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The effectiveness of a supervised physical training model tailored to the individual needs of patients with whiplash-associated disorders – a randomized controlled trial

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Objective: To evaluate the effects of a physical training programme which is supervised and tailored to meet the needs of patients with subacute whiplash-associated disorders.
Design: A randomized controlled trial with follow-up at three and nine months after randomization.
Setting: An interdisciplinary rehabilitation centre.
Subjects: Forty-seven patients with subacute disorders following a whiplash trauma.
Interventions: Patients were randomized to a supervised training group or a self-administered home training group.
Main measures: Primary outcome measures were the Self-Efficacy Scale, the Tampa Scale for Kinesiophobia and the Pain Disability Index. Secondary outcome measures were neck pain intensity, sensory and affective dimensions of pain, pain location and duration, muscle tenderness, grip strength, cervical mobility, sick leave and analgesic consumption.
Results: Forty patients (85%) completed the intervention period, and the drop-outs were followed up by intention-to-treat. The results showed that supervised training was significantly more favourable than home training, with a more rapid improvement in self-efficacy ($P = 0.03$), fear of movement/(re)injury ($P = 0.03$) and pain disability ($P = 0.03$) at three months. Further, supervised training significantly reduced the frequency of analgesic consumption ($P = 0.03$). The improvements were partly maintained at nine months, even though there was no amelioration in pain and physical disorders. Despite the favourable outcome, supervised intervention did not reduce sick leave.
Conclusions: The findings indicate a treatment approach that is feasible in the rehabilitation of patients with subacute whiplash-associated disorders in the short term, but additional research is needed to extend these findings and elucidate treatment strategies that also are cost effective.

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Introduction

Neck pain resulting from motor vehicle accidents and persistent whiplash-associated disorders[1] pose a cumulative problem in modern times in terms of long-term disability and subsequent cost to society. The condition can have an immense impact on patients' quality of life, and to prevent the development of long-term disability, new interventions are needed. Given that whiplash-associated disorder is still a relatively poorly understood condition in pathophysiologic terms, the methods of treatment vary and evidence for most of the treatment approaches is lacking.[2] In the early phase, active intervention is recommended.[3] To prevent persistent symptoms, a multidisciplinary treatment approach is recommended,[4] which should begin during the subacute phase and at the latest three months after injury.[1] The subacute phase is the transitional stage between the acute and the chronic pain. In the management of neck pain, active physical training has positive effects.[5–7] The only studies that address this issue in patients with whiplash-associated disorders are descriptive.[8,9] In addition, most studies often comprise several treatment modalities, making it difficult to draw any conclusions on treatment effectiveness.

Evidence is accumulating that cognitive and psychological factors mediate the rehabilitation outcome for patients with long-lasting pain and disability.[10] It has been suggested that self-efficacy beliefs may be important determinants of disability.[11–14] Self-efficacy refers to personal beliefs about how well one can perform a task or specific behaviour successfully.[15] Cognitive behavioural theorists[16–18] propose that avoidance behaviour due to fear of pain or (re)injury leads to a vicious cycle characterized by decreased self-efficacy, fear, and further avoidance/disability. If a person's self-efficacy could be enhanced, he or she would be more likely to engage in activities that were previously avoided due to fear. Hence, there is an interactive relationship between these cognitive variables. Dolce *et al.*[19] demonstrated that self-efficacy could be enhanced in patients with chronic pain who increased their level of exercise through a rehabilitation programme. Altmaier *et al.*[13] found that in the rehabilitation of patients with low back pain, improvements in self-efficacy significantly predicted better functioning and less reported pain. Söderlund *et al.*[14] suggested that patients' confidence in performing daily activities should be reinforced to optimize treatment. According to Bandura,[12] an intervention must increase self-efficacy to achieve a positive outcome.

In the present study, the hypothesis was that participation in a physical training programme that is supervised and tailored to meet the needs of the individual patient has a greater influence on self-efficacy, fear of movement/(re)injury and disability compared to a self-administered home exercise programme for patients with subacute whiplash-associated disorders. The positive effects were expected regardless of whether the training programme had any effect on pain and physical measures.

Methods

Study design

The present study was a randomized controlled trial carried out on 47 patients with subacute whiplash-associated disorders following a whiplash-type trauma. Subacute disorders were defined as symptoms lasting for more than six weeks but less than three months. The patients were enrolled in an interdisciplinary rehabilitation centre in Göteborg, Sweden. Measurements were made at baseline prior to randomization, after the intervention period of three months, and six months after the completed intervention period. The researcher performing the measurements was kept blinded to the intervention. To ensure blinding, patients were asked not to reveal any information about their treatment allocation to the researcher performing the measurements. Success in blinding the researcher was evaluated throughout the trial. Figure 1 is a flow diagram of the progress through the phases of the study. The study was approved by the regional ethical review board.

Besides the physiotherapists carrying out the interventions, the interdisciplinary team consisted of a psychologist, a physician and a social worker. The amount of time given to the components in the rehabilitation programme was tailored to suit the individual patient. The participants recruited for the study sought help at the rehabilitation centre on their own initiative or at the request of an

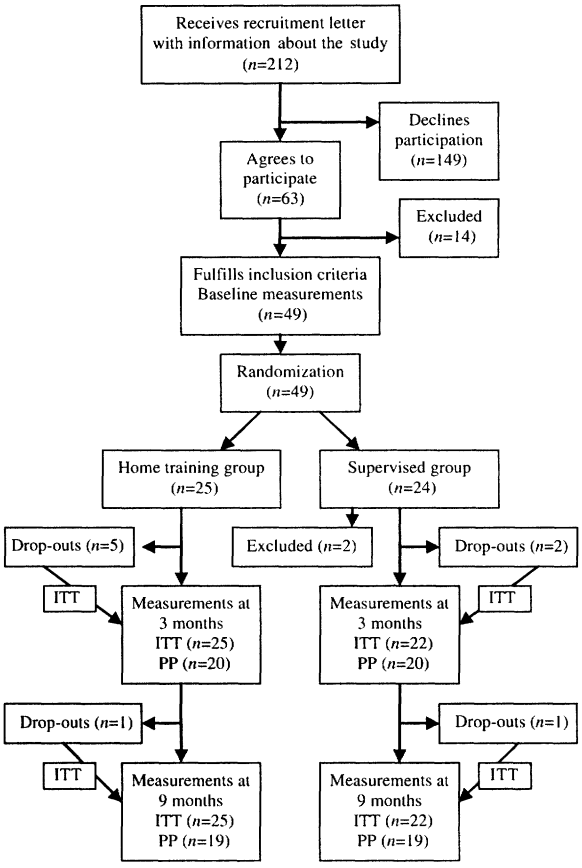

Figure 1 Flow diagram of the phases of the study. ITT, intention-to-treat; PP, per protocol.

emergency department, or they were referred by their general practitioner or another physician. Some of the patients referred by their general practitioner had already been assessed, in some cases including radiographs, and in a few cases including computed tomographic or magnetic resonance imaging scans. Many patients had undergone physiotherapy treatment before entering the study. However, the amount of treatment was comparable between groups. Patients who for some reason had terminated the physiotherapy intervention in the present study were followed up using the method of intention-to-treat.

Inclusion criteria were subacute disorders following a whiplash-type trauma to the neck. Whiplash-associated disorders were defined as a musculoligamental sprain or strain of the cervical region, no fractures, and no dislocations of the cervical spine. Patients who met any of the following criteria were excluded: (1) time interval between the whiplash trauma and randomization of $<$ six weeks or $>$ three months; (2) X-ray evidence of traumatic or severe degenerative lesions of the cervical spine; (3) unrelated disease or additional injury that precludes completion of the questionnaire or would make evaluation difficult; (4) previous severe neck pain causing more than one month of sick leave or disablement pension in the year preceding the accident; (5) inability to understand and speak Swedish.

All patients seeking treatment at the rehabilitation centre were invited to participate in a group session on a regular basis with a team physiotherapist and psychologist who presented information on symptoms and reactions in connection with a whiplash trauma. The session aimed to reduce fear and anxiety and to give advice about self-management and recuperation. If interested in consulting a physiotherapist after the session, the patient could schedule an appointment in the regular treatment programme. After receiving an appointment, the patient was mailed a recruitment letter with information about the study. Patients who were not interested in participating in the study were enrolled in the regular treatment programme. Before randomization, the baseline measurements were performed by the researcher, and the team psychologist conducted a regular screening of all patients to determine the individual need for psychological treatment.

Randomization

Patients were randomized into two physiotherapy interventions: (A) a home training group or (B) a supervised training group. The randomization was conducted by an independent person in blocks with a block size of two by coin flipping. Two sequences were possible for every two participants: (1) the first participant could be randomized to group A and the second to group B (giving sequence AB), or the opposite. To make the randomization schedule the person flipped a coin several times giving the sequence 1 (AB) or 2 (BA). Hence, a possible allocation sequence could be BAABABBABAAB. The person sequentially numbered opaque envelopes, each of which contained the name of the allocation group that

had been determined by the coin flipping. Patients were consecutively recruited to the randomization list by the physiotherapists carrying out the treatment. The envelopes were opened in sequential order as each patient entered the study. Patient allocation was blinded to the researcher. Information about decoding the randomization was not accessed until all measurements had been made and all data collected, nine months after randomization.

Patients

Of the total 212 patients who were mailed the recruitment letter, 63 patients (30%) with subacute disorders were willing to participate in the present study (Figure 1). Of these latter patients, six were excluded because of unrelated diseases making evaluation difficult and eight due to sick leave because of neck pain the year preceding the accident, among whom six had been on sick leave due to a previous whiplash trauma. Forty-nine patients fitting the criteria were included in the present study and randomized. Two patients became ineligible and were thus excluded following randomization due to the detection of a severe unrelated disorder and the receipt of an MRI scan with evidence of severe degenerative lesions of the cervical spine prior to the trauma. Forty-seven patients were finally included in the study, 30 women (64%) and 17 men (36%) with a mean age of 31 years (range 18–61 years). Inclusion took place on average 64 days (range = 42–121 days) after the whiplash trauma.

Measurements

All measurements were carried out in the same sequence by the researcher in a quiet room at room temperature without any external disturbing factors. The primary outcome measures were administered to the patients after the secondary outcome measures in the following order: Tampa Scale for Kinesiophobia, Self-Efficacy Scale, and Pain Disability Index.

Primary outcome measures

Self-efficacy was assessed with the Swedish version of the Self-Efficacy Scale, a 20-item scale aimed to assess the patients' confidence in their ability to successfully complete activities of daily living, such as 'concentrating on a project', 'going shopping' and 'driving the car', despite pain. Scores range from 1 (not at all confident) to 10 (very confident). Total scores range from 0 to 200, higher scores indicating higher confidence. The internal consistency of the Swedish version of the scale was shown to be good,[14] which is in accordance with the psychometric data presented by Altmaier *et al*.[13]

Fear of movement/(re)injury was assessed using the Swedish version of the Tampa Scale for Kinesiophobia. The questionnaire contains 17 statements developed to identify fear of (re)injury due to movement or activities, such as 'It is not safe for a person with a condition like mine to be physically active'. Scores range from 1 (strongly disagree) to 4 (strongly agree). The scores on items 2, 4, 8 and 16 were reversed so that high scores on all items indicate high levels of fear. Total scores range from 17 to 68. The reliability and validity of the Swedish translation of the Tampa scale has been established for patients with low back pain.[20]

Disability related to the pain was measured with the Swedish version of the Pain Disability Index designed to measure both domain-specific and general disability related to chronic pain. The index consists of seven items ranging from 0 (not at all hindered) to 10 (totally hindered). The maximum score is 70, which corresponds to a high degree of disability. The internal consistency of the Swedish version of the index is shown to be good.[14]

Secondary outcome measures

Neck pain intensity was assessed with a visual analogue scale (VAS) in a diary format. The patient rated neck pain intensity on a traditional paper-and-pencil 100 mm VAS in a diary format with the end points 0 (no pain) and 100 (worst pain). The patient was instructed to rate pain intensity twice a day (morning and afternoon) for one week prior to the measurements. The VAS is considered to be a reliable and valid outcome measure.[21,22]

Sensory and affective dimensions of the pain were assessed using the Painometer (Dola Health Systems, Baltimore, USA), an inexpensive, hand-held pain assessment tool. On the back of the Painometer the patients were asked to indicate the quality of the pain by checking as many descriptors from among a total of 23 sensory and affective

words, each of which has been assigned a 'quality of pain' intensity value ranging from 1 to 5. The Painometer has demonstrated good validity and reliability.[23]

Pain location was assessed using the Painometer; the patient marked the location of the pain with a pen on a pullout body chart depicting 79 locations on a human body. The pain location was expressed as percentage of the total body area. Pain duration was assessed using the Painometer to ask whether the pain comes or goes or is continuous.

Muscle tenderness during palpation was measured using a palpometer. The palpometer is a precision device for monitoring the pressure of an examiner's finger during palpation. A predetermined fixed pressure intensity was set to 4, which is equivalent to 1700 g, and the tenderness response was assessed on a scale ranging from 0 (no pain) to 3 (worst pain). Examined points were the upper m. trapezius fibres in the occipital region, the m. levator scapulae and the m. sternocleidomastioideus. The palpometer has demonstrated good reliability.[24]

Grip strength was measured using a Grippit (AB Detector, Göteborg, Sweden), a portable instrument designed for measuring isometric grip strength. Peak force and average values over 10 s were registered. The reliability of the Grippit was demonstrated to be high.[25]

Total cervical mobility was assessed with a cervical range of motion instrument (CROM), a measurement helmet equipped with a goniometer. The range of motion was recorded in degrees in flexion, extension, lateral flexion and rotation. During measurement, the researcher manually stabilized the patient's shoulders and visually controlled the trunk and thoracic spine. The instrument has demonstrated sufficient reliability and validity.[26]

Sick leave following the accident was assessed on a 0–4 scale: 0 days, 1–7 days, 8–30 days, 1–3 months, or > three months. Use of analgesics was assessed with a yes or no, and frequency of consumption was assessed on a 1–4 scale: occasionally, 2–7 times a week, 8–30 times a week, or > 30 times a week.

At the long-term follow-up, nine months after randomization, the patients were to report whether they had done any kind of physical activity and, if so, how many times a week, since the end of the intervention period. Furthermore, they were to report whether they had received any co-intervention because of persistent disorders in the past six months.

Intervention

Five specially trained physiotherapists carried out the intervention. It was not possible to blind the physiotherapists due to the interactive nature of the treatment. Neither was it possible to blind the patients in the present trial. Common for both groups were the following: All patients were provided with a pamphlet concerning neck pain published by the National Corporation of Swedish Pharmacies. The pamphlet aimed to reduce fear and anxiety and provided advice about self-management and recuperation by being physically active. The physiotherapist provided further ergonomic advice including body posture. All patients were encouraged to practise some low-intensity aerobic exercise on their own on a regular basis, such as a daily walk, biking, gymnastics, or light endurance or strengthening exercise, of at least 20 min duration, twice a week. The patients were asked to keep a weekly exercise diary throughout the treatment period. During the intervention period, the use of co-interventions was discouraged. When the treatment period ended, all patients were encouraged to continue exercising on their own.

Home training group

Patients were instructed to do a home exercise programme twice a day. The regimen (Appendix 1) was designed to enhance circulation and range of motion and reduce muscle tension. The exercises were to be done cautiously under the pain limit. The physiotherapist gave practical instructions about how to perform the exercises, and depending on the patient's need, he or she was offered continuous counselling at the rehabilitation centre once every second week where exercise intensity, frequency, and technique were checked.

Supervised training group

The patients attended the rehabilitation centre twice a week for physiotherapy sessions lasting for approximately 1–1½ h. The physiotherapist instructed the patient throughout the individually adjusted training programme, which focused

mainly on the neck and shoulder muscles and was based on recommended principles.[2] The programme was gradually increased and primarily designed to overcome fear of pain and movement and increase self-efficacy in physical activities despite persistent pain. Further, it aimed to increase cervical range of motion, cervical muscle endurance, stabilization, co-ordination and overall functional capacity. The exercises emphasized good posture and pausing, and initial loads were set at a low pain-free level. The number of repetitions and the amount of resistance were adjusted according to the patient's capability. The physiotherapists had a treatment manual with a predetermined number of general exercises to choose between (Appendix 2). A training record was kept of the progression of loading, and when the patient became familiar with the exercises, groups of 3–4 patients were formed. If the patient experienced an increase in neck pain, the load was reduced. Each session concluded with stretching exercises for the neck and shoulder muscles.

Statistical analysis

Power calculation

The required sample size was determined on the basis of the expected clinical change for the most important outcome measure: self-efficacy beliefs.[14] We estimated that 10% of the patients would withdraw. Sample size was calculated with an alpha level of 5% and a power goal of 80%. A two-sided test for proportions was used for statistical calculations in Statistica 5.0. Assuming that 95% of the patients attending the supervised training programme would increase their level of self-efficacy compared to 50% in the group provided with a self-administered home exercise programme, at least 28 patients would be required for the results to have statistical relevance.

Analyses

Baseline variables were evaluated to check if groups were balanced (Table 1). Clinical outcome variables were analysed by intention-to-treat (including all randomized patients) according to a guideline for carrying out clinical trials.[27] Besides this, a per protocol analysis was performed that was restricted to the patients who completed the treatment programme and remained in the group to which they had been randomly assigned. Patients were excluded from the per protocol analysis if they withdrew during the treatment period or underwent a co-intervention during the three-month treatment period. Outcomes were analysed in terms of change from baseline to three and nine months. In order to stick to the ordered structure and non-numerical meaning of the data variables were dichotomized. Statistical differences between treatments with respect to Self-Efficacy Scale, Tampa Scale and Pain Disability Index were tested using the chi-square test by dichotomizing data into improved or unchanged/deteriorated with respect from baseline to three and nine months using both sum and median scores. To test for potential confounders such as the baseline level of self-efficacy and pain disability, logistic regressions were performed on the dichotomized outcome variables. In order to control type I error at multiple significance testing, the overall criterion was defined as all three primary outcome variables to show $P < 0.05$. Statistical comparisons of sick leave, use of analgesics and frequency of consumption between treatments were calculated using the chi-square test. For this purpose, sick leave and use of analgesics were dichotomized into improved or unchanged/deteriorated. The frequency of consumption was dichotomized into reduced or unchanged/increased. If a positive value (e.g. no sick leave/analgesics) was observed at baseline and follow-up, the patient was classified as improved. Statistical differences in pain intensity, sensory/affective dimensions of pain, pain location and duration were calculated by dichotomizing data into improved or unchanged/deteriorated and tested by the chi-square test. If a patient did not return the VAS diary at the nine-month follow-up, the values from the three-month follow-up were carried forward (last value carried forward).

For calculating differences between treatments using the chi-square test with respect to muscle tenderness, the examined points were collapsed into right and left sides of the neck and dichotomized into improved or unchanged/deteriorated. The t-test was used to test differences between treatments with respect to grip force and cervical mobility. All differences between treatments were also estimated with 95% confidence intervals (95% CI) for differences between proportions and means. The sign test was used to test for differences

Table 1 Patient characteristics, accident data and comparisons in primary outcome variables (Self-Efficacy Scale (SES), Tampa Scale for Kinesiophobia (TSK), and Pain Disability Index (PDI)) and secondary outcome variables for the two treatment groups at baseline[a]

Baseline variables	Supervised group ($n = 22$)	Home training group ($n = 25$)
Patient characteristics		
Age (years): mean (SD)	38 (11)	35 (12)
Duration of complaints (days): mean (SD)	64 (21)	64 (20)
Accident data: *n* (%)		
Car	19 (86)	20 (80)
Bus/tram		4 (16)
Truck		1 (4)
Accident involving one vehicle only	1 (5)	
Bicycle	1 (5)	
Fall accident	1 (5)	
Safety equipment: *n* (%)		
Wearing seatbelt	19 (86)	20 (80)
Primary		
SES: *m* (SD)	136 (31)	132 (30)
SES: *m* (r)	7 (3–10)	8 (3–10)
TSK: *m* (SD)	35 (7)	35 (6)
TSK: *m* (r)	2 (1–3)	2 (1–3)
PDI: *m* (SD)	29 (14)	32 (12)
PDI: *m* (r)	5 (0–8)	5 (0–8)
Secondary		
Visual analogue scale: *m* (r)	47 (10–88)[b]	46 (10–79)
Painometer:		
Sensory dimension: *m* (r)	4 (3–5)	4 (3–5)
Affective dimension: *m* (r)	3 (3–5)	4 (3–5)
Pain location: *m* (SD) (%)	14 (9)	12 (5)
Pain duration: *n* (%)		
Intermittent	11 (50)	13 (52)
Constant	11 (50)	12 (48)
Palpometer: *m* (r)		
Right side of the neck	1 (0–4)	1 (0–4)
Left side of the neck	1 (0–7)	2 (0–6)
Sick-leave: *n* (%)[c]	12 (54)	16 (64)
0 days	1 (5)	5 (20)
1–7 days	5 (23)	1 (4)
8–30 days	7 (32)	4 (16)
1–3 months	8 (36)	14 (56)
>3 months	0 (0)	0 (0)
Use of analgesics: *n* (%)	17 (77)	19 (76)
Frequency of consumption[d]	1.6 (1)	1.6 (1)
Never	5 (23)	6 (24)
Occasionally	4 (18)	5 (20)
2–7 times a week	8 (36)	7 (28)
8–30 times a week	5 (23)	6 (24)
>30 times a week	0 (0)	1 (4)
Grippit: *m* (SD)		
Average value (right hand)	245 (111)	231 (113)
Peak force (right hand)	288 (121)	268 (124)
Average value (left hand)	255 (118)	214 (113)
Peak force (left hand)	304 (123)	259 (131)
CROM-total: *m* (SD)	274 (49)	282 (65)

m (r), median (range); *m* (SD), mean (standard deviation); CROM, cervical range of motion.
[a]There were no significant differences between groups at baseline.
[b]Data missing for one patient.
[c]One patient in each group was retired.
[d]1 = occasionally, 2 = 2–7 times a week.
*$P < 0.05$, two-tailed test. n.s. = non-significant.

within treatments. The alpha level was set at 0.05 for all tests. Analyses were done using the Statistical Package for Social Sciences (SPSS 12.0).

Results

Participation rate

Of the 47 patients, 40 (85%) completed the intervention period. The drop-outs were followed-up according to intention-to-treat throughout the trial (Figure 1). The short-term follow-up for the home and supervised training group had a range of 89–128 days and 64–125 days, respectively. In the home training group, the patients were provided with individual physiotherapy counselling on average four times (range 1–9). In the supervised training group, patients attended the rehabilitation centre for an average of 18 sessions (range 12–42). No negative side effects occurred due to any of the treatments. Of the 40 patients who completed the trial, 38 (95%) participated in the long-term follow-up. All seven patients who did not complete treatment according to the randomization were examined at the long-term follow-up and were attributed to the group to which they were initially randomly assigned according to intention-to-treat. The results were included in the statistical analysis. The long-term follow-up for the home and the supervised training groups took place over a range of 173–198 days and 172–197 days, respectively, after treatment was completed.

Drop-outs

Of the 47 patients, seven (15%) dropped out during the treatment period (Figure 1). Reasons given for not completing the treatment in the supervised group were as follows: one patient never began treatment due to lack of time and one patient dropped out due to a desire to receive acupuncture treatment for alleviation of pain. In the home training group, the reasons for withdrawal were that three patients were dissatisfied with the group allocation and wanted supervised treatment and two patients wanted to receive intervention for alleviation of pain. At nine months, two patients dropped out for the following reasons: one patient in the supervised group cancelled the appointment three times and did not respond to further communication by phone or letter; one patient in the home training group moved to another country and could not be reached. None of the drop-outs differed in baseline values or three-month results from the participants who completed the intervention period.

Comparability of groups at baseline

The patient characteristics, accident data and comparisons in primary outcome variables and secondary outcome variables for the two treatment groups at baseline are presented in Table 1. Differences between groups at baseline were non-significant.

Psychological counselling

In addition to the regular screening conducted by the psychologist where the patients were given feedback on the questionnaires, 10 patients in the home training group (40%) and eigth patients in the supervised group (36%) were given psychological counselling for, on average, three times (range 1–31) and three times (range 1–17), respectively.

Co-interventions

At the long-term follow-up, 14 patients (56%) in the home training group had received some kind of co-intervention other than what had been recommended by their physiotherapist in the trial during the past six months. The type of treatments used were physiotherapy exercise (seven patients) and acupuncture/massage (seven patients). In the supervised group, 14 patients (64%) had sought other treatments consisting of physiotherapy exercise (four patients), acupuncture/massage/hot-pack/TENS (six patients), chiropractic/naprapathy (three patients), and cortisone injection (one patient).

Exercise diary

Seventeen patients (85%) in the home training group and 15 patients (75%) in the supervised training group completed the exercise diary. During the intervention period, the patients in the home training group performed the training programme on average 100 times (range 0 [one patient]–206). Daily walks were reported by 13 patients in the home training group on average 56 times (range 5–164) during the intervention

period. Other types of exercises were reported by six patients in the home training group on average 61 times (range 7–146). In the supervised group daily walks were reported by 13 patients on average 77 times (range 7–336). Other types of exercises were reported by six patients in the supervised group on average 29 times (range 11–62).

Success of blinding of the researcher

Five patients (11%) (two patients in the home training group and three patients in the supervised group) inadvertently revealed information about their treatment allocation to the researcher during the follow-up measurements.

Intention-to-treat analysis

Table 2 presents the mean and median changes in outcome measures for the two treatment groups at three and nine months from baseline. Dichotomized data are expressed as the proportion of patients in each group who improved (+).

Primary outcome measures

Self-efficacy, fear of movement/(re)injury, and disability

At three months when treatment ended, the differences between the groups with respect to the proportion of patients improved regarding the sum score changes in the primary outcome measures were significant (Table 2 and Figure 2a–c). In the supervised training group, 15 patients (68%) reported higher levels of self-efficacy compared with nine patients (36%) in the home training group. In the supervised training group, 15 patients (68%) reported a reduced degree of fear of movement/(re)injury beliefs compared with nine patients (36%) in the home training group. Sixteen patients (73%) in the supervised group reported a reduced degree of disability compared with 10 patients (40%) in the home training group.

The degree of self-efficacy and pain disability at baseline could potentially have affected the outcome score at the follow-up, as reported in a previous study.[14] These potential confounders were accounted for by logistic regression, which demonstrated that the baseline scores of these variables had no significant influence on the treatment effect in the present study, that is, the increments that were present for Self-Efficacy Scale and Pain Disability Index in the supervised group after treatment had been completed were not related to the baseline levels.

At the long-term follow-up, the supervised group reported no further improvement in self-efficacy, but most patients maintained the improvement they had experienced at the three-month follow-up (Table 2 and Figure 2a). The home training group reported a slightly positive change in self-efficacy at the long-term follow-up, and the difference between the groups in self-efficacy was not significant. An increase in fear of movement/(re)injury was observed in the supervised training group compared with the home training group, where further reduction was observed at the long-term follow-up and the difference was not significant (Table 2 and Figure 2b). The level of pain disability was further reduced at the long-term follow-up in both groups, but at this point there was no significant difference between the groups (Table 2 and Figure 2c).

Secondary outcome measures

Pain intensity

Although the reduction in pain intensity measured with the VAS diary in the supervised training group tended to be higher than in the home training group at three months, it was not statistically demonstrated when the results were dichotomized (Table 2). No significant within-group differences in pain intensity were found at either three or nine months. In the supervised group, pain intensity had increased again when the treatment was completed (although the intensity did not reach pretreatment levels at nine months).

Pain duration

The groups did not differ significantly from each other concerning changes in the frequency of pain at either three or nine months (Table 2).

Pain location

At baseline, the mean body area marked as painful was 13% (SD = 7) in the whole study group, and there was a dominance of neck pain in the middle and caudal parts of the cervical spine. No significant difference between or within groups concerning change in pain

Table 2 Changes in primary outcome variables (Self-Efficacy Scale (SES), Tampa Scale for Kinesiophobia (TSK), and Pain Disability Index (PDI)) and secondary outcome variables for the two treatment groups at three and nine months from baseline according to intention-to-treat. Dichotomized data are expressed as the proportion of patients in each group who improved (+)

Outcome variables	Change from baseline to three months				Change from baseline to nine months			
	Supervised ($n = 22$)	Home ($n = 25$)	Difference (95% CI)	P-value	Supervised ($n = 22$)	Home ($n = 25$)	Difference (95% CI)	P-value
Primary	(%)	(%)			(%)	(%)		
SES: sumscore (+)	68	36	32 (5.1–59.2)	0.03*	68	64	4 (−22.9–31.3)	0.76
SES: median score (+)	41	32	9 (−18.6–36.4)	0.53	27	52	−25 (−51.7–2.3)	0.09
TSK: sumscore (+)	68	36	32 (5.1–59.2)	0.03*	64	44	20 (−8.4–47.6)	0.18
TSK: median score (+)	50	20	30 (3.9–56.1)	0.03*	9	16	−7 (−25.6–11.8)	0.48
PDI: sumscore (+)	73	40	33 (6.0–59.4)	0.03*	73	84	−11 (−34.8–12.2)	0.35
PDI: median score (+)	55	32	23 (−5.2–50.2)	0.12	86	72	14 (−8.3–37.1)	0.23
Secondary								
Visual analogue scale (+)	48[a]	36[b]	12 (−16.5–39.7)	0.43	43[a,c]	52[d]	−9 (−37.6–19.4)	0.54
Painometer:								
Sensory dimension (+)	41	20	21 (−4.9–46.7)	0.12	36	28	8 (−18.3–35.1)	0.54
Affective dimension (+)	27	20	7 (−17.0–31.6)	0.56	32	32	0 (−26.9–26.5)	0.99
Pain location (+)	50	52	−2 (−30.6–26.6)	0.89	50	68	−18 (−45.8–9.8)	0.21
Pain duration (+)[e]	50	44	6 (−22.6–34.6)	0.68	27	32	−5 (−30.8–21.4)	0.72
Palpometer:								
Right side of the neck (+)	41	28	13 (−14.1–40.1)	0.35	32	32	0 (−26.9–26.5)	0.99
Left side of the neck (+)	27	40	−13 (−39.4–14.0)	0.36	41	52	−11 (−39.5–17.3)	0.45
Sick-leave (+)[f]	50	44	6 (−22.0–35.2)	0.66	48	50	−2 (−31.0–26.2)	0.87
Use of analgesics (+)	36	16	20 (−4.3–45.1)	0.11	18	16	2 (−19.4–23.8)	0.84
Frequency of consumption (+)	64	32	32 (4.4–58.8)	0.03*	46	56	−10 (−39.0–18.0)	0.47
Grippit:	*m* (SD)	*m* (SD)			*m* (SD)	*m* (SD)		
Average value (right hand)	5.9 (41.2)	−14.9 (52.8)	−20.8 (−48.9; +7.3)	0.14	14.6 (62.8)	−16.3 (77.4)	−30.9 (−72.7; +10.9)	0.14
Peak force (right hand)	12.3 (50.8)	−15.8 (145)	−28.2 (−62.0; +5.7)	0.10	18.6 (79.0)	−14.1 (89.6)	−32.7 (−82.6; +17.3)	0.19
Average value (left hand)	−1.7 (32.9)	−22.3 (53.4)	−20.6 (−47.1; +5.9)	0.13	2.1 (53.6)	−26.4 (50.1)	−28.5 (−59.0; +2.0)	0.07
Peak force (left hand)	−1.27 (44.7)	−26.2 (53.7)	−25.0 (−54.2; +4.3)	0.09	0.91 (56.7)	−26.2 (56.5)	−27.1 (−60.4; +6.2)	0.12
CROM-total: *m* (SD)	−0.14 (28.9)	−1.24 (51.3)	−1.1 (−26.0; +23.8)	0.93	−10.3 (47.4)	5.9 (64.2)	16.2 (−17.3; +49.8)	0.34

Data missing for: [a]one patient; [b]two patients treated according to last value carried forward (LVCF); [c]four patients (LVCF); [d]three patients (LVCF).
[e]Three subjects in the home-training group were pain free at 3 and 9 months.
[f]One patient in each group was retired.
*Significant difference at the 5% level.
95% CI, 95% confidence interval; *m* (SD), mean (standard deviation); CROM, cervical range of motion.

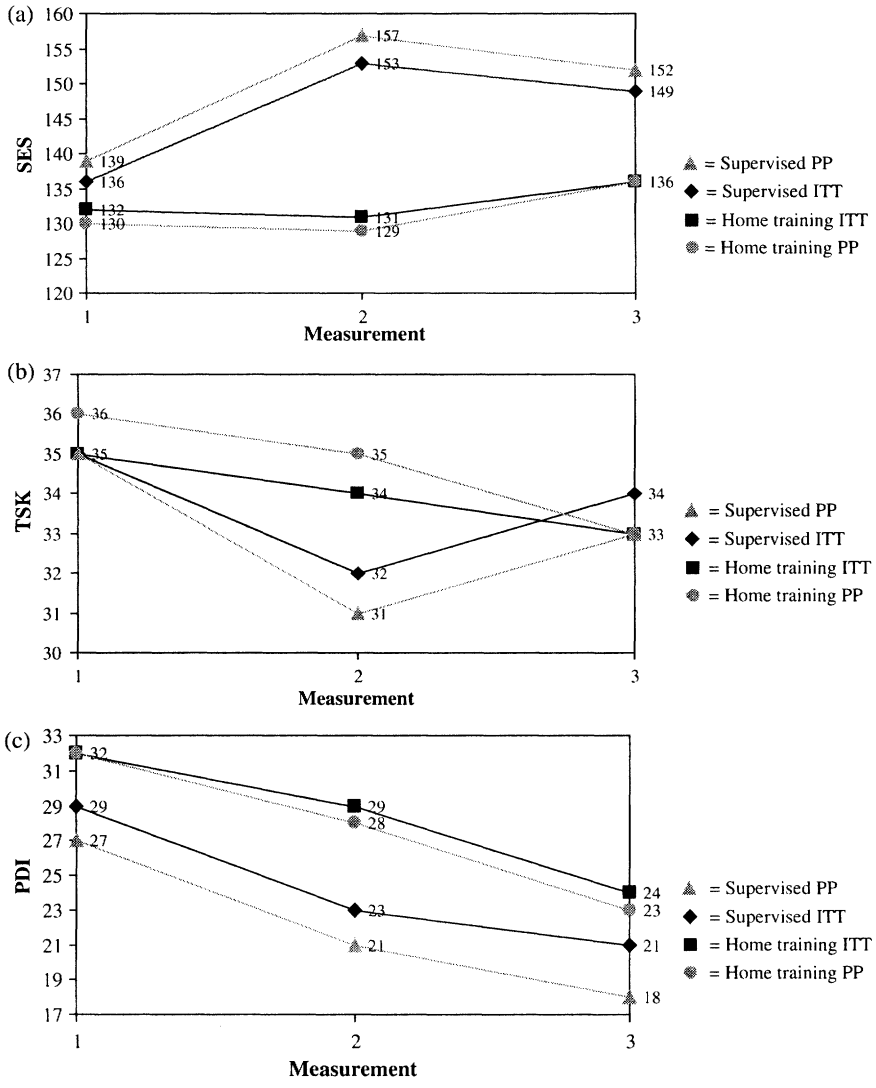

Figure 2 Mean profile of sum scores according to intention-to-treat (ITT) and per protocol (PP) on the (a) Self-Efficacy Scale (SES), (b) Tampa Scale for Kinesiophobia (TSK), and (c) Pain Disability Index (PDI) in the home training group and the supervised group at measurement 1 (baseline), 2 (three months), and 3 (nine months).

location were found at three or nine months after baseline (Table 2).

Sensory and affective dimensions of pain

Differences between and within groups were not significant at baseline or at six months after completed treatment concerning the sensory and affective dimensions of pain measured with the Painometer (Table 2).

Muscle tenderness

There were no significant differences between or within groups regarding the change in muscle tenderness on the right and left sides of the neck at the three- and nine-month follow-ups.

Grip force and cervical mobility

In the home training group, a bilateral reduction in both mean and maximum grip force was

reported at the three-month follow-up, but the differences between groups were non-significant (Table 2). Differences between groups concerning change in cervical mobility measured with the CROM were non-significant at both the three- and the nine-month follow-ups (Table 2). There were no within-group differences in grip force or cervical mobility.

Sick leave and analgesics

After the intervention period, there were no significant between- or within-group differences in either sick leave or use of analgesics. Among the 28 patients on sick leave at baseline, five (18%) had returned to work at the short-term follow-up. At the long-term follow-up, only one more patient had returned to work. However, there was a significant difference between treatments in the frequency of analgesic consumption at three months (Table 2). At the long-term follow-up, the amount of sick leave and use of analgesics was unchanged. However, at the long-term follow-up, the supervised group had increased their consumption again and the differences between groups became non-significant.

Per protocol analysis

The analysis was performed on all outcome variables for the 40 patients who completed the intervention. All between-group differences that were significant in the intention-to-treat analysis were also significant in the per protocol analysis at the three month follow-up. The scores within both groups on the primary outcome measures according to per protocol analysis are presented in Figure 2a–c. At the three-month follow-up there was a significant difference between groups with regard to the use of analgesics ($P < 0.05$). In the supervised group 35% were improved, considering the use of analgesics, compared with 10% in the home training group which corresponds to a difference of 25% (95% CI was 0.003–0.497). Furthermore, at the long-term follow-up the grip force was reduced in the home training group compared with the supervised group; this was statistically demonstrated for all four measurements (Table 3).

Table 3 Change in grip force in the two treatment groups at three and nine months after randomization according to per protocol

Outcome variables	Change from baseline to three months				Change from baseline to nine months			
	Supervised ($n = 20$)	Home ($n = 20$)	Difference (95% CI)	*P*-value	Supervised ($n = 19$)	Home ($n = 19$)	Difference (95% CI)	*P*-value
Grippit: *m* (SD)								
Average value (right hand)	6.5 (43.2)	−18.7 (58.7)	−25.2 (−58.1 to 7.8)	0.13	22.3 (59.0)	−26.8 (54.8)	−49.1 (−85.5 to −12.7)	0.01*
Peak force (right hand)	13.6 (53.3)	−19.8 (69.9)	−33.4 (−73.1 to 6.4)	0.10	25.8 (78.8)	−28.0 (67.7)	−53.8 (−100.8 to −6.8)	0.03*
Average value (left hand)	−1.9 (34.6)	−27.9 (58.6)	−26.0 (−56.8 to 4.8)	0.10	7.7 (52.2)	−29.4 (43.4)	−37.0 (−67.7 to −6.3)	0.02*
Peak force (left hand)	−1.4 (46.9)	−32.8 (58.4)	−31.4 (−65.3 to 2.5)	0.07	6.2 (56.3)	−33.4 (55.3)	−39.6 (−75.3 to −3.9)	0.03*

*Significant difference at the 5% level. **Significant difference at the 1% level.
95% CI, 95% confidence interval; *m* (SD), mean (standard deviation).

Discussion

The results of the present trial show that supervised physical training which was adjusted to meet each patient's needs was significantly more favourable than home training with more rapid improvement in self-efficacy, fear of movement/(re)injury, pain disability and analgesic consumption at the short-term follow-up. This is in accordance with previous studies.[13,19] At the long-term follow-up, the improvement in self-efficacy was more or less stable, while a continued reduction in the degree of pain disability was seen. On the other hand, fear of movement/(re)injury and frequency of analgesic consumption were higher.

Treatment differences in pain and physical measures were non-significant in the intention-to-treat analysis. However, since pain and disability are suggested to have a weak relationship,[28] the aim of the supervised intervention was primarily to improve the activity level of the patients, regardless of persistent disorders, and to change patients' ideas about pain.[2] That the supervised group in the present study did improve in the primary outcome measures despite persistent disorders underlines how factors beyond the physical ones are involved in the late whiplash syndrome.

The exercise diaries documented the activities the patients undertook on their own were comparable between the groups. Compliance was good in the home training group, and the regularity of the exercises performed was higher than in the supervised group. This is in accordance with a previous study.[5] However, the more favourable outcome in the supervised group may be explained by factors beyond the physiological ones. A supportive physiotherapist and a tailored, gradually increased programme may have helped boost the degree of self-efficacy and reduce fear of movement, thereby improving coping with daily activities. In studies with a similar design, outcome measures on the impairment level are mainly used, which makes comparisons difficult. However, that the role of the therapist is essential was confirmed in a previous study.[29] In line with the present study, Kores *et al.*[30] reported that those patients with whiplash-associated disorders who had higher self-efficacy scores after treatment exhibited less pain-related avoidant behaviour and required less medication.

The number of co-interventions sought by each group after treatment had been completed proved to be similar despite the higher self-efficacy in the supervised group. However, the rather high rate of co-interventions weakens the reliability of the results at nine months. In a previous study,[31] further health care consumption when treatment was completed has been reported. Since psychological counselling also aims to enhance the patient's self-esteem, the amount of counselling was assessed. However, the comparable amount of counselling between groups indicates that it could not have influenced the results much.

The per protocol analysis that excludes withdrawals should be interpreted with caution. Moreover, the somewhat higher drop-out rate in the home training group resulted in more baseline values being carried forward in the intention-to-treat analysis, which may present this group with more heterogeneous data. However, the primary objective was to maintain the amelioration within the supervised group, which was fulfilled with the exception of fear of movement/(re)injury and analgesic consumption. These increases may be due to the abrupt termination of the positive support when the treatment was ended, even though the patients were encouraged to adhere to their training programme on their own. The deterioration in these two variables might have been avoided with a few follow-up sessions.

The study population was recruited from an interdisciplinary centre where patients in general had a more complex picture of symptoms, being more emotionally and/or physically affected than these patients are on average. However, the selected group was considered a representative sample of those who remain disabled beyond the healing of

Clinical message

- Physical training that is supervised and adjusted to meet each patient's needs is significantly more favourable than a home training programme in terms of improvement in self-efficacy, fear of movement/(re)injury, pain disability and analgesic consumption in the short term.

any tissue damage in the natural recovery following a whiplash trauma. All sought care because of subacute disorders, mostly on their own initiative. Yet, the style of recruitment may have affected the outcome since a group of patients who were highly motivated were selected. On the other hand, the patients were already scheduled to enter the regular treatment programme, in which the aim was similar to the aim in the supervised group. This may explain the rather low recruitment rate and suggests that randomized patients are comparable with those choosing regular care.

The weaknesses of the study include the failure of blinding the researcher, the small sample size, the relative selection of the patients from the wider group making generalization less good, various reasons for dropping out, and the use of multiple statistical comparisons. Regardless of these shortcomings, the strengths of this trial include the concealment of the randomized controlled trial design, the attempt to follow an established guideline for carrying out clinical trials,[27] the use of a standardized treatment model in accordance with guidelines for clinical practice with these patients,[2] the use of valid and reliable outcome measures, the intention-to-treat analysis, and the 85% compliance rate. These should validate the results.

In spite of the improvements in the supervised group, the length of sick leave was only marginally shortened. This is in accordance with a previous study,[32] where no effect on sick leave was seen in patients with low back pain despite positive improvement in variables considered to be negative prognostic factors for long-term disability. In previous descriptive studies on whiplash-associated disorders that emphasize a multidisciplinary treatment approach,[8,9] greater lengths of sick leave were also reported. The ability of multidisciplinary rehabilitation programmes to enhance re-occupation is low to moderate but improves when adjustments in the working situation are offered in parallel.[33–35] Some authors blame work disability on the benefit system, and previous studies have demonstrated that the greater the economic benefits in connection with a back injury, the less likely the person is to return to work.[36,37] Others dispute the compensation system.[38] However, such influences were not analysed in the present study. Linton[39] suggests that another reason for persistent work disability could be that pain management programmes regard the workplace as something to return to, rather than as an integral part of comprehensive intervention.

On an individual basis, the more favourable outcome in the supervised group is clinically relevant. The higher level of self-efficacy and decreased fear of movement/(re)injury and disability were expected to be important for re-occupation and would thus be beneficial socioeconomically. However, further utilization of health care, persistent sick leave and higher costs for equipment and professional time indicate that supervised intervention is less cost effective than home training. Yet, the results indicate a treatment approach that may be helpful in the management of patients with persistent whiplash-associated disorders and serve as a basis for future studies in this area.

In summary, supervised training was significantly more favourable than home training and promoted more rapid improvement in self-efficacy, fear of movement/(re)injury, and pain disability in the short term. Further, supervised training significantly reduced analgesic consumption. These improvements were partly maintained at the long-term follow-up, even though there was no amelioration in pain and physical disorders. Despite the favourable outcome, the supervised intervention did not reduce sick leave. The findings indicate a treatment approach that is feasible in the rehabilitation of patients with subacute whiplash-associated disorders, but additional research is required to extend these findings and elucidate treatment strategies that also are cost effective.

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Appendix 1 – Home training group

(1) Two warm-up exercises: (a) lifting and (b) rolling the shoulders. (2) Stability and posture training by shoulder blade adduction. (3) Passive cervical rotation by reaching alternately with the right and left arm back and forward in the horizontal plane facing forward. (4) Rowing exercise with an elastic rubber band. (5) Stretching exercise to reduce neck muscle tension. Exercise nos 1–3 were performed in a single set of 10 repetitions and no. 4 was performed in three sets of 20 repetitions.

Appendix 2 – Intervention group

(1) Warm-up on a bicycle ergometer. (2) Specific neck training performed in a supine position on a training bench with adjustable inclination suspended on a set of wall bars. A wedge-shaped pillow provided the filling for the cervical lordosis: (a) cervical rotation by rotating the head in both directions, one at a time starting with the direction with the least restriction, (b) strength and endurance training of the deep neck flexor muscles by lowering the cheek down toward the chest in a discrete nodding motion.

(3) Dynamic exercises for the neck and shoulders by pulls and rows in a sitting position and presses with dumbbells while lying supine on the adjustable training bench. Throughout the programme the bench was gradually raised towards an upright sitting position with the aim to reach above the shoulders. (4) Overall functional restoration that would permit the individual to cope with physical activities including daily chores as well as work demands: a lifting exercise (lifting a crate from the floor to a table with a content that gradually increased in weight) and two exercises to strengthen the abdominal muscles and lower extremities. (5) In cases of balance disturbances: walking on soft bedding, exercises on a balance-plate or a trampoline/rebounder. The goal for each exercise was two to three sets of 20 repetitions.