

APPLIED RELAXATION IN THE TREATMENT OF LONG-LASTING NECK PAIN: A RANDOMIZED CONTROLLED PILOT STUDY

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Objectives: To evaluate the feasibility of study design and method for evaluating effects of interventions on patients with long-lasting neck pain and to compare treatment effects of: (i) a pain and stress management group intervention with applied relaxation, and (ii) individual physiotherapy treatment as usual.

Design: Randomized controlled pilot study.

Subjects: Thirty-seven patients with long-lasting neck pain.

Methods: The patients were randomly assigned either to applied relaxation or treatment as usual. The applied relaxation group received 7 group sessions over a period of 7 weeks and the treatment as usual group an average of 11 individual sessions spread over 20 weeks following baseline. Twenty-nine participants completed the intervention and filled in a self-assessment questionnaire before treatment, and 7 and 20 weeks after baseline. The questionnaire comprised: Neck Disability Index, Coping Strategies Questionnaire, Hospital Anxiety and Depression Scale, Tampa Scale of Kinesiophobia, and questions regarding neck pain, analgesic use, sleep, sick-leave and utilization of healthcare.

Results: The applied relaxation group had better perceived control over pain at the 20 weeks follow-up compared with the treatment as usual group.

Conclusion: The design and methods of this pilot study were feasible and will be suitable for a larger randomized controlled study.

Key words: applied relaxation, coping, neck pain, randomized controlled trial, self-assessment questionnaire.

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INTRODUCTION

Musculoskeletal pain, especially low back and neck pain, is a public health problem (1). Female gender and increasing age are predictors for neck pain (2). Psychosocial factors have been reported as risk factors in the development and maintenance of subacute and chronic musculoskeletal pain (3). While heavy physical workload and exposure to vibration are risk factors for low back pain, repetitive and static work are risk factors for neck-shoulder pain. During the last decades employment conditions have changed: heavy physical

work has decreased while static and repetitive types of work have increased (4). Musculoskeletal pain from neck, shoulder or back are often treated as similar conditions. There are few studies taking into account the conditions related to neck pain compared with low back or shoulder complaints (5). Few physiotherapy techniques for neck pain have been studied and evaluated scientifically. There is a need to identify effective methods of physiotherapy intended for neck pain (6).

Many patients with musculoskeletal pain show symptom-specific, elevated muscle tension responses and extended duration of muscle tension during physical work and in stressful situations. This indicates that abnormal muscle activity contributes to the maintenance of musculoskeletal pain (7, 8). Positive effects of relaxation therapy for chronic musculoskeletal back pain have been confirmed (9).

The applied relaxation method has been described by öst (10). Theories underlying applied relaxation derive from behavioural psychology (11). The purpose of applied relaxation is to break any muscle tension pain cycle that may exist but also to provide the patient with a method for controlling the pain, i.e. teaching the patient to recognize early signals of pain/stress/anxiety and to cope with the pain instead of being overwhelmed by it (10). Relaxation is used as a coping strategy to be applied in everyday situations rather than in a treatment setting. Control is an important component in pain perception (12). Linton & Götestam (13) instructed patients with chronic back/joint pain to apply relaxation skills in risk situations in everyday situations to control pain. The result showed applied relaxation to be as effective as a multi-dimensional pain program with regard to decreasing the level of pain perceived by patients. Studies have been conducted regarding applied relaxation and musculoskeletal pain disorders (13–15) but there is no study regarding the effectiveness of applied relaxation for people with neck pain in particular.

The objectives of this study were: (i) to explore the feasibility of study design and methods, including a comprehensive set of instruments for the evaluation of physiotherapy treatment effects on patients with long-lasting neck pain, and (ii) to compare the treatment effects of a pain and stress management group intervention program with applied relaxation (AR) with individual physiotherapy treatment as usual (TAU) for patients with long-lasting neck pain.

MATERIAL AND METHODS

Study subjects

Patients with various neck disorders seeking physiotherapy treatment at a primary care outpatient rehabilitation clinic in a small city in Sweden, on their own initiative or referred to the clinic by physicians practising in primary care, were consecutively recruited to the study from May to October 2002. The patients were examined by a physiotherapist and were considered eligible if they had musculoskeletal neck pain of long-lasting duration, i.e. more than 3 months, were 18–65 years old and had no signs of neurological symptoms or cervical facet joint pathology. Neck pain was defined as: subjective statements of ache/pain in an area covering from the occipital parts of the head to the acromion on the shoulder and following the scapular spine to the fourth thoracic vertebra, together with palpation tenderness in the same area as assessed by the physiotherapist. The patients were excluded if they had insufficient knowledge of Swedish, had a learning disability, had a medical history of psychotic disorders, were under treatment for a malignant disease, were pregnant or had previously received the relaxation treatment program designed for the intervention group.

The study was approved by the Ethical Committee of the University of Uppsala, Akademiska sjukhuset (number Dnr: Ups 02-088).

Study design and procedure

This was a randomized controlled study. The participants were given written and oral information concerning the study and gave their written, informed consent. After completing a self-assessment questionnaire, the participants were assigned randomly to either the intervention program AR or to TAU. A physiotherapy-assistant who was not involved in the AR or the TAU administered the questionnaires and the opening of envelopes containing group allocation. These sealed envelopes were prepared by the second author prior to the enrolment of patients to the study. Group allocation was carried out with the help of permuted blocks of 2, 4 and 8 individuals sequentially located at random. Follow-up was conducted by means of the self-assessment questionnaire after the 7-week intervention program or, for the TAU group, 7 weeks after inclusion, and at 20 weeks after inclusion/treatment onset. All 3 questionnaires were similar. The follow-up self-assessment questionnaires were sent to the home address of the participants, and then returned by post. Follow-up assessment questionnaires were not sent to the participants who withdrew from the study or to those who had not returned the previous questionnaire.

All 7 physiotherapists working at the rehabilitation centre were informed and agreed to give TAU to the control group. However, the participants in the TAU group were asked not to reveal to their physiotherapists that they were participating in the study.

Intervention program

The AR consisted of an information and training program carried out with groups of patients, including both participants in the study and other patients with musculoskeletal pain referred to the rehabilitation centre. The program contained 7 1.5-hour sessions, over a period of 7 weeks. The sessions consisted of applied relaxation training, 4 body awareness exercises (16), and information about pain and stress management. This group program had been offered on a regular basis at the rehabilitation clinic for several years. The relaxation training was largely derived from the method of applied relaxation, as described by öst (10). The rationale was that the patient was taught an active coping skill to prevent or control pain. Participants were first taught to relax using progressive and autogenic relaxation methods. As the participants improved their ability to relax through practice, the length of instruction and time allowed to reach relaxation were gradually decreased. Secondly, they were taught conditioned relaxation exercises, also called cue-controlled relaxation, which involves saying "relax" while exhaling. When participants were able to reach a relaxed state quickly, they practised relaxation in variety of situations where they began to feel pain (or increased pain). They were instructed how to identify "risk situations" consisting of any stimuli: activity, movement or thought, which were believed to cause the individual's pain, and to apply the relaxation in these real-life stressful situations to prevent the pain from starting or to control it. The participants were instructed to practise

relaxation exercises twice a day at home between sessions in addition to applying new relaxation skills in everyday situations. The purpose of the 4 recurrent body awareness exercises was to increase the awareness of bodily signals and to provide an opportunity to practice and apply relaxation when standing and during movement. The sessions also consisted of theoretical information about anatomy, aetiology, physiology of pain and stress, and pain and stress management.

TAU entailed individual physiotherapy sessions according to current practise and was not a standardized treatment procedure. The type of treatment, frequency of visits and duration of contact were left to the discretion of the physiotherapists and their patients. The participants in the TAU group were not to receive relaxation training of any kind. The physiotherapists at this outpatient primary care rehabilitation clinic had 4–30 years of professional experience.

Data collection and instruments

Outcome was assessed using a self-administered questionnaire. The questionnaire consisted of demographic data, a set of instruments frequently used in studies concerning musculoskeletal pain, previously tested for validity and reliability and some additional questions defined as "single questions".

Demographic and socioeconomic data. Information regarding the participants' age, gender, duration of neck pain, occurrence of pain from other bodily locations and sick-leave related to neck pain were collected by means of self-reports.

Healthcare utilization. The number of self-reported healthcare visits (physicians, physiotherapists, other healthcare providers) due to neck pain in the 3 months prior to inclusion in the study, as well as during the 3 months following intervention, prior to the 20-week follow-up, was recorded. Information regarding the numbers and type of physiotherapy modalities given to the participants in the TAU group was collected from the physiotherapy records.

Pain and analgesics. Pain intensity was assessed using an 11-point ordinal scale ranging from 0 (no pain) to 10 (maximal pain) (17). The participants reported duration of neck pain in days since onset and presence of pain from other bodily locations ("yes", "no"). Consumption of analgesics due to neck pain, or to pain from other parts of the body was reported on a Likert-type scale (0 "never", 1 "a couple of days per month", 2 "1 or 2 days per week", 3 "every second day", 4 "every day").

Disability. Perceived interference with daily activities due to discomfort in the neck was assessed using the Neck Disability Index (NDI) (18, 19) which contains 10 items, scored from 0 to 5. A higher score indicates a greater degree of disability.

Coping strategies. Type and use of pain-related coping strategies were assessed by means of the Coping Strategies Questionnaire (CSQ) (20, 21) which contains 48 items describing different ways of dealing with pain. The participants rated the frequency with which they engaged in various cognitive and behavioural activities on a 7-point Likert scale from "never" 0 to "always" (6). Summarized responses form 8 subscales of 6 items each: Diverting attention, Reinterpreting sensations, Ignore pain sensations, Coping self-statements, Praying and hoping, Catastrophizing, Increasing activity level and Pain behaviours. Two further questions assess the subject's perceived ability to control and decrease pain.

Fear of movement/(re)injury. Pain-related fear of movement or of (re)injury was measured using the Tampa Scale for Kinesiophobia (TSK) (22) which contains 17 items. The participants rated their degree of agreement with 17 statements on a 4-point Likert scale from "strongly disagree" to "strongly agree". A higher score indicates a greater amount of pain-related fear of movement. Six items from Fear-Avoidance Beliefs Questionnaire (FABQ) (23) regarding physical activity-related (3 items) and work-related (3 items) fear avoidance were also included in the assessment questionnaire. They are referred to as "single questions".

Depression and anxiety. Presence of depression and/or anxiety was measured by the Hospital Anxiety and Depression Scale (HAD) (24) which contains 14 items reflecting depression and anxiety. Summarized responses form 2 subscales of 7 items each: depression sum score and

anxiety sum score. HAD has been found to be a reliable instrument for detecting states of depression in medical outpatient clinical use as well as a valid measure of the severity of these emotional disorders. Cut-off points recommended by Zigmond & Snaith (24): scores of 7 or less in each subscale are regarded as non-cases, scores of 8–10 as doubtful cases and scores of 11 or more as definite cases.

Additional questions. Single questions regarding ability to fall asleep, quality of sleep, feelings of tenseness or stress, depression, anxiety, loss of control over pain and satisfaction with care were assessed by means of 5-point Likert-type scales from “very bad” to “very good” or from “completely disagree” to “completely agree”. They are referred to as “single questions”.

Statistical analysis

Data were analysed for all participants who completed treatment (on treatment analysis). For continuous variables that were not approximately normally distributed and for ordinal variables, the Mann-Whitney *U* test was used. The Friedman test was applied to evaluate changes within groups. A *p*-value ≤ 0.01 was accepted as statistically significant. All analyses were conducted using SPSS 10.0 for Windows (Statistical Package for Social Sciences).

RESULTS

Feasibility of study design and method

Participant flow through the trial. In total, 58 patients were screened for inclusion in the study. A flow-chart of the study is illustrated in Fig. 1. Fourteen patients were excluded. Seven patients declined to participate. Thirty-seven participants (34 women and 3 men) aged 19–67 years, were randomly assigned: 18 to the AR group and 19 to the TAU group.

Two participants, from the AR group, withdrew before the intervention started referring to psychological problems. Six participants did not return the follow-up self-assessment questionnaires. In total, 29 participants (78%) participated in both the 7-week and the 20-week follow-ups.

Participation in the intervention programs. In all, 4 consecutive groups receiving the pain and stress management program were involved. The number of patients in the groups, both participants in the study and other patients with musculoskeletal pain, varied between 5 and 11. Attendance at group-sessions among

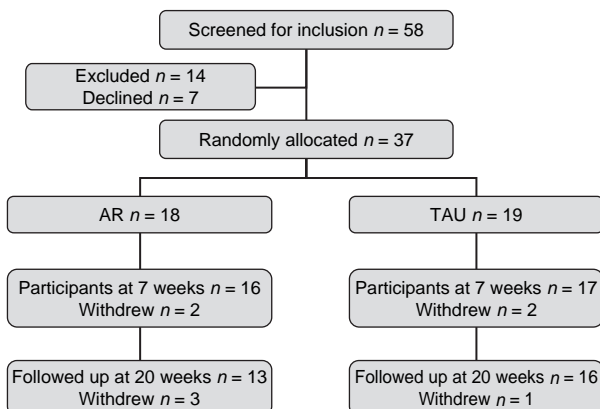


Fig. 1. Flow-chart of the study. AR = applied relaxation; TAU = treatment as usual.

AR participants was high. Nine participants attended all 7 sessions. None of the participants attended less than 5 sessions (70% of sessions). The TAU group received an average of 11 treatment sessions (ranging from 2 to 32). Six participants in the TAU group had completed their treatment at 7-week follow-up and 6 were still in treatment at the 20-week follow-up. TAU consisted of: acupuncture, massage, spinal mobilization techniques, hot-pack, transcutaneous electric nerve stimulation (TENS), ultrasound and/or introducing the patient to different exercise programs: gym-based exercises, home-exercise programs or water-exercise programs.

Self-assessment questionnaire. The response rate was high, all of the 29 analysed participants answered all the items on the self-assessment questionnaire at all follow-ups. No apparent floor or ceiling effects were observed for any of the instruments included in the self-assessment questionnaire.

Effects of the intervention program

Comparisons between groups at baseline. Characteristics and baseline measures of the 29 participants who completed all follow-ups are shown in Table I.

The AR group was older, had a longer duration of neck pain and a higher average number of days of sick-leave as well as a larger number of healthcare visits, during the 3 months preceding the study than the TAU group. The AR group also had a higher consumption of pain-reducing medication both with regard to neck pain as well as to pain from other parts of the body. At baseline, the TAU group reported a better ability to control pain (CSQ) compared with the AR group.

Withdrawals. The 8 participants who withdrew during the study were compared with the 29 participants who completed all follow-ups. At baseline, compared with the participants, the dropouts had a higher number of days of sick-leave before the study ($p = 0.017$) and poorer sleep ($p = 0.018$). Of all participants, the 2 persons with the highest scores on HAD Depression scale, withdrew from the study before starting treatment, referring to performance anxiety.

Outcome: comparisons between groups. Outcome at 7 weeks and 20 weeks after baseline for the AR group and TAU group are presented in Table II.

Coping and control. At the 20-week follow-up, the AR group, compared with the TAU group, reported both better ability to control pain ($p = 0.003$) and better ability to decrease pain ($p = 0.003$) by use of coping strategies as per the 2 overall effectiveness questions in the CSQ.

Fear and avoidance. The AR group reported a lower work-related fear of future neck injury than the TAU group ($p = 0.009$) as per single question, derived from FABQ.

Depression and anxiety. Both groups had low ratings on the HAD Depression subscale. The median score did not reach the cut-off point defined in the literature as clinical depression.

Table I. Characteristics at baseline of treatment groups applied relaxation (AR) and treatment as usual (TAU)

Variable (range)	AR group (n=13)		TAU group (n=16)	
	Median	IQR	Median	IQR
Gender (female/male)	13/0		15/1	
Age (years)	43	36–54	36	24.5–48.5
Duration of neck pain (months)	72	14–156	33	12.5–60
Days of sick-leave (during the preceding 3 months)	23*	0–82.5*	0	0–12.2
Healthcare visits due to neck pain (during the preceding 3 months)	4	2.5–10.5	1.5	1–3.8
Perceived pain (0–10)	6	2.5–8	6.5	5–7.8
Analgesics due to neck pain (0–4)	2	1–3.5	1	1–2.8
Analgesics due to pain from other parts of the body (0–4)	1	0–2.5	0	0–1
NDI (0–50)	17	9–25.5	14	10–24
CSQ Diverting attention (0–36)	11	6–18	13.5	8.8–15
CSQ Reinterpreting pain sensations (0–36)	3	1–5	3	0–8
CSQ Ignoring sensations (0–36)	14	7.5–18.5	12.5	7.8–17.2
CSQ Coping self-statements (0–36)	22	16.5–24.5	17.5	15–18.8
CSQ Praying/hoping (0–36)	9	6–13.5	11	6.2–14.8
CSQ Catastrophizing (0–36)	9	5.5–14	8	2.2–13.8
CSQ Increased behavioral activities (0–36)	15	7–22	16.5	13.2–19.5
CSQ Pain behaviors (0–36)	19	15.5–25.5	19	15.2–23.8
CSQ Ability to control pain (0–6)	3	2.5–3.5	4	3–4
CSQ Ability to reduce pain (0–6)	3	2–3	3	3–3.8
TSK (0–51)	9	8–15	12.5	8.2–17.8
HAD Depression sum score (0–21)	3	1.5–7.5	2	1–5
HAD Anxiety sum score (0–21)	5	3–7	7.5	4–11
Single question: Quality of sleep (1–5)	3	2.5–4.5	3	3–4
Single question: Ease of falling asleep (1–5)	3	2–4.5	3	3–3
Single question: Loss of control over pain (1–5)	2	1–3	3.5	2–4
Single question: Work-related fear of pain (1–5)	3	1–3.5	2.5	2–4.8
Single question: Work-related fear of future injury (1–5)	2	1–3.5	3	2–4

*n=12, IQR=interquartile range, NDI=Neck Disability Index, CSQ=Coping Strategies Questionnaire, TSK=Tampa Scale of Kinesiophobia, HAD=Hospital Anxiety and Depression Scale.

The AR group reported a lower HAD Anxiety sum score than the TAU group at the 20-week follow-up ($p=0.001$).

There were no statistically significant differences between the groups regarding healthcare utilization, pain and analgesics, disability, pattern of coping strategies, fear and avoidance as regarded by TSK or single questions regarding sleep.

Outcome: within-group changes over time. Changes within the groups between baseline and the 7-week and 20-week follow-ups are presented in Table III.

Healthcare utilization. At the 20-week follow-up, the AR group had a reduction in reported numbers of healthcare visits during the preceding 3 months compared with the 3 months preceding the intervention ($p=0.035$), whereas, the TAU group reported an increase ($p=0.052$). However, these changes were statistically non-significant.

Pain and analgesics. There was no reduction in self-rated neck pain in any group at follow-ups. Consumption of neck pain analgesics was lowered in the AR group at both follow-ups ($p=0.008$). In contrast, consumption of analgesics increased in the TAU group at follow-ups, both regarding neck pain ($p=0.017$) and pain from other parts of the body ($p<0.001$).

Coping and control. The 2 groups altered their coping strategies according to some of the CSQ subscales. The AR group increased their reporting on the CSQ subscale Hoping and

praying ($p<0.001$) and decreased their reporting on the Coping Self-statements subscale ($p=0.011$) at follow-ups compared with the period before the intervention. Both the AR group and the TAU group increased their reporting on the CSQ subscale: Increased behavioural activities ($p<0.001$ and $p<0.001$). The TAU group increased their reporting on the CSQ subscale: Catastrophizing ($p=0.011$).

The AR group increased their ability to decrease pain ($p=0.003$) by use of coping strategies as per 1 of the 2 overall effectiveness questions in CSQ. The TAU group, on the contrary, decreased their ability to control pain ($p=0.002$) and ability to decrease pain ($p=0.003$).

Depression and anxiety. The TAU group reported a small but statistically significant increase in depressive signs at follow-ups ($p=0.007$).

DISCUSSION

Feasibility of study design and method

The study design, patient selection procedure and randomization were found to be feasible. The method of collecting data by a self-assessment questionnaire was well accepted by the participants.

Of 58 patients screened for inclusion, 14 were excluded. Two patients with diagnosed depression, who were included in the

Table II. Outcome at 7 weeks and 20 weeks for applied relaxation (AR) and treatment as usual (TAU) group

	7-week follow-up			20-week follow-up		
	AR group (n = 13)	TAU group (n = 16)		AR group (n = 13)	TAU group (n = 16)	
	Median/IQR	Median/IQR	p-value*	Median/IQR	Median/IQR	p-value*
Days of sick-leave (during the preceding 3 months)				0/0–48.8†	0/0–30	0.401
Healthcare visits due to neck pain (during the preceding 3 months)				2/0–5	5/0.5–9.5	0.101
Perceived pain (0–10)	6/2–7.5	6/3.2–7	0.506	5/2–7.5	7/4.2–8	0.255
Analgesics due to neck pain (0–4)	1/1–2.5	1/1–1.8	0.439	1/1–2	2/1–2	0.153
Analgesics due to pain from other parts of the body (0–4)	1/0–2.5	1/0–1	0.781	1/0.5–2	2/0.2–2	0.567
NDI (0–50)	15/7–21.5	14.5/8–20.8	0.843	14/10–22.5	14/6.8–23	0.809
CSQ Diverting attention (0–36)	10/5.5–16	14.5/7.5–18	0.292	12/4.5–15.5	12/2–17	0.877
CSQ Reinterpreting pain sensations (0–36)	3/0–6	5/2–12	0.318	2/0–8.5	6/0–11.8	0.473
CSQ Ignoring sensations (0–36)	11/5.5–19	17/10.5–19.5	0.428	15/9.5–17.5	15.5/9–18	0.860
CSQ Coping self-statements (0–36)	18/11.5–22	18.5/10.2–23.5	0.895	13/10–19.5	15/8.2–17.8	0.645
CSQ Praying/hoping (0–36)	8/5.5–10	9.5/4.2–12	0.538	20/13–25.5	20.5/5.2–30.8	0.948
CSQ Catastrophizing (0–36)	11/4–16	8/0–14.5	0.427	13/7.5–20.5	21/3.8–27.8	0.709
CSQ Increased behavioral activities (0–36)	17/11.5–22	15.5/7.8–16.5	0.861	33/25–37.5	33/21–38.5	0.913
CSQ Pain behaviors (0–36)	24/17–25	21/14.5–24.8	0.628	22/13–30.5	24/9.2–28.5	0.792
CSQ Ability to control pain (0–6)	4/3–5	3/2–4	0.148	4/3–4.5	2/2–3	0.003
CSQ Ability to reduce pain (0–6)	3/3–4	3/2–4	0.333	4/3–4	2/2–2.8	0.003
TSK (0–51)	10/5.5–11	15/9.2–20.8	0.099	12/6–14.5	13/8–19.2	0.356
HAD Depression sum score (0–21)	2/1–5	4/3–9	0.137	3/1–5	3.5/1–7.5	0.639
HAD Anxiety sum score (0–21)	3/2–6.5	7/4.2–11.2	0.023	3/1–4	7.5/6.2–12.5	0.001
Single question: Sleep quality (1–5)	3/2.5–4	3/2.2–3	0.616	3/2–3.5	3/3–4	0.387
Single question: Ability to fall asleep (1–5)	3/2–4	3/2–3	0.369	3/1.5–4	3/3–3	0.431
Single question: Loss of control over pain (1–5)	1/1–2	2/1–3	0.022	1/1–2	2.5/1–3.8	0.035
Single question: Work related fear of pain (1–5)	3/2–4.5	3/2–5	0.653	2/2–3	4/2–4.8	0.082
Single question: Work related fear of future injury (1–5)	2/1–3	3/2–3.8	0.130	1/1–2	2.5/2–4.8	0.009

*Mann-Whitney *U* test.

†*n* = 12.

IQR = interquartile range, NDI = Neck Disability Index, CSQ = Coping Strategies Questionnaire, TSK = Tampa Scale of Kinesiophobia, HAD = Hospital Anxiety Depression Scale.

study, withdrew due to performance anxiety and an additional inclusion criterion regarding depression and anxiety should be considered in a future study. Approximately 22% of those included in the study withdrew, of which the majority was lost since they did not return the postal self-assessment questionnaires. It is recommended that a larger study should allow for a withdrawal of similar proportions when calculating sample size. The self-assessment questionnaire was found to be suitable for capturing changes in control over pain and for showing changes of pattern in coping strategies as well as screening of occurrence of depressive states.

The number of participants recruited to the study was small during the 6 months of inclusion and consequently differences in treatment effects of small magnitude could not be ascertained.

A future study should have a sufficient number of participants for statistical power to ascertain plausible treatment effects, which are small but clinically significant. The aim of this pilot study was to explore the feasibility of study design and method and no primary outcome variable was identified in advance. Instead a broad variety of outcome

assessments were used, in order to explore plausible primary outcome measures in relation to patients with long-lasting neck pain. AR is used to increase the patient's control over pain, whilst other treatments often intend to reduce pain itself. A common primary outcome in intervention studies regarding long-lasting pain is "intensity of pain" and the result is often that there is no difference between treatment and no treatment (25). Regarding people with long-lasting neck pain, the question is: can perceived pain be reduced, or is an improvement in ability to cope and control pain a more realistic treatment goal? This needs to be discussed and could contribute to formulating important *a priori* hypotheses for future randomized controlled trials. According to the results of this study, perceived control over pain rather than perceived pain might be the most appropriate primary outcome variable in a future larger study. Consequently, in accordance with other authors (26) we suggest that instead of level of pain the outcome measures should reflect broader aspects, e.g. the level of activities and participation as in the model of International Classification of Functioning and Health (ICF) (27).

Table III. Within-group comparisons in the applied relaxation (AR) and treatment as usual (TAU) groups

	AR group (n = 13)				TAU group (n = 16)			
	Baseline Median/IQR	7 weeks Median/IQR	20 weeks Median/IQR	p-value*	Baseline Median/IQR	7 weeks Median/IQR	20 weeks Median/IQR	p-value*
Days of sick-leave (during the preceding 3 months)	23/0–82.5†		0/0–48.8†	0.414	0/0–12.2		0/0–30	0.655
Healthcare visits due to neck pain (during the preceding 3 months)	4/2.5–10.5		2/0–5	0.035	1.5/1–3.8		5/0.5–9.5	0.052
Pain level (0–10)	6/2.5–8	6/2–7.5	5/2–7.5	0.928	6.5/5–7.8	6/3.2–7	7/4.2–8	0.867
Analgesics due to neck pain	2/1–3.5	1/1–2.5	1/1–2	0.008	1/1–2.8	1/1–1.8	2/1–2	0.017
Analgesics due to pain from other parts of the body	1/0–2.5	1/0–2.5	1/0.5–2	0.565	0/0–1	1/0–1	2/0.2–2	<0.001
NDI	17/9–25.5	15/7–21.5	14/10–22.5	0.020	14/10–24	14.5/8–20.8	14/6.8–23	0.147
CSQ Diverting attention	11/6–18	10/5.5–16	12/4.5–15.5	0.447	13.5/8.8–15	14.5/7.5–18	12/2–17	0.223
CSQ Reinterpreting pain sensations	3/1–5	3/0–6	2/0–8.5	0.786	3/0–8	5/2–12	6/0–11.8	0.050
CSQ Ignoring sensations	14/7.5–18.5	11/5.5–19	15/9.5–17.5	0.869	12.5/7.8–17.2	17/10.5–19.5	15.5/9–18	0.448
CSQ Coping self-statements	22/16.5–24.5	18/11.5–22	13/10–19.5	0.011	17.5/15–18.8	18.5/10.2–23.5	15/8.2–17.8	0.041
CSQ Praying/hoping	9/6–13.5	8/5.5–10	20/13–25.5	<0.001	11/6.2–14.8	9.5/4.2–12	20.5/5.2–30.8	0.024
CSQ Catastrophizing	9/5.5–14	11/4–16	13/7.5–20.5	0.484	8/2.2–13.8	8/0–14.5	21/3.8–27.8	0.011
CSQ Increased behavioral activities	15/7–22	17/11.5–22	33/25–37.5	<0.001	16.5/13.2–19.5	15.5/7.8–16.5	33/21–38.5	<0.001
CSQ Pain behaviors	19/15.5–25.5	24/17–25	22/13–30.5	0.168	19/15.2–23.8	21/14.5–24.8	24/9.2–28.5	0.632
CSQ Ability to control pain	3/2.5–3.5	4/3–5	4/3–4.5	0.024	4/3–4	3/2–4	2/2–3	0.002
SQ Ability to reduce pain	3/2–3	3/3–4	4/3–4	0.003	3/3–3.8	3/2–4	2/2–2.8	0.003
TSK	9/8–15	10/5.5–11	12/6–14.5	0.775	12.5/8.2–17.8	15/9.2–20.8	13/8–19.2	0.983
HAD Depression sum score	3/1.5–7.5	2/1–5	3/1–5	0.247	2/1–5	4/3–9	3.5/1–7.5	0.007
HAD Anxiety sum score	5/3–7	3/2–6.5	3/1–4	0.162	7.5/4–11	7/4.2–11.2	7.5/6.2–12.5	0.15
Single question: Sleep quality (1–5)	3/2.5–4.5	3/2.5–4	3/2–3.5	0.250	3/3–4	3/2.2–3	3/3–4	0.407
Single question: Ability to fall asleep (1–5)	3/2–4.5	3/2–4	3/1.5–4	0.205	3/3–3	3/2–3	3/3–3	0.053
Single question: Loss of pain control (1–5)	2/1–3	1/1–2	1/1–2	0.037	3.5/2–4	2/1–3	2.5/1–3.8	0.024
Single question: Work related fear of pain (1–5)	3/1–3.5	3/2–4.5	2/2–3	0.282	2.5/2–4.8	3/2–5	4/2–4.8	0.529
Single question: Work related fear of future injury (1–5)	2/1–3.5	2/1–3	1/1–2	0.066	3/2–4	3/2–3.8	2.5/2–4.8	0.687

*Friedman Test.

†n = 12.

IQR = interquartile range, NDI = Neck Disability Index, CSQ = Coping Strategies Questionnaire, TSK = Tampa Scale of Kinesiophobia, HAD = Hospital Anxiety and Depression Scale.

Effects of the intervention program

This pilot study suggested a difference in treatment effects between AR and TAU, but since there were imbalances at baseline between the groups, imbalances in gender and the study sample was of limited size, the results should be interpreted with caution. Despite these limitations the results highlights plausible differences in effects between the 2 treatments under study and important questions are raised, core questions in rehabilitation and rehabilitation research.

The difference in treatment effects between AR and TAU indicates that the AR group adapted more appropriate pain coping skills. It is not surprising that the AR did not decrease, more than to a very small extent, the level of perceived pain since the participants all had a history of long-lasting, persistent pain. The AR pain and stress management program aims at improving the patient's ability to cope with pain and ability to control pain. Coping strategies directed towards pain refer to the way the individual who experiences pain develops ways to tolerate, minimize or reduce pain (20, 21). The results of this study indicate that AR, in fact, did have a positive impact on control over pain, and consequently served as an adaptive coping strategy. Control is regarded as an important factor in pain treatment as it promotes independence and self-confidence (12). The findings of decrease in consumption of neck pain medication in the AR group, between baseline and 20-week follow-up, might be effects of a more adaptive coping strategy.

In contrast, between baseline and the 20-week follow-up, the TAU group had a significant increase in consumption of pain reducing medication, both regarding neck pain and pain from other parts of the body. These increases might be associated with increased pain, but also altered coping strategies. Many patients are reluctant to take drugs and to become "addicted". Physiotherapists often regard analgesics as an adaptive coping strategy and encourage their patients to take medication, supposedly making the patient more active, which in turn is assumed to have positive effects on the cardio-vascular system, stamina as well as health-related quality of life and is considered to counteract disability. However, while the AR group increased their perceived ability to decrease pain by use of coping strategies, the TAU group, in contrast, decreased their ability to control pain and their perceived ability to decrease pain.

Furthermore, the TAU group increased their reporting on the CSQ Catastrophizing, indicating a lack of confidence and control and an expectation of negative outcome (28). It is notable that the TAU group reported a small but statistically significant increase in depressive signs at follow-ups. The results of this study indicate that TAU increases catastrophizing, which is regarded as an inappropriate pain-coping strategy that intensifies the experience of pain and depression and decreases the patient's own capability to control pain (20). Further studies are needed in order to confirm and explore the mechanisms of the outcome patterns as revealed in the TAU group.

This pilot study shows that: (i) the study design and method, with some modifications, and the patient selection criteria were feasible for a larger randomized controlled study, and (ii) the intervention program, AR, had an impact on control over pain, although there was no difference in self-rated pain. Perceived control over pain appeared to be the most appropriate primary outcome variable for a future intervention study regarding long-lasting neck pain.

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