7)
Sick leave ≥ 30 days for all patients§	2/21	3/23	1/22	6/22
Sick leave days for patients 16-65	2/19	3/23	1/21	6/22
Total costs (£)	8024	19835	96245	21225
(all patients) (€)	11689	28894	14021	30918
(\$)	15097	37320	18109	39935
Mean costs (£)	382	862	437	965
(all patients) (€)	557	1256	637	1405
(\$)	719	1623	823	1815
SD of costs (£)	617	1861	626	1531
(all patients) (€)	900	2710	912	2231
(\$)	1162	3497	1178	2881
Total costs (£)	7846	19835	9536	21225
(16-65 yr) (€)	11430	28894	13891	30918
(\$)	14763	37320	17942	39935
Mean costs (£)	413	862	454	965
(16-65 yr) (€)	602	1256	661	1405
(\$)	777	1623	854	1815
SD of costs (£)	643	1861	566	1531
(16-65 yr) (€)	936	2710	825	2231
(\$)	1209	3497	992	2881
Received interventions from sources outside the control of this study¶	3/21	9/23	5/22	9/21

*First value is median change in Visual Analogue Scale (VAS) (25th and 75th percentile). Second value is mean change (SD). Negative values indicate a decrease in pain level.

†Proportion of patients reporting ≤10 in VAS.

‡Sick leave during the preceding 6 months as estimated by the patient: mean no. of working days (SD).

§No. of patients reporting sick leave ≥30 days during the preceding 6 months due to whiplash injury (after/no. of patients with sufficient data).

||The costs calculated as initial physical therapy treatment costs and estimated costs for production loss during the previous half-year.

¶The no. of patients who received interventions from sources outside the control of this study. Data is missing from one patient in Group 4.

Table 3. Three-Year Follow-Up

	Group 1	Group 2	Group 3	Group 4
Intervention	Active	Standard	Active	Standard
Intervention initiated	<96 hr	<96 hr	>2 wk	>2 wk
No.	18	21	18	16
Change in pain intensity*	-17 (-2, -28); -21 (27.6)	-5 (18, -23); -1.8 (29.7)	-15.5 (-8, -28); -15.8 (22.4)	-10 (11, -20); -5.2 (27.3)
Low pain at follow-up†	39% (7/18)	43% (9/21)	61% (11/18)	31% (5/16)
Sick leave days for all patients‡	11.2 (44)	40.2 (71)	10.0 (42)	20.5 (50)
Sick leave days for patients 16–65 years of age	12.7 (46)	40.2 (71)	10.6 (44)	20 (50)
Sick leave ≥30 days for all patients§	1/17	6/21	1/18	3/15
Sick leave ≥30 days for patients 16–65 years of age§	1/15	6/21	1/17	3/15
Total costs (£)	3780	16425	3029	5377
(all patients) (€)	5503	23909	4409	7827
(\$)	7102	30854	5690	10101
Mean costs (£)	222	782	168	358
(all patients) (€)	324	1138	245	522
(\$)	418	1469	316	673
SD of costs (£)	392	1363	338	738
(all patients) (€)	570	1983	491	1075
(\$)	736	2559	634	1387
Total costs (£)	13860	16425	9279	5377
(16–65 yr) (€)	20170	23909	13498	7827
(\$)	24232	30854	16202	10101
Mean costs (£)	240	782	173	358
(16–65 yr) (€)	350	1138	252	522
(\$)	451	1469	325	673
SD of costs (£)	415	1363	347	738
(16–65 yr) (€)	604	1983	506	1075
(\$)	780	2559	653	1387

*First value is median change in Visual Analogue Scale (VAS) (25th and 75th percentile). Second value is mean change (SD). Negative values indicate a decrease in pain level.

†Proportion of patients reporting ≤10 in VAS.

‡Sick leave during the preceding 6 months as estimated by the patient: mean no. of working days (SD).

§No. of patients reporting sick leave ≥30 days during the preceding 6 months due to whiplash injury (after/no. of patients with sufficient data).

||The costs calculated as initial physical therapy treatment costs and estimated costs for production loss during the previous half-year.

All *P* values less than 0.05 were considered statistically significant. The computer program Epi Info version 6.04c (CDC, Atlanta, GA) was used for one-way ANOVA. The computer program SAS version 6.11 (SAS Institute) was used for two-way ANOVA and Friedmann's test.

■ Results

Of 97 patients correctly included, 88 (91%) could be followed up at 6 months. 73 (75%) participated in the 3-year follow-up. Dropouts are presented in Figure 1. The small baseline differences between the four groups in age, sex, initial pain intensity, and cervical range of motion (Table 1) were not statistically significant.

The mean number of involvement/interventions in the AII groups was 3.95. Symptoms persisting more than 20 days were seen in 63% (27 of 43) of patients in the AII group. They were subsequently reexamined and treated with a complete mechanical diagnosis and therapy according to the McKenzie evaluation.¹⁵ The number of patients receiving interventions from sources outside the control of this study did not differ statistically between groups (Table 2) but were numerically higher in the SI groups.

Changes over time were generally more favorable in the AII group compared with the SI group (Tables 2, 3), and all statistically significant differences between groups were in favor of the AII group (Table 4). The results are divided into two groups: all patients and for

patients 16 to 65 years of age normally covered by the Swedish insurance system. The time factor did not influence costs and no interaction between the treatment factor and the time factor was found.

■ Discussion

The contribution AII makes to patient utility or welfare through better health was demonstrated in the significant pain reduction and reduced amount of reported sick leave.¹⁰ Costs were also lower for the AII regarding healthcare costs and loss of production.

The health economic analysis does not claim to be exhaustive but considers some of the most important direct and indirect costs involved. The aim of economic evaluation is to ensure that the benefits from healthcare programs implemented are greater than the opportunity costs. If we assume that less pain and fewer sick leave days indicate effectiveness of the AII, then the lower costs should enable care providers to consider this intervention in patients exposed to whiplash trauma in an automobile crash. A weakness of the study was the absence of an instrument to measure self-perceived disability from neck pain, including that which may arise in WAD such as the Whiplash Disability Questionnaire.²⁰

The two-factor design not only divided patients into groups but also calculated *P* values using a two-way

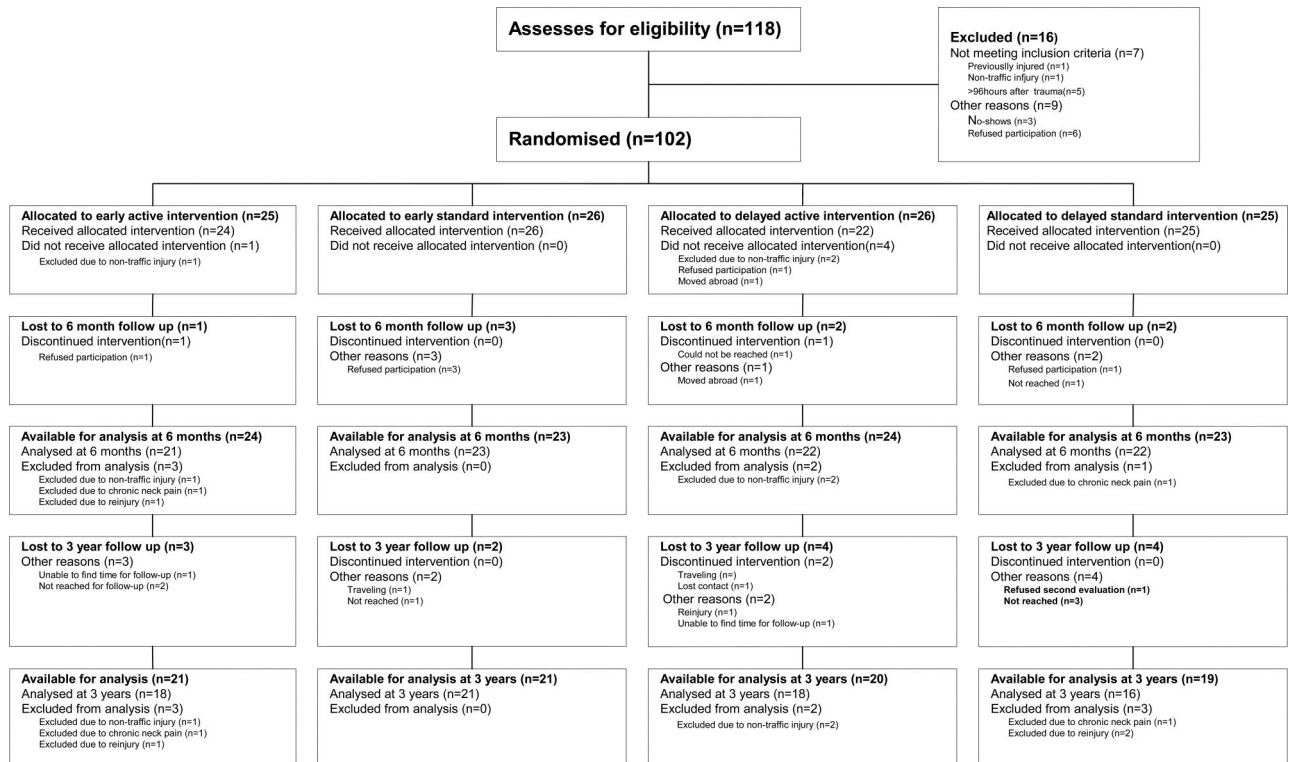


Figure 1. Flow of participants.

ANOVA or Friedmann's test. In these statistical tests, all four groups were used simultaneously in the calculation of any *P* value. Thus, the number used to calculate the *P* values in Table 4 were not 16 *versus* 21, or 18 *versus* 18, but simply 88 or 73. The two-factor design reduces the large numbers of patients required when several one-factor trials are used.

Regarding the AII, a distinction has been made between involvement and intervention due to the nature of the initial contact with the physical therapist who only examined, informed, and instructed the patient on self-treatment in a home exercise program. The protocol did not initially include any hands-on techniques

or passive methods to emphasize the patient's own key role in the healing process, thus avoiding the risk for therapist dependency and preparing the patient for personal responsibility in the rehabilitation process. According to the Ontario experience of a secondary prevention program for musculoskeletal disorders, "courses of action offered within the acute stage of injury appear to be successful only . . . when geared more toward early involvement than intervention."²¹ The involvement in this study at the initial visit was information, reassurance, and encouragement to movement (regularly performed cervical rotation) and activity in accordance with this distinction. Interven-

Table 4. Differences in Outcome (*P* Values) Between Active Intervention and Involvement *Versus* Standard Intervention

	6-Month Follow-Up		3-Year Follow-Up	
	ANOVA*	Friedmann†	ANOVA	Friedmann
Change in pain intensity‡	0.0004	0.0009 (0.019)	0.020	0.026 (0.028)
Sick leave days for all patients§	—	NS	—	0.030
Sick leave days for patients 16–65 years of age§	—	NS	—	0.048
Change in total CROM	NS	NS	NS (0.092)	NS (0.062)
Costs for all patients¶	—	0.036	—	0.0008
Costs for patients 16–65 years of age¶	—	0.035	—	0.0011

NS = not significant.

*In case of skewed data, the nonparametric test described by Friedmann was used (—). In such cases, this is noted by.

†Friedmann's test is usually performed on raw data. In a visual analogue scale (VAS), it may also be performed on transformed data where improvement is coded as +1, worsening as -1, and unchanged as 0. The outcome of Friedmann's test used on transformed data is given within parentheses.

‡Comparison between groups of the mean change in VAS.

§Comparison between groups of mean no. of days on sick leave during the preceding 6 months as estimated by the patient.

||Comparison between groups of the mean change in total cervical range of motion (CROM).

¶Comparison between groups of the mean costs per patient calculated as initial physical therapy treatment costs and estimated costs for production loss during the previous half-year.

tion was first introduced after 20 days only if symptoms showed little or no tendency to resolve. The emphasis of the intervention was then on self-treatment.

Patients could thus be helped with a small number of visits (average of 3.95) and with little dependency on apparatus making this treatment accessible to most therapists including those with limited resources.

From the perspective of the healthcare system, costs for the AII were higher than the costs for the standard treatment, which consisted of an information folder but no physical therapy treatment. No consideration was made for the costs of outside interventions. As seen in Table 2, there were numerically more interventions outside the study for patients in the standard group. Thus, assuming this was a true observation and if the costs for these interventions were added to the costs for both interventions, the differences in healthcare costs would be somewhat less than our present analysis, thus increasing the cost advantage of the AII.

Again, this study does not claim to make an exhaustive cost analysis, but the benefits of the treatment combined with relatively low costs should aid healthcare providers in choosing a treatment alternative for patients with WAD.

From the viewpoint of society, faster recovery and resumption of preaccident functioning seen for the AII should considerably affect insurance and litigation costs, although these costs were not studied in this trial.

Adverse Events

An adverse event was a painful reaction to a test movement performed during the McKenzie evaluation. The movement was cervical retraction, which has during recent years been shown to be the probable injury mechanism in many whiplash injuries.^{22–24} The test movement was subsequently used with caution or eliminated in evaluations, and there were no subsequent negative side effects. The cervical rotation exercises for gentle mobilization of the joints and nerves caused slight discomfort in some patients. These patients were instructed to perform the exercise supine as opposed to the sitting position. No further adverse events were recorded.

External Validity

The study population was selected consecutively from a large area consisting of patients from both urban and rural populations. It was estimated that the majority of patients exposed to whiplash trauma in this area who fulfilled the inclusion criteria were included,²⁵ thus establishing the generalizability of the sample.

Conclusion

Active involvement and intervention is a cost-saving alternative compared with a standard intervention in patients exposed to whiplash trauma, when costs related to physical therapy treatment and productivity were considered. It should thus be considered in the choice of treatment of these patients.

Key Points

- Significant clinical benefits of an active involvement and intervention for patients with whiplash injury are presented.
- The cost and consequences of the competing interventions are analyzed and compared in the study.
- A modified cost-effectiveness analysis was used.
- An active involvement and intervention was both less costly and more effective than a standard intervention.

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