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Neck Collar, "Act-as-Usual" or Active Mobilization for Whiplash Injury?

A Randomized Parallel-Group Trial

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Study Design. Randomized, parallel-group trial.

Objective. To compare the effect of 3 early intervention strategies following whiplash injury.

Summary of Background Data. Long-lasting pain and disability, known as chronic whiplash-associated disorder (WAD), may develop after a forced flexion-extension trauma to the cervical spine. It is unclear whether this, in some cases disabling, condition can be prevented by early intervention. Active interventions have been recommended but have not been compared with information only.

Methods. Participants were recruited from emergency units and general practitioners within 10 days after a whiplash injury and randomized to: 1) immobilization of the cervical spine in a rigid collar followed by active mobilization, 2) advice to "act-as-usual," or 3) an active mobilization program (Mechanical Diagnosis and Therapy). Follow-up was carried out after 3, 6, and 12 months postinjury. Treatment effect was measured in terms of headache and neck pain intensity (0–10), disability, and work capability.

Results. A total of 458 participants were included. At the 1-year follow-up, 48% of participants reported considerable neck pain, 53% disability, and 14% were still sick listed at 1 year follow-up. No significant differences were observed between the 3 interventions group.

Conclusion. Immobilization, "act-as-usual," and mobilization had similar effects regarding prevention of pain, disability, and work capability 1 year after a whiplash injury.

Key words: neck pain, whiplash injuries, randomized controlled trials, prospective studies, physical therapy, immobilization. **Spine 2007;32:618–626**

Forced acceleration-deceleration trauma to the cervical spine, known as a whiplash injury, is often accompanied by regional neck pain, neck stiffness, headache and shoulder pain in the early posttraumatic period.[1–3] In some patients, these and more remote symptoms may persist as a chronic condition termed chronic whiplash associated disorder (WAD).[4] Reported risks of developing chronic WAD after a whiplash injury vary considerably ranging from 0% in Lithuania[5] and Greece,[6] 8% to 30% in Denmark, Norway, and England[7–9] and up to 79% in Sweden.[10] Prevention of chronic WAD is an important issue both to reduce personal suffering and from a socioeconomic point of view.

The mechanisms underlying the maintenance of WAD are not fully identified although both biomechanical and psychosocial factors seems to be at play.[11,12] Previous studies observed high initial pain intensity[11] and reduced neck mobility[7] to be important risk factors for development of chronic WAD. Assuming that these factors are treatable, early intervention directed toward neck pain and dysfunction may be important to avoid long-term consequences. Based on the logic that the acute whiplash injury represents a distortion of cervical structures,[13,14] treatment suggestions in the acute phase vary from immobilization to recommending "act-as-usual" or exercise therapy.[15–21] At present, there is no strong evidence to support one specific treatment strategy for another, and costly treatments are frequently offered without any evidence of effect. Mobilization programs have been shown to have a somewhat better effect than a soft collar and passive treatment methods.[22–26] Also, advice to act as usual was superior to a soft collar,[20] whereas immobilization in a semirigid neck collar for 4 weeks was reported to be superior to a mobilization regimen.[15] Based on previous trials, active treatment strategies have been recommended.[18,27] However, the effect of such active strategies has only been compared with simple information in one trial, which showed advice to stay active to be as good as exercise therapy, with a trend in favor of advice.[28] If cervical distortion plays a role in the development of acute and long-term symptoms after whiplash injury, mobilization as well as immobilization of the cervical spine in the first weeks after injury may have a beneficial effect. Thus, in order to study the spectrum of treatment regimens, we have chosen to include immobilization in a semirigid collar, mobilization of the cervical spine, and advice only.

The focus of this trial was on the possibility to prevent chronic sequelae after a whiplash injury using interventions directed towards soft tissue damage in the cervical

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spine. The specific aim was to compare the effect of 3 intervention strategies to prevent the development of WAD after acute whiplash injury following a car collision. The interventions were: 1) immobilization of the cervical spine in a semirigid collar, 2) advice to "act-as-usual" (no active treatment), and 3) active mobilization.

■ Materials and Methods

This prospective, randomized trial was carried out at 2 university research centers between May 10, 2001 and June 17, 2004, with the recruitment period ending in June 2003. The study was approved by the local ethical committees and conducted in accordance with the Helsinki II declaration.

Participants. Participants were recruited from emergency units and general practitioners in 4 Danish counties covering 1,695,808 inhabitants in 2001.[29] Potential participants were informed about the study and design in the written invitation for pre-enrollment.

Subjects 18 to 70 years of age who had been exposed to a rear-end or frontal car collision experienced symptoms within 72 hours and could be examined within 10 days of the collision qualified for inclusion. Exclusion criteria were: fractures or dislocations of the cervical spine, amnesia or unconsciousness in relation to the accident, injuries other than the whiplash injury, self-reported average neck pain during the preceding 6 months exceeding 2 on a box scale 0 to 10, where 0 = no pain and 10 = worst possible pain, significant preexisting somatic or psychiatric disease, and known alcohol or drug abuse. Subjects were also excluded if they did not read or understand Danish.

Randomization Procedure. Potential participants were visited in their homes by a project-nurse, who provided information about the project and performed the inclusion. Subjects who consented to participate were allocated into 2 trials based on an allocation score. In accordance with our previous observations that only about 1 of 10 acute whiplash-injured will develop long-term handicap,[7] it was the idea to select those whiplash injured at higher risk for developing chronic WAD for an intervention trial. The allocation score was developed from identified risk factors for chronic WAD as observed in previous trials.[7,11] Briefly, the identified risk factors were gender, pain, number of nonpainful complaints and cervical range of motion. These factors were combined into a "risk score" which determined allocation to the intervention trial. Pain above 4 or summarized cervical range of motion of 240° or less was considered high risk on its own.

Those with marked symptoms and an expected increased risk of developing persistent symptoms were included in the present intervention trial, and those who reported milder symptoms were included in another study (to be reported elsewhere). Participants in the intervention trial were randomly assigned into one of 3 treatment groups by means of computerized minimization performed independently in the 2 centers.[30] Using computerized minimization, the randomization sequence was generated when participants were registered. Allocation to treatment was in this way automatically concealed. Variables equally distributed through minimization were age (4 groups), gender, pain intensity (4 groups), and cervical range of motion (4 groups).

Intervention Protocols. All participants had information with an emphasis on a generally good prognosis of the condition and simple advice about the use of ice and mild analgesic medication for pain. The information was summed in a pamphlet.

Immobilization in Neck Collar. A semirigid Philadelphia neck collar (Rehband, Otto Bock Scandinavia AB, Sweden) was applied by the project nurse, and participants were instructed to wear it during all waking hours during a 2-week period. Participants could maintain normal activity to the degree this was possible while the neck was immobilized. Participants consulted the physiotherapist at the end of the 2-week period and were instructed in an active mobilization program similar to that done in the last 4 weeks in the active mobilization group (described below). A maximum of 2 treatment sessions per week during a 4-week period were given.

Act-as-Usual. Participants received thorough information about whiplash injuries and about the rationale for staying active in spite of symptoms. The checklist-based information, about whiplash and handling of pain, given by a research nurse, aimed at reducing fear and motivating participants to resume normal activities. It was explained that acute pain is an expected event after injury due to soft tissue damage. The information emphasized the importance of staying active, that additional muscle spasm might be reduced by attempting to move as naturally as possible, and it was described how focus on pain can enhance pain. Individual questions were answered in agreement with the messages of the checklist. The information session lasted approximately one hour.

Active Mobilization. This intervention was carried out by one physiotherapist at each center using the principles of Mechanical Diagnosis and Therapy (MDT), which are based on repetitive movements directed by pain response.[31] One of the physiotherapists had a MDT diploma from the McKenzie Institute International and trained the other physiotherapist before the study. Consultations took place a maximum of twice weekly for 6 weeks. For 3 weeks after the accident participants were

Table 1. Grading of Compliance to Interventions

Compliance	Neck Collar	Active Mobilization
Good	Did wear the neck collar more than 10 days AND followed instructions from the physiotherapists	All appointments with the physiotherapists were attained and home exercises were performed
Average	Did wear the collar 4–10 days AND followed instructions from the physiotherapists OR did wear the collar more than 10 days but did not follow instructions from the physiotherapists	Appointments with the physiotherapists were attained but instructions not adequately followed OR did not attain one or more appointments
Poor	Did wear the collar for less than 4 days OR did wear collar 4–10 days but did not follow instructions from the physiotherapists	Did not attain any appointment OR had some contact to the physiotherapists but did not follow instructions

instructed to do light repetitive rotational movements within the pain-free range of motion performed in series of 10 every waking hour. In addition, participants were instructed to move the neck in end range of motion once in each movement direction every day, and guidance regarding posture was given. Participants who still had symptoms after 3 weeks were examined according to the MDT protocol. According to this, exercises and advice about posture and physical activities were prescribed. During the 3-week program, exercises were adjusted according to symptom response. In case of no direction preference, participants were instructed to move the neck in all planes as far as possible without worsening of symptoms. They were advised to gradually increase range of motion as pain declined. If symptoms did not respond to the MDT testing or if the there was insufficient response to the active intervention during the course of treatment, passive mobilization and soft tissue techniques to the cervical spine and upper back were added. The therapists could be contacted by phone during the 6-week intervention period.

Compliance to the treatment arms was graded as good, average, or poor according to the criteria listed in Table 1.

Outcome Measures

Primary Outcome Measures. Self-reported data at the 1-year follow-up were used as primary effect measures. Participants scored their average neck pain and headache the preceding week on a box scale 0 to 10 (0 = no pain and 10 = worst possible pain).[32] Neck disability was measured by the 15-item Copenhagen Neck Functional Disability Scale (0 = no neck disability and 30 = extremely disabled).[33] The scales for measuring pain and disability have been validated in other spinal pain populations.[33,34] Self-reported working ability during the 12th month after the injury was registered by marking days with sick listing and reduced working hours in a calendar, which was checked with participants at the research center when they met for the final clinical examination.

Secondary Outcome Measures. Changes in neck pain and headache from baseline to 1-year follow-up were evaluated as secondary outcome parameters. Medication and general health status measured by SF-36[35] were also included as secondary outcome parameters.

Clinical examinations included measurements of neck mobility and a neurologic examination. Neck mobility was measured as described previously[7] as the maximal active range of motion in 3 planes by a cervical range of motion device (Performance Attainment Associates, Roseville, MN). The neurologic examination was performed according to common clinical standards and included cranial nerve function, muscle strength, tendon reflexes, and sensory testing. The examiners were blinded with respect to patients' treatment groups and had no access to the database coupling identification numbers and names with intervention group. Participants were instructed not to mention their treatment program during clinical examinations.

Socio-demographic factors, crash-related factors, and the degree of traumatic stress reaction (Impact of Event Scale[36]) were recorded.

Statistical Methods. We estimated that in the present high-risk group approximately 15% in the information group would be sick-listed after 1 year. This was based on previous observations that reduced work capacity occurred in 8% of whiplash injured.[7] With a similar event rate in one of the other groups and a reduction in event rate to not less than 4.5% in the last group, 150 persons would be required in each group in order to obtain a 90% power with an estimated 10% dropout rate. This power calculation was based on a simulation study of 10,000 repeated measures. The treatment difference was set at this level based on the feasibility to carry out a study on a nonfatal pain disorder in 2 centers within a reasonable time period.

Data are presented as medians with interquartile ranges (IQR) and analyzed by nonparametric methods. The distributions of baseline data were compared between the 2 centers before pooling the data. The outcome parameters, neck pain, headache, and neck disability, were analyzed both as continuous outcomes and dichotomized into "minimal" and "considerable." Pain scores from 0 to 3 and disability scores from 0 to 6 were defined as "minimal" based on previously suggested

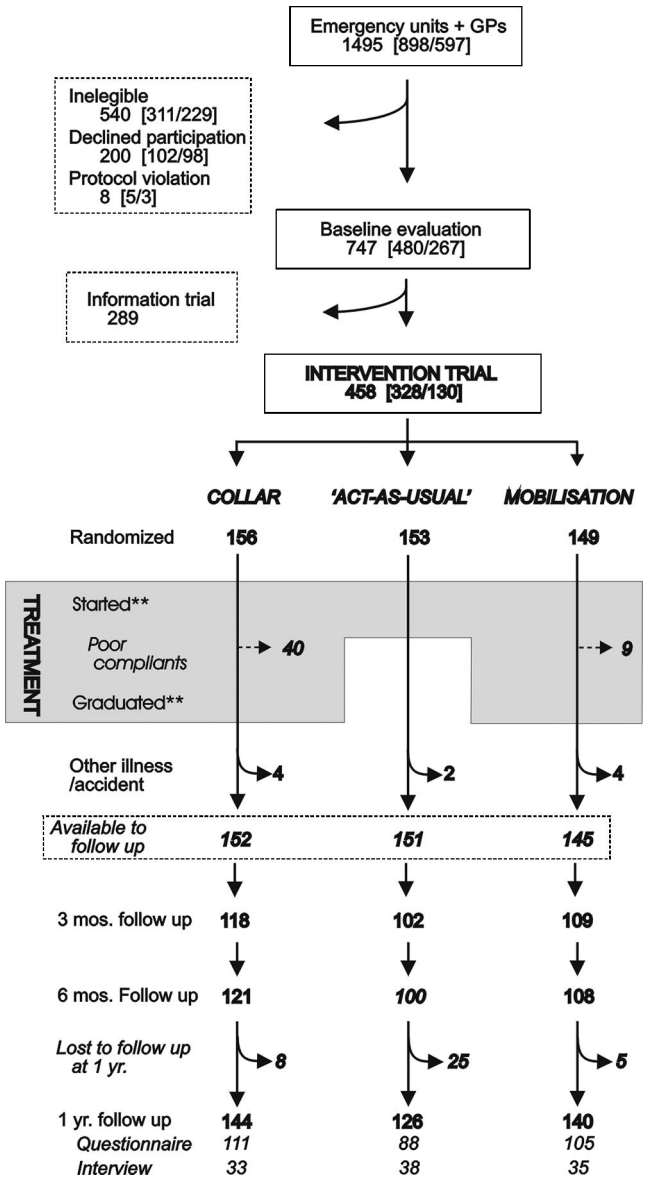

Figure 1. Flow of participants. Participants referred to the project and included for the present intervention trial. Broken arrows indicate noncompliant participants, who were not excluded from the further analyses. Numbers in brackets represent females/males.

Table 2. Baseline Characteristics of Participants in Each of the Intervention Groups

Characteristic	Neck Collar	Act-as-Usual	Active Mobilization	All Participants
No. enrolled	156	153	149	458
Gender (% male)	29	27	29	28
Age (yr) [median (IQR)]	33 (26–42)	34 (26–41)	33 (25–45)	34 (26–43)
Days from accident to inclusion [median (IQR)]	5 (3–6)	4 (2–6)	4 (3–6)	4 (3–6)
Onset of symptoms (%) within 1 hr	56	50	46	51
Car collision direction				
Rear-end, direct (%)	56	48	61	55
Frontal, direct (%)	14	18	18	17
Rear-end, oblique (%)	17	17	13	16
Frontal, oblique (%)	13	17	7	12
Vocational education (%)				
Unskilled worker	23	25	24	24
Skilled worker	30	38	33	34
Academic, max. 4 yr	24	19	21	21
Academic, >4 yr	6	6	9	7
Other	17	12	13	14
Occupation (%)				
Self-employed	5	5	5	5
White-collar	38	34	42	38
Blue-collar	27	28	17	24
Student/trainee/apprentice	18	18	26	21
Unemployed (including on leave, pensioner etc.)	12	15	10	12
Neck pain intensity box-scale (0–10) [median (IQR)]	5 (4–6)	5 (4–7)	5 (4–7)	5 (4–6)
Headache intensity box-scale (0–10) [median (IQR)]	5 (3–7)	5 (3–7)	5 (3–7)	5 (3–7)
Total cervical range of motion (°) [median (IQR)]	252 (197–294)	248 (190–298)	244 (198–286)	248 (197–294)
No. of nonpainful complaints (0–11) [median (IQR)]	4 (3–6)	4 (3–6)	4 (3–6)	4 (3–6)
General health status, SF-36 [median (IQR)]				
Physical health summary	55 (52–58)	55 (50–58)	56 (52–58)	55 (51–58)
Mental health summary	58 (55–60)	57 (52–60)	57 (53–60)	57 (53–60)
Impact of event (0–75) [median (IQR)]	12 (5–24)	12 (5–22)	10 (3–20)	11 (4–22)

IQR indicates interquartile range.

categories[33] and the distribution of the variables. Missing items in the neck disability scale were replaced by worst case scores if a maximum 2 of 15 items were missing, and no disability score was calculated if more items were missing. Work capability had a dichotomous distribution and was split into 1) "unaffected work capability" if no days with sick-listing or reduced working hours were reported during the 12th month after the accident and 2) "affected work capability" if any sick listing or days with reduced working hours were reported during that period, or if no longer working because of the accident.

Change in pain scores from baseline to 1-year follow-up were defined as improved (difference: 3; 10) unchanged (difference: −2; 2), and worse (difference: −3; −10).[37]

Analyses were performed by means of linear and logistic regression using robust variance estimations. Regression models were adjusted for age, gender, center, baseline cervical range of motion, and baseline impact of event. Analyses of neck disability and work capability were furthermore adjusted for baseline neck pain because these parameters have previously been observed to influence on the outcome.[7,11,38]

Primary outcome parameters were determined *a priori* and data analyses were performed blinded to treatment groups. The treatment group was mistakenly revealed to the blinded observer before the clinical examination in 5 cases. Two of these belonged to the neck collar group and 3 to the active mobilization group. Follow-up data were included in the analyses since effect-measures were self reported, and questionnaires were filled in before the last examination. Hypothesis-testing was 2-sided and intention-to-treat analyses were performed. Secondarily to these, 2 per-protocol analyses were performed: 1) including only participants who did not seek any neck-treatment in addition to that prescribed in the project, and 2) excluding participants with poor compliance to treatment. STATA 8.2 was used for all data management.

■ Results

Participants

A total of 458 participants were included in the present trial. The flow-chart is shown in Figure 1. Baseline characteristics were similar in the 3 treatment groups (Table 2). The distributions of baseline data were comparable in the 2 centers (data not shown). In the "act-as-usual" group, 25 participants were lost during follow-up as compared with 8 in the immobilization group and 5 in the active mobilization group. Those lost to follow-up did not differ significantly from others as regards baseline parameters (Table 3).

Interventions

The median number of consultations in both treatment groups was 2 (range, 0–9) plus 1 contact by phone (range, 0–6). Median duration of consultation time in the neck collar group was 40 minutes (IQR, 35–45) and in the mobilization group 38 minutes (IQR, 34–43). No adverse affects were registered in any of the intervention groups. Eight participants in the neck collar group and 11 in the active mobilization group progressed to passive mobilization techniques, and 6 and 12 in the respective groups received soft tissue treatment in addition to exercises.

Good compliance was accomplished by 80 of 151 (~53%) in the collar group and by 106 of 140 (~76%)

Table 3. Baseline Characteristics in Participants Who Completed the Trial and Those Who Dropped Out

Characteristic	Neck Collar		Act-as-Usual		Active Mobilization	
	Complete	Lost for Follow-up (n = 8)	Complete	Lost for Follow-up (n = 25)	Complete	Lost for Follow-up (n = 5)
Gender (% male)	28	50	29	20	29	40
Age (yr) [median (IQR)]	34 (26–43)	28 (23–32)	36 (27–44)	27 (22–35)	33 (25–45)	38 (35–52)
Neck pain (0–10) [median (IQR)]	5 (4–6)	4 (2–7)	5 (4–6)	5 (4–7)	5 (4–7)	7 (5–8)
Headache (0–10) [median (IQR)]	5 (3–7)	5 (1–8)	5 (3–7)	5 (4–7)	5 (3–7)	5 (2–8)
Sick listed at baseline (%) (95% CI)	54% (45–62)	50% (5–95)	52% (43–61)	48% (27–69)	55% (46–63)	60% (33–67)

IQR, interquartile range; CI, confidence interval.

in the active mobilization group. Poor compliance was registered in 40 of 151 (~26%) and 9 of 140(~6%) in these groups, respectively. Participants with poor compliance in the collar group were less likely to be sick listed at baseline. Other baseline data did not differ between compliance groups. Poor compliant participants in the collar group reported a better outcome at 1-year than others (Table 4), whereas the outcome of poor compliants to active mobilization could not be reliably estimated since only 4 of 9 completed follow-up.

A total of 121 of 327 participants (~37%) had received other neck interventions in addition to those prescribed in the project at the 3-month follow-up. In the collar, "act-as-usual," and mobilization groups, this was reported by 35%, 44%, and 32%, respectively ($P = 0.2$). Both frequency and types of treatment methods were similar in the 3 groups (Table 5). Participants reporting cotreatment after 3 months recovered less well on neck pain (estimated difference 1.7, $P < 0.001$), headache (estimated difference 1.7, $P < 0.001$), neck disability (estimated difference 4.2, $P < 0.001$), and work capability (odds ratio 2.7, $P < 0.001$) than others. An additional group of 9, 10, and 5 patients from the respective groups who did not report cotreatment at 3-month follow-up reported so after 6 months.

Primary Outcome Measures

During the observation period, all 3 groups reported reduced headache and neck pain intensity. Improvement occurred mainly during the first 3 months after injury. Pain and neck disability scores at each follow-up are shown in Figure 2. Participants followed only by interview did not score box-scales and disability scores. Neck disability scores could not be calculated in 31 participants because of missing items, and worst case replacement of one or 2 items was performed in 29, 30, and 41 scales in the collar, "act-as-usual," and mobilization groups, respectively. Working ability 12 months after the accident is shown in Figure 3. Outcomes at the 1-year follow-up are summarized in Table 6. As shown, differences between groups were nonsignificant ($P = 0.1–0.6$).

Secondary Outcome Measures

An improvement from baseline to 1-year follow-up was reported by 38% in the collar group, 33% in "act-as-usual," and 40% in the mobilization group. Worsening was reported by 12%, 17%, and 10% in the respective groups ($P = 0.6$). For headache, the percentages of participants improved/worsened in the 3 groups respectively were 24 of 18, 23 of 13, and 28 of 10, ($P = 0.5$). Other secondary endpoints did not reveal any group differences either (Table 6).

Per-Protocol Analyses

Group comparisons performed after exclusion of data from those participants who had other neck-directed treatment in addition to the intervention in the project generally revealed results close to those of the intention-to-treat-analyses. The largest difference to main analyses was an

Table 4. Baseline Variables and Outcome in Good and Poor Compliers to the Neck Collar

	Neck Collar*			
	Good Compliers (N = 80)	Poor Compliers (N = 40)	Act-as-Usual (N = 153)	Mobilization (N = 149)
Baseline				
Neck pain [median (IQR)]	5 (4–7)	5 (4–6)	5 (4–7)	5 (4–7)
Headache [median (IQR)]	5 (3–7)	4 (2–7)	5 (3–7)	5 (3–7)
Sick listed (%)	62	38	52	54
1-yr				
Neck pain [median (IQR)]	4 (2–7)	1.5 (0–4)	4.5 (0–8)	3 (0–6)
Headache [median (IQR)]	4 (1–7)	2 (0–6)	3.5 (0–7)	2 (0–7)
Not returned to work (%)	16	12	12	12

*Results for participants with average compliance not shown.
IQR indicates interquartile range.

Table 5. Treatment Modalities Received by Participants in the Three Intervention Groups Outside the Research Setting

Treatment Modality	Neck Collar (n = 118)	Act-as-Usual (n = 102)	Active Mobilization (n = 109)
Neck-directed intervention (massage, mobilization, manipulation)	35% (n = 113)	44% (n = 99)	32% (n = 108)
Ultrasound, laser, electrotherapy	10% (n = 109)	10% (n = 96)	9% (n = 106)
Acupuncture, zone therapy	7% (n = 106)	17% (n = 96)	13% (n = 107)
Blocks	3% (n = 104)	0 (n = 94)	0 (n = 103)
Psychological therapy	4% (n = 104)	4% (n = 93)	5% (n = 103)
Others	14% (n = 109)	15% (n = 95)	12% (n = 104)
Any treatment other than prescribed in the project	46% (n = 116)	52% (n = 102)	43% (n = 109)

All group differences were nonsignificant.

estimated higher risk of altered working ability in the neck collar group (*vs.* act-as-usual OR = 2.3, *vs.* mobilization OR = 3.2, $P < 0.05$). Also, the per-protocol analysis, excluding participants with poor compliance to the prescribed intervention, revealed generally small differences to the primary analyses. The main difference was a poorer outcome regarding disability for the neck collar group (*vs.* act-as-usual OR = 2.4, *vs.* mobilization OR = 1.7, $P < 0.05$). No other statistical significant group differences were observed.

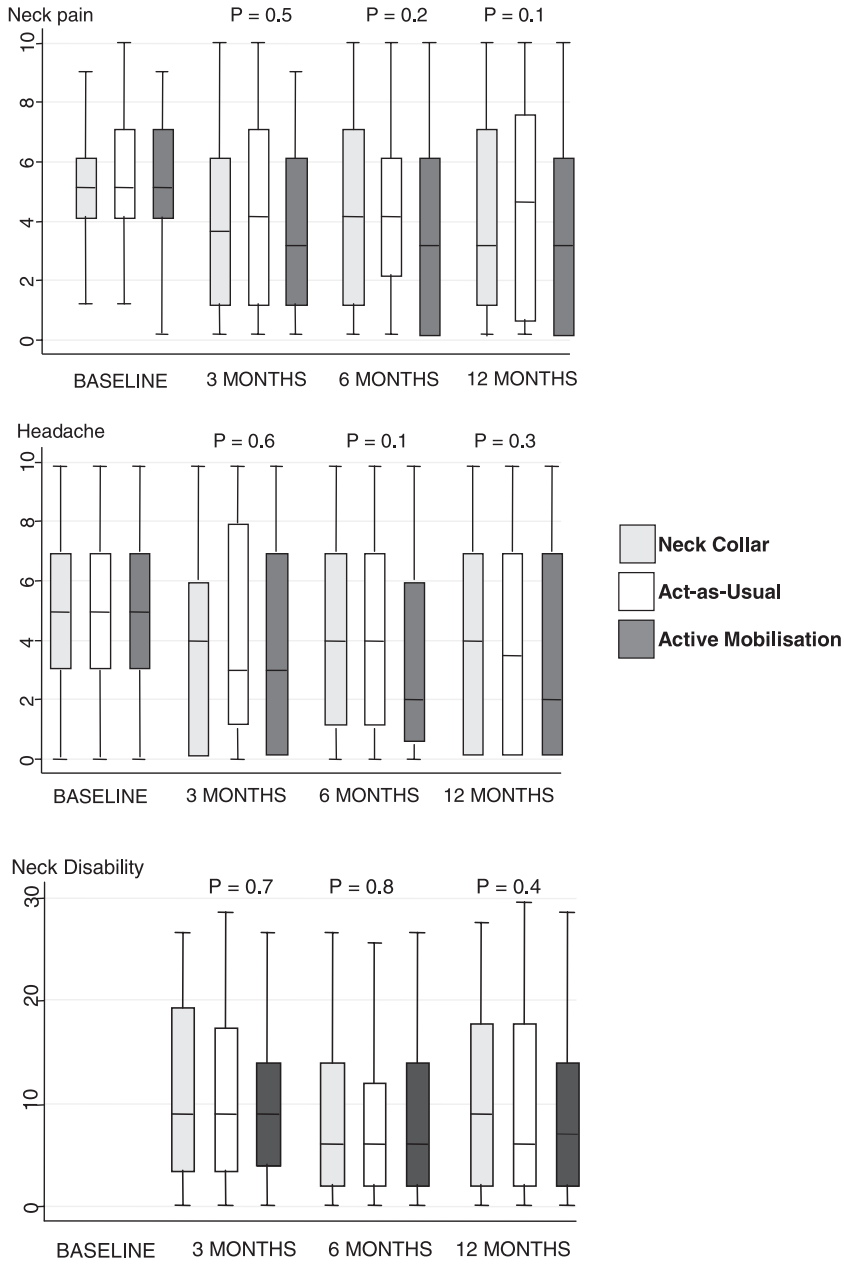

Figure 2. Neck pain, headache, and neck disability following whiplash injury. The plots illustrate neck pain, headache, and disability at baseline and after 3, 6, and 12 months. *P* values indicate tests of group differences.

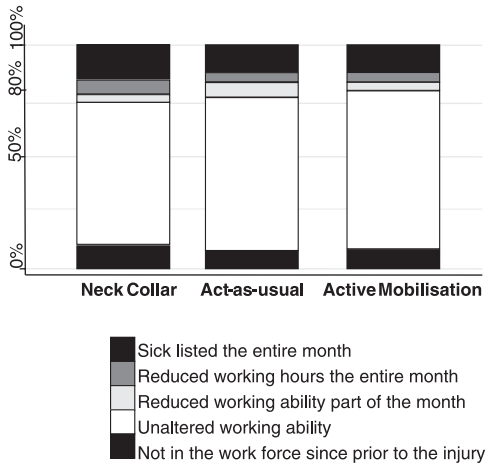

Figure 3. Working ability in the 12th month after a whiplash injury.

■ Discussion

Almost similar outcomes regarding pain intensity, disability, and work capability were observed across the 3 treatment groups, indicating that advice to "act as usual" is as effective as prescribing immobilization or a structured mobilization program. This is in line with previous results indicating that education by GPs and education and exercises by physiotherapists were of similar effectiveness.[28]

This trial was the largest prospective trial to date addressing this issue. The study was powered to detect differences for rates of lowered working ability of approximately 10%. This corresponds to the number needed to treat of approximately 10 for a very robust outcome parameter. For a nonfatal condition like WAD, we consider this to be a clinically relevant difference. It is unlikely that a smaller effect may have been missed because both primary and secondary outcome parameters had very similar distributions across the groups.

Two issues complicate the interpretation of the present trial: poor compliance to treatment and the frequent use of treatment other than prescribed. We used a simple, novel 3-point scale to quantify compliance, which was shown to be associated with outcome. Those withdrawing from wearing the collar generally had a better prognosis than the remaining study population. The reason for this is not clear, but one possibility is that those who did better ignored treatment. It may be speculated that poor compliance to the collar was more likely to occur in patients without fear-avoidance behavior,[39] and that this could be one explanation for the superior outcome in this group. Since withdrawal from the collar did not impede recovery, it could not mask a possible treatment effect. Poor compliance to active mobilization was only registered in 9 participants, a number too small to influence the general outcome in that group.

Cotreatments were numerous, but the type and extent of cotreatment did not differ between project groups. Hence, a similar number of participants in each treatment group did not find the prescribed intervention sufficient. Intention-to-treat analyses were chosen to mimic a realistic setting, in which patients possibly are as likely to choose additional interventions, as in a research setting. Per-protocol analyses showed results very close to the primary analyses, but the neck collar group tended to have a poorer outcome.

In the "act-as-usual" group, more participants were lost for follow-up than in the other groups. This could be due to dissatisfaction with a feeling of lacking treatment, and recovery in that group may therefore be overestimated. However, at least at baseline, those lost to follow-up did not differ from those completing the trial.

Early intervention after whiplash injury using MDT principles has previously been observed to have an effect on the outcome.[21,22] In one trial, mobilization starting

Table 6. Outcome at the 1-Year Follow-up

	Neck Collar	Act-As-Usual	Active Mobilization	All Participants	Adjusted *P*
Neck pain intensity box-scale (0–10) [median (IQR)]	3 (1–7)	4.5 (0–8)	3 (0–6)	3 (1–6)	0.1
Subjects with neck pain >3% (95% CI)	47 (37–56)	56 (44–66)	44 (34–53)	48 (43–54)	0.3
Headache intensity box-scale (0–10) [median (IQR)]	4 (0–7)*	3.5 (0–7)	2 (0–7)	3 (0–7)	0.3
Subjects with headache >3% (95% CI)	54 (44–64)	50 (39–61)	44 (34–53)	49 (44–55)	0.3
Neck disability (0–30) [median (IQR)]	9 (2–18)†	6 (2–18)‡	7 (2–14)§	7 (2–17)	0.4
Subjects with disability >6% (95% CI)	59 (49–69)	46 (35–57)	53 (43–63)	53 (47–59)	0.2
Subjects with affected work ability (%) (95% CI)	28 (20–36)‖	25(17–33)¶	22 (15–30)	25 (21–29)	0.6
Medication (%) (95% CI)					
Any analgesic used	59 (49–68)	62 (52–72)	48 (38–58)	56 (50–62)	0.1
Strong analgesics used 5–7 days/wk	6 (2–11)	11 (5–18)	4 (0–8)	7 (4–10)	0.1
General health status, SF-36					
Physical health summary [median (IQR)]	46 (34–56)	46 (35–54)	46 (40–55)	46 (36–55)	0.6
Mental health summary [median (IQR)]	55 (47–58)	54 (41–58)	54 (43–58)	54 (44–58)	0.8

Outcome measures at the 1-year follow-up.
*One missing value from participants completing questionnaires.
†Fourteen missing values from participants completing questionnaires.
‡Eight missing values from participants completing questionnaires.
§Nine missing values from participants completing questionnaires.
‖One missing value from participants completing questionnaires or interview.
¶Three missing values from participants completing questionnaires or interview.
IQR indicates interquartile range, CI, confidence interval.

within the first 4 days was compared with onset after 2 weeks, showing a better effect on pain outcome for the earliest start.[21] However, the number of patients with late pain were small in that study. In the present larger trial, only very few participants started intervention less than 4 days after the accident; thus, we cannot arrive at a firm conclusion as regards this issue.

As a consequence of the nature of the investigated condition good compliance and adherence to a protocol can be difficult to achieve. However, we find our results adequately sound to conclude that earlier recommendations of active treatment regimens[21,27] cannot be supported. Moreover, taking the per protocol analyses into account, use of a stiff neck collar should be discouraged as a standard approach.

The study had a biomechanical approach and determined if prescription of early neck immobilization, mobilization, or acting as usual had different influence on the outcomes 1 year after a whiplash injury. The fact that the outcomes were similar in the intervention groups might be a consequence of subgroups within the population, which respond differently to the intervention. The results further suggest that other factors than biomechanics also play a role for the development of chronic WAD. This is based on the observation that in our study the prognosis was relatively poor as compared with in Greece[6] and Lithuania[5] and the lack of a better effect of physical treatments than information. Part of the explanation for the poor prognosis seen in the present study is the inclusion of whiplash injured with relatively severe complaints, but such a relatively high risk of nonrecovery is in line with other Scandinavian trials.[7,8] In addition to investigating whether mechanical subgroups responding differently to treatments exist, psychosocial and cultural factors are factors that need to be explored in more depth regarding their influence on the course of events following a whiplash injury.

The present trial shows clearly that active intervention in the first weeks after an injury does not result in a better outcome than an "act as usual" program when prescribed to a high-risk patient group. There might be subgroups that respond to treatment, but in a large group of patients the prognosis was not improved by active treatment. Until such subgroups have been identified, our general recommendation is that advice to act as usual, the less expensive intervention, should be the preferred treatment.

■ Key Points

- Long-lasting pain and disability may develop following whiplash injuries, and it is unclear whether chronic symptoms can be prevented by early intervention.
- Immobilization, advice to "act-as-usual" and active mobilization had similar effects in terms of preventing long-lasting pain and disability.
- Approximately 50% of a population with marked acute symptoms following a whiplash injury reported lasting pain, and roughly 25% experienced diminished work capabilities 1 year after the car collision.

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