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ORIGINAL REPORT

A RANDOMIZED STUDY OF NEW SLING EXERCISE TREATMENT VS TRADITIONAL PHYSIOTHERAPY FOR PATIENTS WITH CHRONIC WHIPLASH-ASSOCIATED DISORDERS WITH UNSETTLED COMPENSATION CLAIMS

John Vikne, RPT MSc[1], Arit Oedegaard, MD[1], Even Laerum, MD, PhD[2], Camilla Ihlebaek, PhD[3] and Gitle Kirkesola, RPT[4]

From the [1]Friskvernklinikken, [2]The Communication Unit, The Norwegian Back Pain Network, Ullevål University Hospital, Oslo, [3]The Research Unit, The Norwegian Back Pain Network, Unifob health, University of Bergen, Bergen, and [4]S-E-T Clinic, Oslo, Norway

Background: **Many patients with chronic whiplash-associated disorders have reduced neuromuscular control of the neck and head. It has been proposed that a new sling exercise therapy may promote neuromuscular control of the neck.**
Objectives: **To compare the effects of traditional physiotherapy vs traditional physiotherapy combined with a new sling exercise therapy on discomfort and function in patients with chronic whiplash-associated disorders who have unsettled compensation claims; and to investigate possible additional effects of guided, long-term home training.**
Design: **A randomized multi-centre trial with 4 parallel groups.**
Methods: **A total of 214 patients were assigned randomly to 4 treatment groups, and received either traditional physiotherapy with or without home training, or new sling exercise therapy with or without home training. Outcome measures were pain, disability, psychological distress, sick leave and physical tests.**
Results: **A total of 171 patients (80%) completed the study. There were no important statistical or clinical differences between the groups after 4 months of treatment. There was a small statistically significant effect at 12-month follow-up in both groups with home training regarding pain during rest ($p = 0.05$) and reported fatigue in the final week ($p = 0.02$).**
Conclusion: **No statistically significant differences were found between the traditional physiotherapy group and the new sling exercise group, with or without home training. Since the groups were not compared with a control group without treatment, we cannot conclude that the studied treatments are effective for patients with whiplash-associated disorder, only that they did not differ in our study.**

Key words: chronic whiplash-associated disorders, unsettled claims, randomized trial, traditional physiotherapy, sling exercises.

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Correspondence address: John Vikne RPT MSc, Friskvernklinikken, Postboks 552, NO-1373 Asker, Norway.
E-mail: John@friskvern.no

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INTRODUCTION

Whiplash was defined in 1995 by the Quebec Task Force as an injury mechanism that may result in bony or soft tissue injuries (whiplash injury), which in turn may lead to a wide variety of clinical manifestations; reduced balance, dyscoordination, increased muscular tension (whiplash-associated disorders; WAD; 1). A significant proportion, ranging from 14% to 42% (2, 3), of patients with WAD have long-lasting psychosocial problems and symptoms (4, 5). Despite a large number of studies, little is known about what causes the patients' discomfort.

Several studies conclude that pain affects motor control mechanisms in the cervical spine (6–8). In line with this, differences have been shown to occur in muscular activity patterns during certain movements (9). Changes in activation of cervical flexor muscles may be an indication of loss of normal function in deep, stabilizing neck muscles (8, 9). Furthermore, a substantial number of patients with chronic neck problems have reduced strength, endurance and neuromuscular control of the neck muscles (10–13). Additionally, the stabilizing muscles of the scapula appear to play an important role in patients with chronic neck problems (11). The deep cervical muscles function as local stabilizers of the cervical spine and thus serve as important elements of the neuromuscular control system (14–17). It has also been reported that in patients with long-lasting pain and dysfunction of the neck, these muscles undergo atrophy (18).

Many treatment options for WAD have been studied in clinical trials (19, 20). In general, however, the level of documentation and the effect sizes are described as insufficient. Traditional physiotherapy (TP) has shown only limited or no effect (14, 21). Two systematic reviews conclude that the effect of different treatments is inconclusive (22, 23). Despite the low quality of the studies, there appears to be a tendency towards better outcome of active treatment compared with passive treatment. Graded training of cervical muscles has shown results in reducing pain and improving function (21, 24), as well as a positive effect of neuromuscular training (25).

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The proposal that a new approach using sling exercises might be superior to TP is based on a number of positive case reports experienced by several physiotherapists. The method combines neuromuscular training and the aim of improving strength and endurance. The latter aim, however, is also present in TP. This is a new treatment approach; performing specific stabilizing exercises and at the same time focusing on establishing neuromuscular control of the neck and shoulder girdle. The equipment used was developed to focus on specific stabilizing exercises and it is easy to adapt the level of exercise to the individual. Exercises are supplemented by a patient self-training manual.

Sling exercises have been demonstrated to be beneficial as part of the intervention for patients with pelvic girdle pain after pregnancy (26). Regarding the treatment of patients with chronic WAD who have unsettled insurance claims, it has been argued that such a situation may influence the treatment outcome and/or the natural course of WAD in a negative way (27, 28). One large insurance company (Gjensidige NOR) in Norway, starting in 1999, offered a new rehabilitation programme to patients with long-term WAD. It consisted of clinical evaluation and a treatment programme (New Sling Exercise Therapy, NSET) which included TP treatment plus a new exercise approach using sling exercises. To our knowledge, sling exercises have not been used in previous studies of the treatment of WAD.

We experienced promising results with the use of sling exercise therapy in selected patients with chronic WAD, regarding increased function and decreased pain. We also had the impression that patients who carried out guided, long-term training reported better outcomes. Thus, the aim of the present study was to compare, in patients with chronic WAD, the effect in terms of discomfort and function (pain, disability, psychological distress, sick leave and physical tests) of TP vs specific exercises in using sling therapy combined with TP (NSET), and to investigate whether there were any additional effects of guided, long-term home training (home exercise programme for 12 months after intervention).

METHODS

Participants

Patients were recruited through the insurance company from 2000 to 2002. The insurance company's executive officers (n = 7) were fully informed about the project, and the inclusion criteria for selection of patients. Patients of both genders (age range 18–60 years) from all 5 main regions of Norway, who had experienced a traffic accident 6–12 months previously, and with grade 1–2 WAD symptoms (1) were included. The exclusion criteria were: ongoing treatment that the patient did not wish to terminate; pregnancy; known abuse of alcohol and drugs; serious illness that could influence the intervention; and pronounced language difficulties. Approximately 85% of the invited patients agreed to participate, resulting in 214 patients entering the study. A total of 171 (80%) of these (57 (33%) men, 114 (67%) women) completed the study (Fig. 1). The drop-out rate was almost identical in the 4 treatment groups (NSET+: n = 10, NSET: n = 12, TP+: n = 10, TP: n = 11). For one-third of the patients who dropped out, withdrawal was considered to have no correlation to the treatment programmes (e.g. reasons such as pregnancy, travel distance). The remaining two-thirds had (or probably had) a correlation to the interventions (e.g. reasons such as the study being too comprehensive, or lack of time). Six patients were excluded at the end of the study because of incomplete adherence with the training procedures.

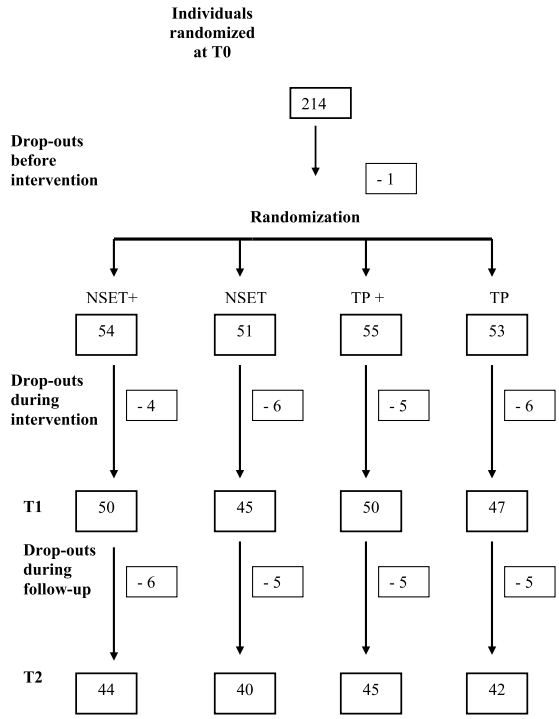

Fig. 1. Study flowchart. T0: test before intervention, T1: test after 4 months, T2: test 12 months after intervention. NSET: new sling exercise therapy, TP: traditional physiotherapy, +: home exercise programme for 12 months after intervention.

Design and randomization

Patients were randomized by an external research institute to the 4 intervention groups. There were 2 main groups (TP and NSET), and in each of these groups half of the patients were randomized to receive guided home training and follow-up for 12 months (TP+ and NSET+). Patients were numbered from 1 to 214, and these numbers were used to randomly assign the patients to follow-up in one of the 4 sub-groups, blinded to the examiners (Fig. 1).

Interventions

A total of 105 physiotherapists performed the treatments.

Patients in the TP group were treated by 80 of these physiotherapists, working in different institutes. The patients received the usual exercises given to this patient population in Norway, focusing on strength and endurance training of the neck, back and abdominal muscles. Varying approaches are commonly used, for example, use of the patient's own body weight as resistance, patient manuals, and fixed training devices.

Twenty-five physiotherapists conducted the NSET treatment. These physiotherapists received special training prior to the intervention, and applied a protocol comprising 10 graded exercises. The NSET group received, in addition to TP, specific exercises in a ceiling-mounted sling (Fig. 2).

Examples of the exercises used in NSET group are:

- The patient sits with flexed knees and a wide sling around the upper part of the thorax holding onto the ropes attached to the sling. Their cervical lordosis is actively straightened a little and they are

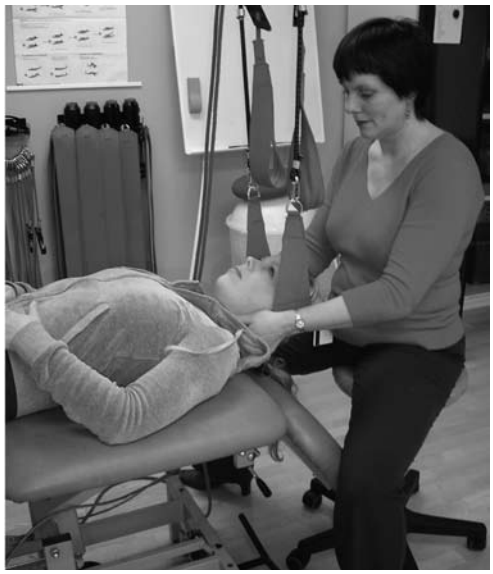

Fig. 2. Sling exercise therapy in a ceiling-mounted sling.

instructed to lean backwards gradually, maintaining the position of the cervical spine.

- Using 3 wide slings, the patient's body is suspended hanging in a supine position. The head rests on an air-filled balance cushion. Pressing the occipital region into the cushion and extending the head on the cervical spine, the patient moves their body gently using their neck and head muscles. Rotation of the extended head can be added to this procedure.

Passive treatment (e.g. massage, electrotherapy, manipulation and acupuncture) was given in all groups when indicated. It was however recommended to give as little passive treatment as possible.

The home training programmes started after 3 weeks in all 4 groups. The TP groups carried out exercises based on the programme followed at the institute, and the NSET groups carried out exercises in a ceiling-mounted sling at home. All groups commenced their home training programme during the intervention period (4 months). The TP+ and NSET+ groups also continued home training in the follow-up period (12 months). Uniform protocols describing all types of treatment modalities, including type and number of exercises, dosage (series and repetitions), were registered and reported monthly by all participating physiotherapists.

Procedures

NSET group. During a period of 4 months, 24 sling exercise sessions were performed. The home training programme with the sling apparatus started after 3 weeks. All training was stopped after 4 months. Thereafter the patients were contacted by telephone by their physiotherapist, asked questions and encouraged to continue training every fourth month for 1 year.

NSET+ group. This group received the same treatment in the intervention period as the NSET group. During the follow-up period they continued their home training programme. Once a month the patients' home training programme was adjusted at the institute.

TP group. Traditional exercises were performed for a period of 4 months. The home training programme was based on these exercises and started after 3 weeks. All training was stopped after 4 months. Thereafter patients were contacted by telephone by their physiotherapist, asked questions and encouraged to continue training every fourth month for one year.

TP+ group. This group received the same treatment in the intervention period as the TP group. During the follow-up period they continued their home training programme. Once a month the patients' home training programme was adjusted at the institute.

Outcome measures

Referred patients completed questionnaires and underwent physical examination at the Friskvern clinic at inclusion (T0), after the intervention period (T1), and after the 12-month follow-up period (T2). Patients were examined by 3 blinded assessors (a specialist in physical medicine and rehabilitation, a specialist in manual therapy, and a physiotherapist). At T0 the patients were examined by the same physician and manual therapist, but different physiotherapists. At T1 and T2 the patients were examined by the same manual therapist as at T0, but by different physiotherapists. A psychiatric nurse assisted the patients in completing all questionnaires.

Pain and complaints. Complaints, i.e. pain related to activity, at rest and at night, tiredness and lack of concentration during the last week, were registered on a scale from 1 to 9 (1 = minimum, 9 = maximum). In addition, patients were asked to indicate their neck/shoulder pain on a visual analogue scale (VAS) describing average pain intensity for the last 14 days.

Self-reported disability. A modified version of the Roland & Morris disability questionnaire (29) was applied, using "neck" instead of "back" in describing symptom localization.

Sick leave. Patients reported if they were on current sick leave.

Psychological distress. The Hopkins Symptom Checklist (HSCL), a 25-item questionnaire was used to register psychological distress with the sub-dimensions anxiety, depression and somatization during the last week (30, 31).

Clinical tests

The validity, reliability and responsiveness of the clinical tests applied are described in the respective references below.

Cervical range of motion. Active cervical range of motion (ROM) were measured using the Cervical Measurement System (32) with the patient in a sitting position. By using a device formed as a helmet and mounted with a compass on top, side and front, one can read the ROM in all directions.

Neck stabilization/endurance. Neck stability testing was registered as the patients' ability to stabilize the neck/head (in seconds) in a fixed position (33). The patient was lying supine, holding his or her head in a mid-position slightly elevated from the surface. The patient was instructed to slightly withdraw his or her cheek to achieve a mid-position. Pain, exhaustion and complaints were registered during the test using VAS scales. The test was stopped if any value exceeded 8 on the scale.

Cervicocephalic kinesthetic sensibility. A cervicocephalic kinesthetic sensibility test (15, 34) was carried out with the patient placed in a chair at a distance of 90 cm from a target with a co-ordination system. The system consisted of 1×1 cm squares. Using a laser-pen fixed to the forehead, the blindfolded patient's ability to relocate the centre of the co-ordination system was registered after performing one rotation. After 10 subsequent rotations in each direction the average deviation from the centre was calculated.

Additionally the following tests were applied, but these did not yield any significant information: abdominal and back muscular strength, thoracic outlet related symptoms, cervical segmental testing and shoulder examination.

Statistical analyses

Data were sent for statistical analysis immediately after each registration. All analyses were performed using SAS (ver.8.2) or SPSS (ver.12.0.1) for Windows. Demographic variables were tested with one-way ANOVA or χ^2 tests. To describe the observatory variation, a 95% confidence

interval and a 5% significance level were used. To examine for overall treatment effects, variables were tested with procedure general linear models (GLM) for repeated measures (full-factorial model, type III sum of squares, Wilk's λ), thus taking into consideration baseline characteristic differences. The 3 different points in time measures (T0, T1, T2) for the outcome variables were used as time factor (within-subject factor) and analysed by intervention group (between-subject factor). The least significant difference pair-wise multiple comparisons test was used for *post hoc* pair-wise comparisons. In addition, separate GLM analyses were conducted examining differences between the NSET (grouping NSET+ and NSET) and TP (grouping TP+ and TP) from T0 to T1. The sole effect of follow-up with home training was also examined with separate GLM tests (T1 to T2), by grouping the NSET+ and the TP+ group, and the NSET and the TP group. Differences in sick leave within groups were analysed with Wilcoxon signed-rank tests.

Power analysis was performed as an interim analysis after 100 patients had completed the study, showing that a total of another 110 patients (allowing for 20% drop-outs) had to be included, choosing a statistical level of significance of 5%, power of 80% and minimal clinical difference of ≥ standard deviation (SD) on a summarized score of included pain variables.

Ethics

Informed written consent was obtained from all patients. The study was approved by the regional committee for medical research ethics.

RESULTS

Baseline characteristics

There were no statistically significant differences in background variables between the 4 intervention groups regarding age, percentage of women, self-reported educational level, sick leave at inclusion and level of regular exercise (n = 171) at baseline.

Pain and complaints

Regarding neck and shoulder pain, or any of the general pain and complaint scales, there were no significant differences between the 4 intervention groups (p = 0.07–0.82) (Fig. 3).

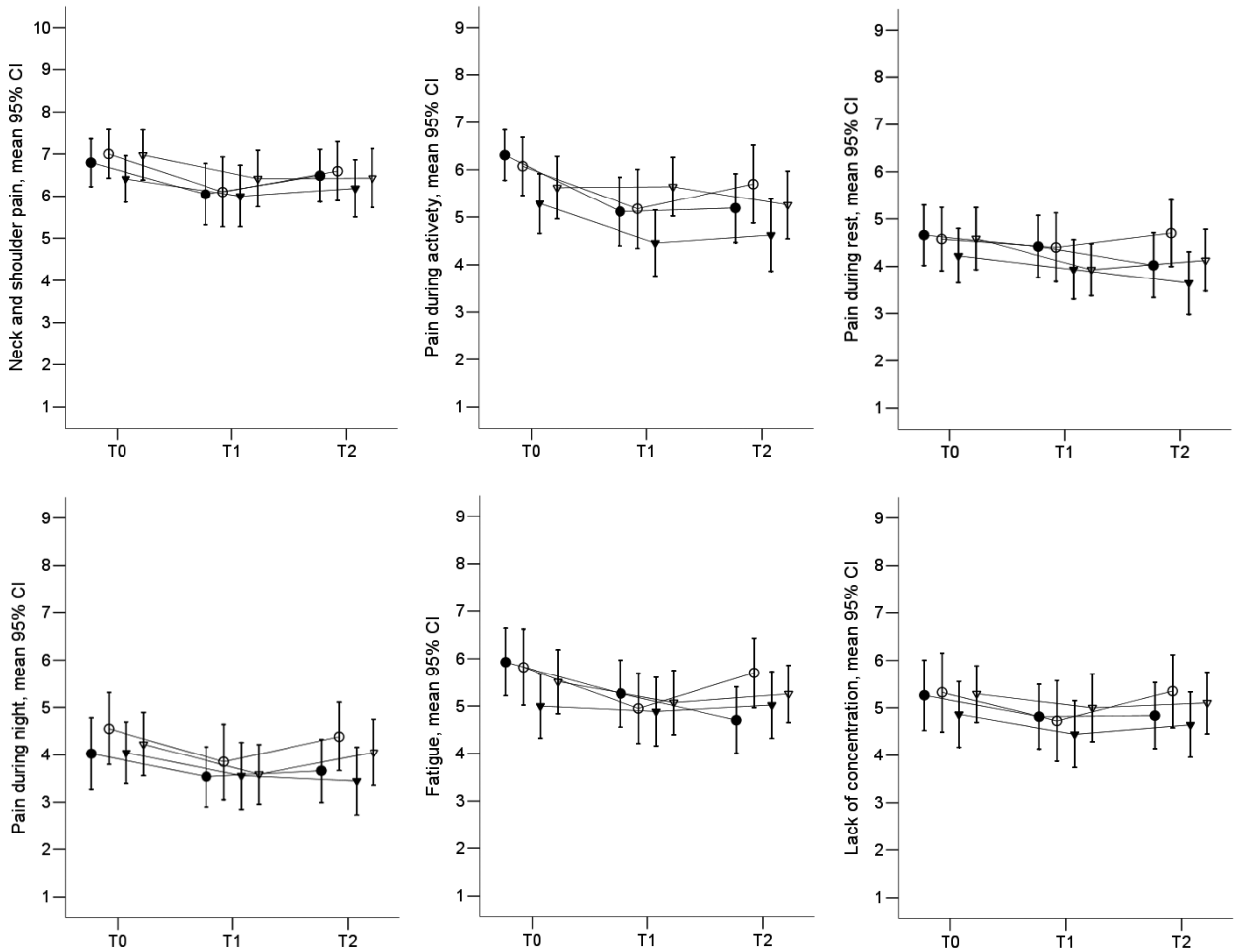

Fig. 3. Mean scores (95% confidence intervals (CI)) of pain and discomfort outcome measures for the 4 intervention groups at T0 (before intervention), T1 (after intervention) and T2 (12 months after intervention). ●: new sling exercise therapy + home exercise programme for 12 months after intervention; ○: new sling exercise therapy; ▼: traditional physiotherapy + home exercise programme for 12 months after intervention; ▽: traditional physiotherapy.

There were also no significant differences between T1 to T2 for the 2 groups that received follow-up with home training and the 2 groups that did not, except for a small positive statistically significant effect on pain during rest ($p = 0.05$) and on reported fatigue in the final week ($p = 0.02$).

Self-reported disability

There were no significant differences between the 4 intervention groups on the modified Roland & Morris disability score ($p = 0.32$–0.75). There were also no significant differences between the 2 groups that received follow-up with home training and the 2 groups that did not (Fig. 4). Only 2.3–8.3% of the subjects reported high levels of disability, i.e. scores of 14 or more.

Sick leave

There was an increased prevalence of sick leave at T1 compared with T0 in all groups. Reported sick leave increased from 48% to 56% in the NSET+ group, and 35% to 38% in the NSET group. The increase was from 28% to 45% in the TP+ group and from 47% to 66% in the TP group. However, the increase was statistically significant only in the TP group ($p = 0.01$). The prevalence of sick leave decreased from 56% to 40% from T1 to T2 in the NSET+ group and increased from 38% to 40% in the NSET group. In the TP+ group from 45% to 21% ($p = 0.01$) and in the TP group from 66% to 53%. In the TP and NSET groups there was no statistically significant change ($p = 0.68$) from T0 to T2 and sick leave was even higher than before the intervention.

Psychological distress

There was a high prevalence of psychological distress. In the total patient group ($n = 213$) 43.9% scored 1.75 or higher ("psychiatric cases") at baseline on the HSCL total score. There were no significant differences between the 4 intervention groups in any of the HSCL scores; nor were there any significant differences between the 2 groups that received follow-up with home training and the 2 groups that did not (Fig. 4).

Clinical tests

Neck stability/endurance. There were no significant differences between the 4 interventions groups on effect on neck stability (Fig. 5). However, when results for the 2 NSET and the 2 TP

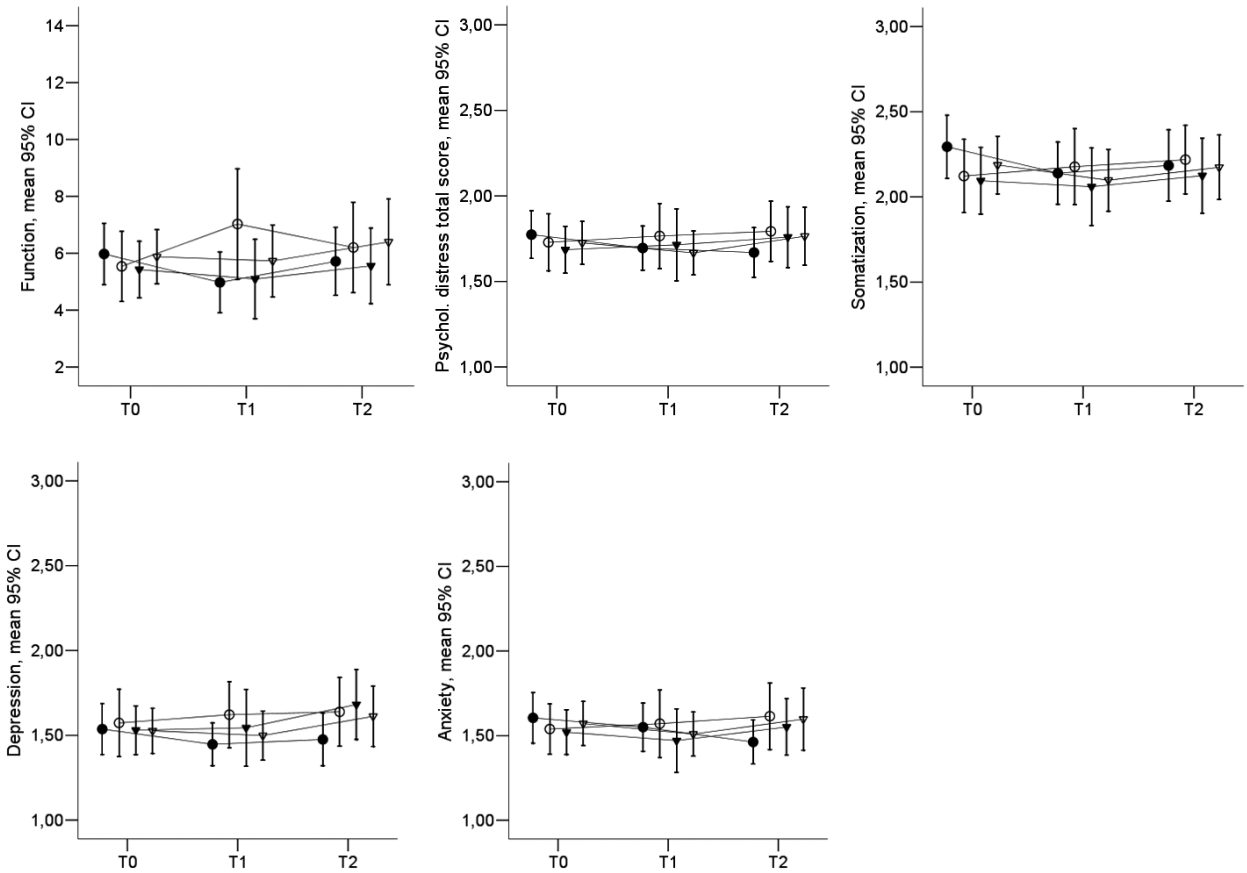

Fig. 4. Mean scores (95% confidence intervals (CI)) of function (modified Roland & Morris) and psychological distress Hopkins Symtom Checklist for the 4 intervention groups at T0 (before intervention), T1 (after intervention), and T2 (12 months after intervention). ●: new sling exercise therapy + home exercise programme for 12 months after intervention; ○: new sling exercise therapy; ▼: traditional physiotherapy + home exercise programme for 12 months after intervention; ▽: traditional physiotherapy.

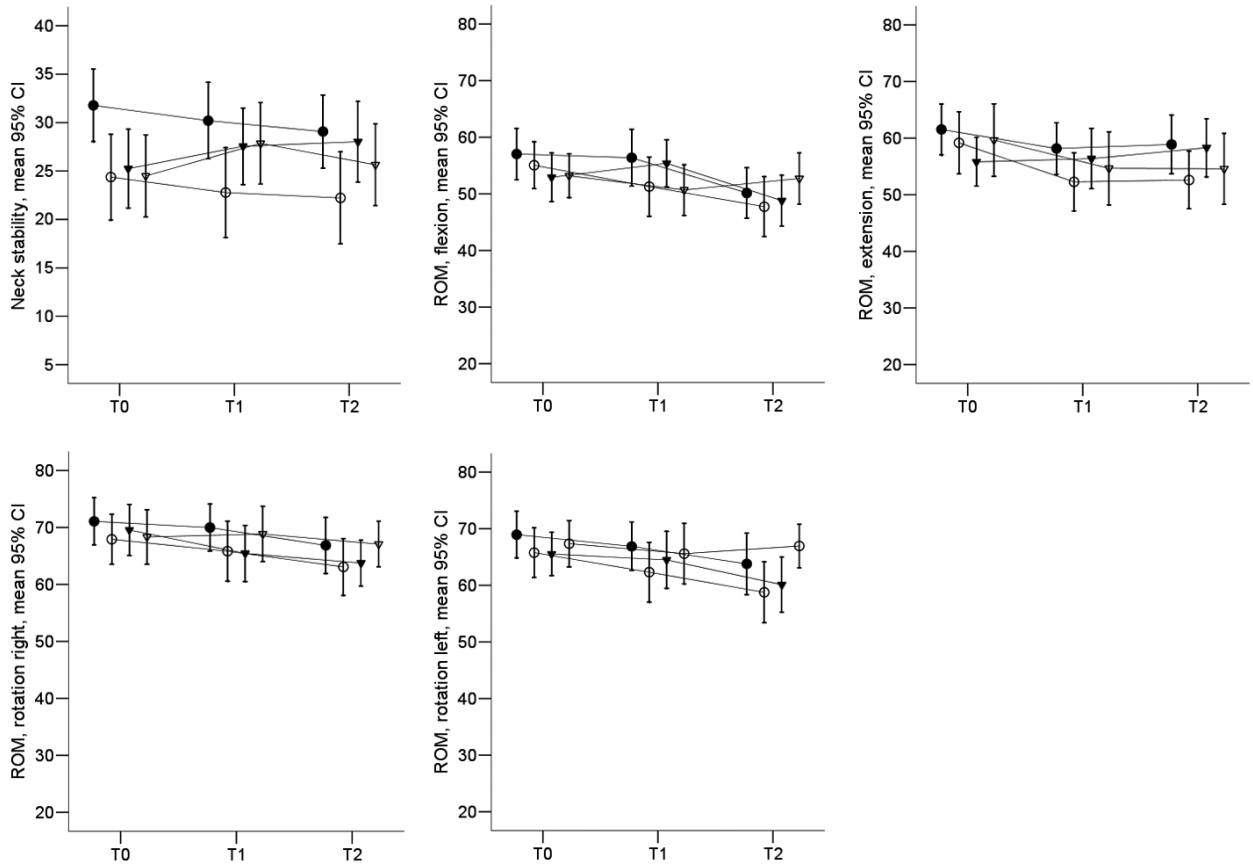

Fig. 5. Mean scores (95% confidence intervals (CI)) of physical tests in the 4 intervention groups at T0 (before intervention), T1 (after intervention), and T2 (12 months after intervention). ●: new sling exercise therapy + home exercise programme for 12 months after intervention; ○: new sling exercise therapy; ▼: traditional physiotherapy + home exercise programme for 12 months after intervention; ▽: traditional physiotherapy.

groups were pooled, there was a small, but statistically significant, difference in effect on neck stability in favour of the TP group ($p = 0.01$). There were no significant differences between the 2 groups that received follow-up with home training and the 2 groups that did not.

Cervical range of motion. There were no significant differences between the 4 groups regarding cervical ROM (flexion, extension, right and left rotation; $p = 0.14–0.82$; Fig. 5), nor were there any significant differences between the 2 groups that received follow-up with home training and the 2 groups that did not.

Cervicocephalic kinesthetic sensibility. There were no significant differences between the 4 interventions groups regarding neck stability (detailed results not presented), nor was there any significant difference between the 2 groups that received follow-up with home training and the 2 groups that did not.

DISCUSSION

The main purpose of this study was to evaluate differences between 2 different treatment programmes for patients with chronic WAD. No statistically or clinically significant differences were found in pain, function, psychological distress, sick leave or physical findings. There were also no differences in the results of long-term follow-up with or without home exercises, although there was a decrease in pain during activity, and in reported fatigue and sick leave.

Regarding sick leave, there was an increase in sick leave at T1 compared with T0 in all 4 groups, which was probably due to practical factors, i.e. caused by patients being subjected to treatment in the clinics. There was, however, a decrease in sick leave from T1 to T2 in all groups except the NSET group, in which there was a small increase. Overall, it is difficult to determine whether the interventions had any effects of clinical importance.

Perhaps this study examined not so much the differences between treatments, but more the additional effects of on-going compensation claims. The fact that all patients had on-going, unresolved insurance claims may have affected the study outcome, and could explain why there were no differences within or between the intervention groups. Cassidy et al. (27) found that eliminating compensation for pain and suffering was associated with a decrease in incidence and improved prognosis of whiplash injury. In general, insurance and com-

pensation systems may have a large impact on recovery from acute whiplash injuries (5). However, as suggested by Cote et al. (35), large cohort studies investigating a wide range of prognostic factors are necessary to increase our understanding of this problem.

The present study has some further limitations that may have influenced the outcome. One possible explanation for why no effects were recorded could be insufficient training and lack of experience of the therapists in using the new treatment modality. However, this seems unlikely, as the 25 physiotherapists involved in this treatment were given extensive training prior to the intervention and were instructed to follow a strict protocol. In addition, the outcome for the one-third of patients who were treated by the 4 most experienced clinicians was no better. A multi-centre study including 105 physiotherapists may result in dispersion and diluting of results. We consider, however, that the large number of participating physiotherapists increases the likelihood that they are representative for common clinical practice, thus, reflecting "treatment as usual".

Lack of patient compliance may affect the outcome of intervention studies. In our study, however, the patients showed high compliance during the institute treatment period, in which they were continuously observed by a physiotherapist, and attended almost 100% of the training sessions. It is not known whether the patients complied with the home training protocol. However, patients were asked questions and encouraged at each monthly consultation to continue to follow this programme.

It could be argued that using inadequate outcome measures could influence the results in a negative way. By using a modified Roland & Morris inventory we cannot be certain about the accuracy of this outcome measure. We chose to use this instrument because other inventories do not, to the same extent, measure consequences regarding neck dysfunction. It seems unlikely that the questionnaires and scales applied are explanatory factors for the lack of differences between or within the groups.

Earlier research on unsettled compensation claims has shown that it may be difficult to measure any treatment effects before a compensation claim has been settled. We also found no treatment effect in our whole study population. However, due to the study design, which lacked a control group with settled claims, we cannot conclude that the intervention had no beneficial effect, only that the outcome of the 2 interventions did not differ.

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Conflict of interest

Even Laerum has received funding as a medical consultant and Gitle Kirkesola is employed in Nordisk Terapi A/S.

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