Naprapathic Manual Therapy or Evidence-based Care for Back and Neck Pain

A Randomized, Controlled Trial

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Objectives: To compare naprapathic manual therapy with evidence-based care for back or neck pain regarding pain, disability, and perceived recovery. Naprapathy that is common in the Nordic countries and in some states in the United States is characterized by manual manipulations with a focus on soft and connective tissues, aiming to decrease pain and disability in the musculoskeletal system.

Methods: Four hundred and nine patients with pain and disability in the back or neck lasting for at least 2 weeks, recruited at 2 large public companies in Sweden in 2005, were included in this randomized controlled trial. The 2 interventions were naprapathy, including spinal manipulation/mobilization, massage, and stretching (*Index Group*) and support and advice to stay active and how to cope with pain, according to the best scientific evidence available, provided by a physician (*Control Group*). Pain, disability, and perceived recovery were measured by questionnaires at baseline and after 3, 7, and 12 weeks.

Results: At 7-week and 12-week follow-ups, statistically significant differences between the groups were found in all outcomes favoring the Index Group. At 12-week follow-up, a higher proportion in the naprapathy group had improved regarding pain [risk difference (RD) = 27%, 95% confidence interval (CI): 17-37], disability (RD = 18%, 95% CI: 7-28), and perceived recovery (RD = 44%, 95% CI: 35-53). Separate analysis of neck pain and back pain patients showed similar results.

Discussion: This trial suggests that combined manual therapy, like naprapathy, might be an alternative to consider for back and neck pain patients.

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Pain and disability in the back and neck are very common, cause great suffering, and have vast economic societal consequences.[1–4] There is an increase in outpatient attendance for back and neck pain during the last decade, and these patients are very common in a general practitioner's everyday practice.[3,5] This indicates the need of studies performed in a way that the results may be implemented in real life conditions and in primary care practice. Consensus regarding the treatment for nonspecific back and neck pain consists of advice and support from the caregiver, aiming to empower the patient with the understanding that it is best for recovery to stay active and live as normal a life as possible, including work and physical activities.[4,6–9] Manual therapies are common and performed by different therapists, but studies evaluating their effect have contradictory results.[10]

The profession of naprapathy was initiated in 1907 in the United States by Dr Oakley Smith, and rejected the "subluxation-theory" used in manual therapies at that time. Naprapathy, which literally translates as "to correct cause," is a health profession characterized by viewing the musculoskeletal system as a whole where shortened soft and connective tissues around the spine and other joints are believed to cause pain and disability.[11–14] Naprapathy combines manual techniques like spinal manipulation/mobilization, massage, and stretching to treat the shortened tissues to decrease pain and disability. Naprapathy is practiced in Sweden (935 are licensed), United States (250 licensed), Finland (110 licensed), Norway, and some other countries. Education centers are located in Sweden, United States, and Finland.

No trial has evaluated naprapathy, the way it is carried out as a whole. Meta-analyses of some of the manual techniques practiced by naprapaths and other manual therapists showed that spinal manipulative therapy alone was not superior to other standard treatments for acute or chronic low-back pain or mechanical neck disorders.[15,16] Benefits were found from multimodal care including spinal manipulation/mobilization

for subacute/chronic mechanical neck disorders.[16] Massage was found to be beneficial for patients with subacute or chronic nonspecific low-back pain.[17]

The aim of this trial was to compare the effectiveness of naprapathic manual therapy (Index Group) and evidence-based care defined as support and advice on staying active and on pain coping strategies, according to guidelines and the best scientific evidence available, provided by a physician (Control Group), for patients with pain and disability in the back or neck lasting for at least 2 weeks, regarding pain, disability, and perceived recovery. The intention was not to evaluate the different components in the treatments separately, but to compare the treatments, standardized as far as possible, the way they usually are carried out in outpatient clinics.

MATERIALS AND METHODS

This pragmatic randomized controlled trial, called "the BJORN-trial," was approved by the Ethics Committee of the Karolinska Institutet (Diary number 03-657) and registered in a public registry (Current Controlled Trials).

Setting and Participants

Participants were recruited by advertising mainly among employees at 2 large public companies (about 40,000, mainly women in the healthcare sector, schools, and in the postal service) in Stockholm, Sweden from March to September 2005. Potential participants were asked to contact the study administration if they fulfilled the inclusion criterion, which was the presence of back and neck pain of the kind that brought about marked dysfunction at work or in leisure time, for at least 2 weeks.

The study administrator informed the participants and made the first step exclusions (symptoms too mild, pregnancy, specific diagnoses such as acute slipped disc or spinal stenos, inability to understand Swedish, visits to a naprapath in the preceding 2 mo or another manual therapist in the preceding month with the exception of massage). Participants fulfilling the criteria for participation were then asked to visit the study center.

At the study center, patients gave their informed consent and answered an extensive self-administered questionnaire. After that, an experienced physician (1 of 4) performed a medical examination (about 20 min) using a standardized form, made a diagnosis, and prescribed medication if necessary. Further exclusions were made on the basis of the following exclusion criteria: too mild symptoms (the physicians' *subjective* opinion based on the estimated pain and disability in the questionnaires filled in before the examination, and the results of the anamnesis and physical examination), evidence-based advice during the past month, surgery in the painful area, acute prolapsed disc, spondylolisthesis, stenosis, or "red flags" (older than 55 when the pain debut for the first time, recent trauma in the area, constant pain or pain getting worse in the night, cancer in the past or at present, consumption steroids now or recently, drug abuser, HIV, very bad general health, significant weight loss, very bad disability, intensified pain at the smallest movement, obvious structural deformity of the spine, saddle anesthesia/sphincter disturbance, extended muscle weakness, inflammatory or rheumatic diseases, marked morning stiffness, long-lasting severe disability, or peripheral joints affected).[4]

Randomization and Interventions

Included patients were assigned to 2 groups by randomization and no prestratification or blocking was used. An assistant not involved in the project prepared 500 opaque, sequentially numbered sealed envelops with cards numbered 1 or 2 (randomized by a computer), indicating the 2 interventions. Patients were sequentially numbered in the order they came to the study center and received the assignment envelope with the corresponding number. The unmasking was performed by the physician after the medical examination, so that the assistant, the physician, and the patient were all blind to the group assignment until after all patient baseline data were collected.

The treatments in both groups were conformed to the patients' condition, but standardized as far as possible concerning, for example, the length of treatment sessions and how to perform them in different situations, by several group meetings held in advance with the physicians and the naprapaths. The naprapaths were told only to use techniques they had learned at the education center in Sweden. The content in the evidence-based advice and support were carefully discussed in group with the physicians to make the care reliable.

Naprapathic Manual Therapy (Index Group)

For patients randomized to the Index Group, 1 of the 8 participating experienced licensed naprapaths was contacted for an appointment within a week. The choice of the naprapath was pragmatic, on the basis of time schedule and location. A maximum of 6 treatments were given within 6 weeks in the naprapath's own clinic and a combination of naprapathic manual techniques (such as spinal manipulation/mobilization, massage, and stretching) was given adapted to the patient's condition. Preventive and rehabilitating advices on physical activity and ergonomics were often given. Each appointment lasted for about 45 minutes, and precise notes were kept about the treatment, the progress, and any adverse reactions.

Evidence-based Care Provided by a Physician (Control Group)

Evidence-based care is, in this study, defined as support and advice on staying active and on pain coping strategies including locus of control, according to guidelines, and evidence-based reviews.[4,6–9] The evidence-based care was given in direct conjunction with the medical examination (an additional 15 min). The care involved advice and support according to the best scientific evidence available, aiming to empower the patient with an understanding of the importance of staying active and living as normal a life as possible, including work and

physical activities,[4,6–9] The care also aimed to improve the pain coping strategies. Advice on exercises was general and adapted to the patient's condition. A booklet with examples of exercises and general information on back and neck pain was provided. Precise notes were kept and a second consultation (about 15 min) was scheduled after 3 weeks. Additional consultation could be offered if necessary.

Outcomes and Follow-up

All outcomes in the trial were self-rated by web-based (61%) or postal questionnaires 5 times during the year following the inclusion. Starting from the day of inclusion, data from 3-week, 7-week and 12-week follow-ups are included in this report.

Primary Outcomes

The primary outcomes pain and disability were measured by a slightly modified Chronic Pain Questionnaire (CPQ) originally developed by von Korff, with 6 items with a numerical 11-point scale and 1 item on the number of disability days.[18–21] In the current trial, we changed the questions to concern the past 4 weeks instead of the past 6 months. Three items rated pain and concerned the current pain, the worst pain experienced during the preceding 4 weeks, and an average of the pain during the preceding 4 weeks. The ratings were labeled "no pain" (= 0) at the bottom and "maximum imaginable pain" (= 10) at the top. A pain score was constructed from the mean of these 3 items. Three items rated disability and concerned to what degree pain "interfered with your daily activities," "changed your ability to take part in recreational, social, and family activities," and "changed your ability to work (including housework)" in the past 4 weeks. The ratings were labeled "no interference" (= 0) at the bottom, and "unable to carry on with these activities" (= 10) at the top. The disability score was the mean of these 3 items. Disability was also measured in a more detailed way by a modified version of the Whiplash Disability Questionnaire (WDQ), developed by Hoving et al, with 13 items about how pain influences the life situation each with a numerical 11-point scale.[22–24] In the current context, we modified the items by replacing the word "whiplash" with "back or neck pain." This disability score was the mean of the 13 items.

On the basis of these scales, 4 dichotomized outcomes were defined grounded on what is believed to correspond to a clinical significant improvement[25–27]:

(1) *Improvement in pain:* at least a 2-step decrease (compared with baseline) in pain score (CPQ)
(2) *Improvement in disability (von Korff):* at least a 1-step decrease (compared with baseline) in disability score (CPQ)
(3) *Improvement in disability (Hoving):* at least a 1-step decrease (compared with baseline) in disability score (WDQ)
(4) *Totally recovered:* a pain score less or equal to 1 and a disability score equal to 0 (CPQ).

Secondary Outcomes

The secondary outcome was perceived recovery. Perceived recovery is a retrospective assessment considered to have great value in trials like this,[16,28] in this case measured by a single question "How have your symptoms changed since the trial started?" The ratings were on a numerical 11-point scale labeled "very much worse" (= −5), "no change" (= 0), and "very much better" (= 5). On the basis of this scale, a dichotomized outcome was defined as *very much improved* (having stated "I am very much better since the trial started"/not very much *improved*). Other cut-off points for perceived recovery was analyzed, but not reported because the results were similar.

Statistical Analysis

Power analyses based on the primary outcomes were performed in advance to determine the sample size. A total of 400 patients indicated a power of > 80% to detect a relative risk (RR) of 1.2 to 1.3 for a clinically important improvement in pain and disability.

The analyses were performed using an "intention to treat" principle aimed at analyzing patients in the group to which they were originally assigned and to keep the dropouts in the assigned group no matter what the reason.[29] Follow-up data were not available for all randomized patients. To estimate the impact of missing responses, additional sensitivity analysis for the primary outcomes was performed using multiple imputation.[30] Differences between the groups at baseline were tested using χ^2 tests. Changes in mean scores at follow-up compared with baseline, and differences in changes between groups were calculated by unpaired t test.

To compare the groups regarding the dichotomized outcomes, RR and risk differences together with corresponding 95% confidence intervals (CI) were calculated. Mantel-Haenszel's method was used to investigate and adjust for potential confounding.[31]

In the analyses of the dichotomized outcomes improvement in pain and improvement in disability, patients with scores at baseline less than required to attain these improvements were excluded. In analyses of neck and back pain patients, respectively, patients with concurrent pain in the neck and back (n = 25) were treated both as neck pain patients and back pain patients.

All analyses were performed using SAS statistical software version 9.1. All data registration was handled by an assistant who was not involved in the project, and the analyses were performed by a statistician who was not aware of the meaning of the allocation. The sources of funding had no influence on the design, the conduct, or the reporting of the trial.

RESULTS

Study Population and Study Sample

In response to advertising mainly at 2 big public companies, 522 participants contacted the trial

administration. Of these, 431 were eligible and 409 were randomly assigned after they had given their informed consent. The assigned patients had a mean age of 47 years, were mainly women (71%), and were mainly suffering from neck pain (58%). For many, duration of pain was more than a year (56%). The flow of participants through each stage of the trial and details about dropouts are shown in Figure 1.

Main Analysis

Baseline demographics and clinical characteristics of the groups are shown in Table 1. Figure 2 shows that the course of outcomes over time differed significantly between the groups. Baseline values, changes in the mean of the outcomes for patients taking part in the follow-ups at 3, 7, and 12 weeks, respectively compared with baseline for these persons and difference in mean changes between groups are shown in Table 2. There were statistically significant changes within both groups compared with baseline, and there were statistically significant differences in changes between the groups favoring the Index Group for all outcomes at 7 and 12 weeks.

The similarity between groups and stratified analyses indicated no confounding when the RR and risk

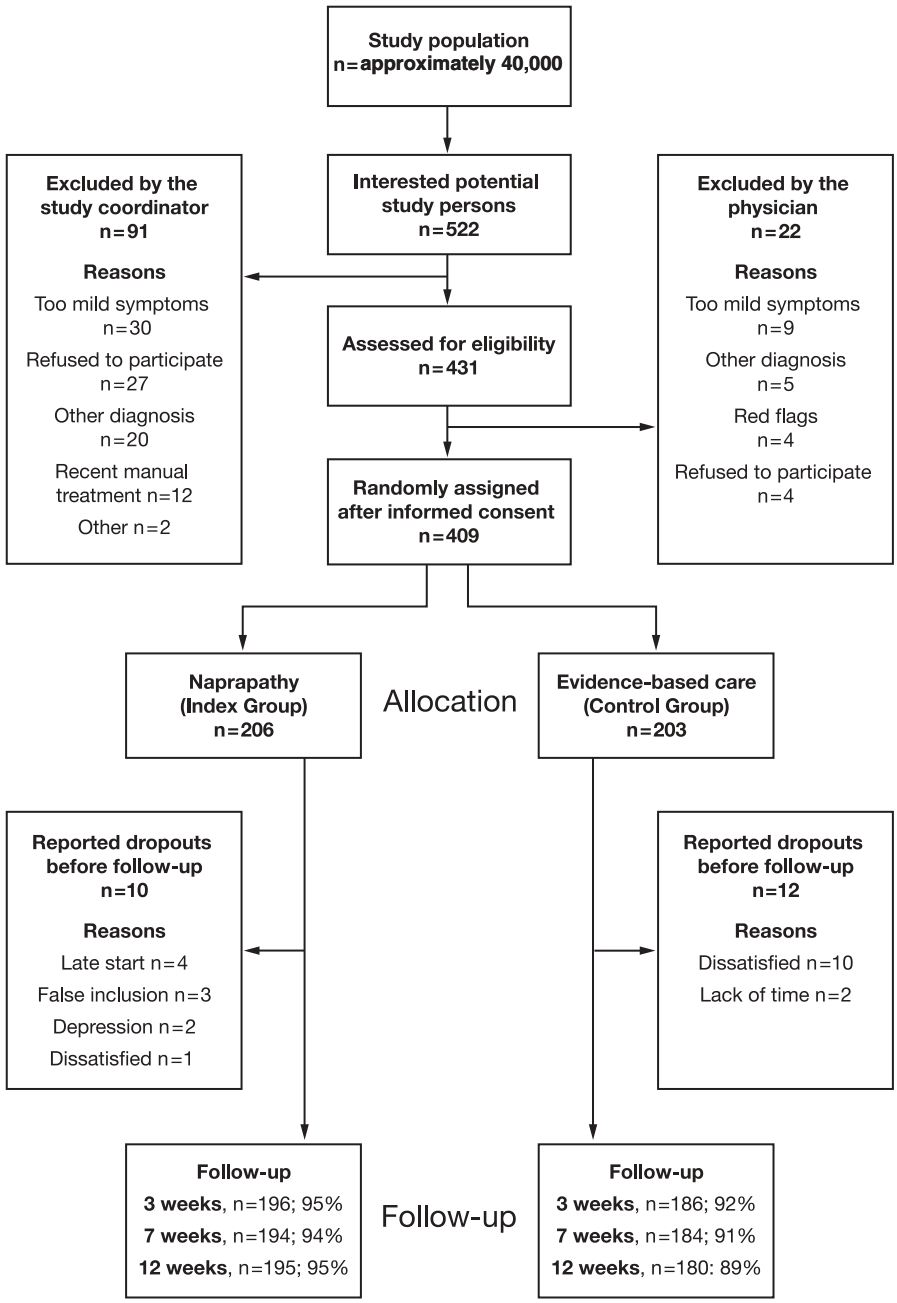

FIGURE 1. Flow chart describing the progress of patients through the trial.

TABLE 1. Prognostic Indicators

Prognostic Indicators	Index Group (n = 206)	Control Group (n = 203)
Mean age (SD), y	46 (11)	48 (10)
Women, %	74	68
Location of the worst pain, %		
Neck	56	61
Back	36	34
Neck and back	8	5
Duration of pain, %		
< 3 mo	22	29
3-12 mo	20	18
> 12 mo	58	54
Previous episodes of current pain in back or neck, %	88	85
Pain or trouble from 5 body regions or more, %	67	56*
Education, at least, %		
1-9 y	13	11
10-12 y	34	34
13-16 y	45	47
> 16 y	8	8
Depression, %	22	24
Poor general health,† %		
Physical function	84	78
Social function	65	67
Role emotion	45	43
Bodily pain	98	97
Sleeping problems, %	26	29
Daily smoking, %	15	13
Physical training medium high or high effort at least 20 min each time, %		
Never	38	28*
1-2 times/wk	21	33*
> 3 times/wk	41	39
Obesity, %	10	15
On sick leave now due to back/neck pain, %	3	5
Mean no. days absent from work the preceding 6 mo	3	4
Physical demands at work, %	39	35
Job strain,‡ %	22	15
Bullying from superiors or workmates, %	13	14
Life events ($\geq$ 2) the preceding 5 y, %	81	75

*Statistical significant difference between groups ($P \leq 0.05$).
†Swedish SF-36 health survey.
‡Swedish version of the demand-control-support model by Karasek-Theorell.

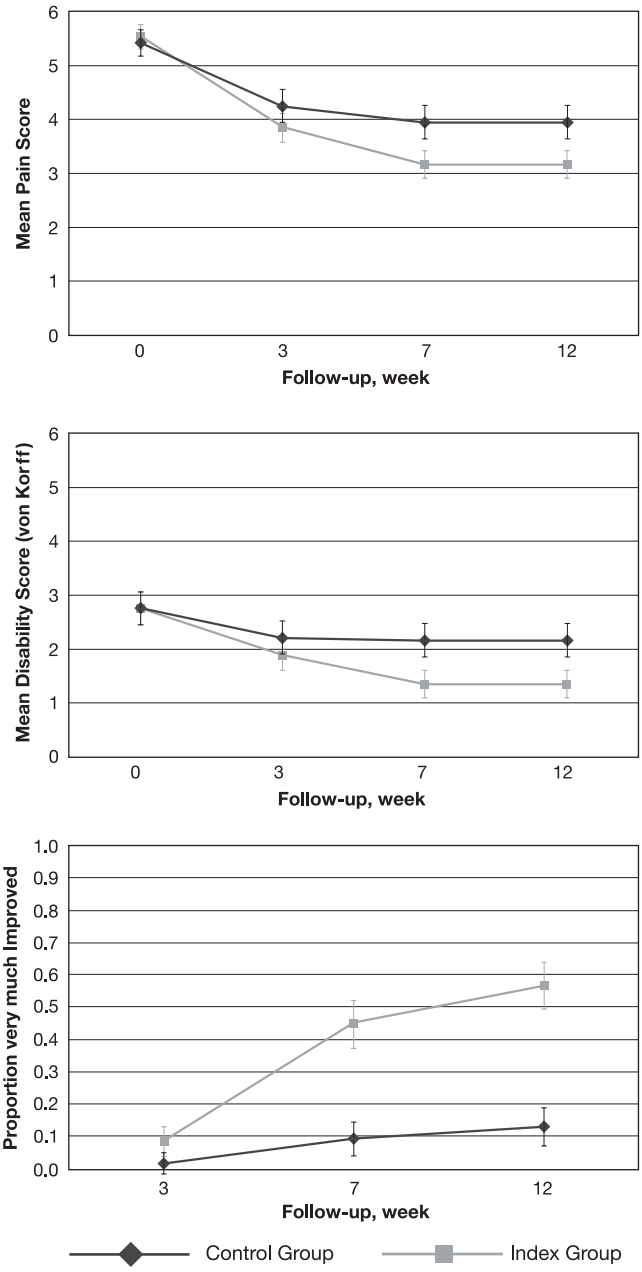

FIGURE 2. The mean scores of pain, the mean scores of disability, and the proportion of ''very much improved'', with corresponding 95% CI, for the intervention groups during the follow-up period.

difference for the dichotomized outcomes was calculated. After 12 weeks, a higher proportion in the Index Group stated that they were *very much improved* (RR = 4.5, 95% CI: 3.0-6.8) (Table 3); had *improvement in pain* (RR = 1.6, 95% CI: 1.4-2.0); had *improvement in disability* on CPQ (RR = 1.3, 95% CI: 1.1-1.6) and on WDQ (RR = 1.4, 95% CI: 1.2-1.7); and had *totally recovered* (RR = 2.7, 95% CI: 1.5-4.9) (Table 4). During the 12-week follow-up, 12 patients in the Index Group, and 6 in the Control Group had taken additional naprapathic treatments.

Sensitivity analyses were performed to evaluate the potential bias from missing values and they showed no systematic differences in results between analyses with and without imputed primary outcome values.

Naprapathic Manual Treatment and Adverse Reactions

Among the patients in the Index Group, 98% received massage, 83% stretching, 57% spinal mobilization, and 81% received spinal manipulation at the second consultation. Adverse reactions in the Index Group were recorded and none were serious, but minor short-term reactions such as muscle soreness, tiredness, and increased pain were reported, most commonly after the first and second treatments (Table 5).

TABLE 2. Baseline Values for the Index and Control Groups, Changes in the Mean of the Outcomes for Patients Taking Part in the Follow-up at 3, 7, and 12 wk, Respectively, Compared With Baseline for These Persons and Difference in Mean Changes Between Groups

	Baseline	3 wk		7 wk		12 wk	
	Baseline Value (95% CI)	Change* (95% CI)	Differences in Change (95% CI)	Change* (95% CI)	Differences in Change (95% CI)	Change* (95% CI)	Differences in Change (95% CI)
Pain							
Index Group	5.5 (5.3-5.8)	1.7 (1.4-1.9)	0.4 (0.0-0.8)	2.3 (2.1-2.6)	0.8 (0.4-1.2)	2.9 (2.6-3.2)	1.3 (0.9-1.7)
	n = 204	n = 193	—	n = 189	—	n = 192	—
Control Group	5.4 (5.2-5.7)	1.3 (1.0-1.5)	—	1.5 (1.2-1.8)	—	1.6 (1.3-1.9)	—
	n = 203	n = 185	—	n = 182	—	n = 179	—
Disability (CPQ)							
Index Group	2.7 (2.5-3.0)	0.9 (0.6-1.1)	0.3 (-0.1-0.8)	1.4 (1.1-1.7)	0.8 (0.3-1.2)	1.5 (1.2-1.8)	0.7 (0.2-1.2)
	n = 206	n = 192	—	n = 192	—	n = 194	—
Control Group	2.8 (2.3-3.1)	0.6 (0.2-0.9)	—	0.6 (0.3-0.9)	—	0.8 (0.5-1.2)	—
	n = 202	n = 183	—	n = 180	—	n = 180	—
Disability (WDQ)							
Index Group	3.0 (2.8-3.2)	—	—	1.3 (1.0-1.5)	0.6 (0.3-0.9)	1.5 (1.3-1.7)	0.7 (0.3-1.0)
	n = 206	—	—	n = 194	—	n = 195	—
Control Group	3.0 (2.8-3.3)	—	—	0.7 (0.4-0.8)	—	0.8 (0.5-1.0)	—
	n = 205	—	—	n = 183	—	n = 179	—

*The difference in the group mean of the outcomes at follow-up compared with baseline.

Additional Analysis

When neck and back pain patients were analyzed separately, results similar to the main analyses were observed. The differences in mean score change for neck pain patients and also back pain patients favored the Index Group in all outcomes after 12 weeks (Table 6). Naprapathic manual therapy implied a higher probability to report *very much improved* after 12 weeks for neck pain patients (RR = 4.3, 95% CI: 2.6-6.9) and also for back pain patients (RR = 5.9, 95% CI: 2.7-13.0) (not in table).

DISCUSSION

Patients were recruited from a mainly female working population in a professional area that typically exhibits pain and disability in back and neck. We found significant improvements in both intervention groups. The differences between groups were in favor of naprapathic manual therapy in all outcomes measured after 7-week and 12-week follow-ups. Some differences (in pain and perceived recovery) were distinct as early as the 3-week follow-up. Separate subgroup analysis of neck and back pain patients showed similar results, indicating that naprapathy is effective for both groups.

The study design was pragmatic, allowing for differences in numbers and in lengths of treatment sessions between the groups and to some extent to adapt the treatments within the groups, to the patients' conditions. The differences were allowed to evaluate the 2 treatments as they usually are performed in everyday practice. The content in the interventions was discussed in several meetings held in advance to standardize the treatments as far as possible without trespassing on the pragmatic design. Analyses of the treatments actually given in the Index Group showed that a majority of the patients had received a combination of massage, stretching, or spinal manipulation/mobilization.

The nonspecific effects of the hands-on approach and the potentially intensive patient-therapist interaction in the Index Group may have contributed to the observed differences between the groups. The fact that the differences still remained at 12-week follow-up, that is, several weeks after completed treatments suggests that the

TABLE 3. The Proportion of Very Much Improved in the Groups, the RR, and the Risk Difference (RD) Between the Groups for Being Very Much Improved, Together With 95% CI

Very Much Improved* at	Index Group (Imp/Not Imp)†	Control Group (Imp/Not Imp)†	RR, 95% CI	RD, 95% CI
3 wk	8% (16/179)	2% (3/183)	5.1 (1.5-17.2)	6% (2-11)
7 wk	45% (86/106)	9% (16/163)	5.0 (3.1-8.2)	36% (28-44)
12 wk	57% (107/82)	13% (22/153)	4.5 (3.0-6.8)	44% (35-53)

*Very much improved means having stated that "I am very much improved since the study started."
†Numbers of very much improved/not very much improved in the intervention groups.

TABLE 4. The Proportion of Favorable Dichotomized Outcomes in the Intervention Groups, the RR, and the Risk Difference (RD) for: Improvement in Pain and Disability, Respectively,* and Being Totally Recovered,† Respectively, With Corresponding 95% CI at 7-wk and 12-wk Follow-ups

Improvement in	Index Group (Imp/Not Imp)‡	Control Group (Imp/Not Imp)‡	RR, 95% CI	RD, 95% CI
7 wk				
Pain*	59% (n = 111/76)	43% (n = 79/103)	1.4 (1.1-1.7)	16% (6-26)
Disability* (CPQ)	70% (n = 113/48)	45% (n = 67/80)	1.5 (1.3-1.9)	25% (14-35)
Disability* (WDQ)	62% (n = 109/68)	40% (n = 66/98)	1.5 (1.2-1.9)	22% (11-32)
12 wk				
Pain*	69% (n = 131/59)	42% (n = 75/104)	1.6 (1.4-2.0)	27% (17-37)
Disability* (CPQ)	73% (n = 119/44)	55% (n = 81/66)	1.3 (1.1-1.6)	18% (7-28)
Disability* (WDQ)	66% (n = 117/61)	46% (n = 74/86)	1.4 (1.2-1.7)	19% (9-30)
Totally recovered†	Index Group (rec/not rec)§	Control Group (rec/not rec)§	RR 95% CI	RD 95% CI
7 wk	11% (n = 21/168)	7% (n = 12/169)	1.7 (0.8-3.3)	4% [(−1)-10]
12 wk	19% (n = 37/155)	7% (n = 13/167)	2.7 (1.5-4.9)	12% (5-19)

*A clinically important decrease corresponding to at least a 2-step decrease in pain score from baseline or at least a 1-step decrease in disability score from baseline, respectively.

‡Numbers of very much improved/not very much improved in the intervention groups.

†A pain score less or equal to 1 and a disability score equal to 0 of von Korff's CPQ questionnaire.

§Numbers of totally recovered/not totally recovered in the intervention groups.

superiority of naprapathy is explained primarily by other factors, such as that the combined manual techniques enabled patients to carry out physical activities to a greater extent.

No study is published that has evaluated the effect of naprapathic manual therapy, which precludes comparing the results to earlier findings. Nevertheless, there are trials evaluating combined manual therapies performed by other therapists, with conflicting results. Koes et al[32,33] compared the effectiveness of manual therapy, physiotherapy, and treatment by a general practitioner for nonspecific back and neck complaints. After 12 weeks, both physiotherapy and manual therapy decreased the severity of complaints more compared with continued treatment by the general practitioner.[32,33] Skargren et al[34,35] compared the effects and costs of chiropractic with physiotherapy among low-back and neck pain patients, and found no differences after 6 or 12 months. Hoving et al[36] compared manual therapy, physical therapy, and continued care by a general practitioner for neck pain patients and found manual therapy to be superior to continued care by the practitioner or physical therapy after 7 weeks. The differences between the groups decreased and lost statistical significance at 13-week and 52-week follow-up.[37] Dziedzic et al[38] found no statistically significant differences between the arms; advice and exercise plus manual therapy, advice and exercise plus electrotherapy or advice and exercise alone among patients with neck disorders, after 6 months.

Strengths of our trial include the great number of patients and the relatively few dropouts, which led to a high internal validity. The kind of back and neck pain

TABLE 5. Numbers of Adverse Reactions in the Index Group

	No. Reactions* After Treatment Number:					
Type of Reaction	1 (n = 196)	2 (n = 193)	3 (n = 192)	4 (n = 181)	5 (n = 141)	Total
Muscle soreness	39	16	6	1	1	63
Tiredness	21	12	2	1	1	37
Increased pain	8	11	5	3	0	27
Headache	6	4	4	2	3	19
Dizziness	3	1	1	0	0	5
Stiffness	0	0	2	1	1	4
Other	10	6	2	3	0	21
Total	87	50	22	11	6	176

*Most common after the first and second treatment, none serious.

TABLE 6. Baseline Values for the Index and Control Groups, Changes in the Mean of the Outcomes for Participants Taking Part in the Follow-up at 12 wk, Compared With Baseline for these Persons and Difference in Mean Changes Between Groups for Neck Pain and Back Pain Patients, Respectively

	Neck Pain			Back Pain		
	Baseline	12 wk		Baseline	12 wk	
	Baseline Value (95% CI)	Change* (95% CI)	Differences in Change (95% CI)	Baseline Value (95% CI)	Change* (95% CI)	Differences in Change (95% CI)
Pain						
Index Group	5.6 (5.4-5.9) n = 129	2.8 (2.4-3.2) n = 120	1.3 (0.8-1.8) —	5.5 (5.2-5.8) n = 92	2.9 (2.5-3.4) n = 89	1.2 (0.6-1.9) —
Control Group	5.5 (5.2-5.8) n = 134	1.5 (1.1-1.9) n = 115	— —	5.4 (5.5-5.7) n = 80	1.7 (1.2-2.2) n = 73	— —
Disability (CPQ)						
Index Group	2.8 (2.4-3.1) n = 131	1.5 (1.1-1.9) n = 121	0.6 (0.0-1.2) —	2.8 (2.4-3.3) n = 92	1.5 (1.0-2.0) n = 90	0.8 (0.1-1.6) —
Control Group	2.7 (2.3-3.1) n = 133	0.9 (0.4-1.3) n = 116	— —	3.0 (2.4-3.5) n = 80	0.6 (0.1-1.2) n = 73	— —
Disability (WDQ)						
Index Group	3.0 (2.7-3.3) n = 131	1.4 (1.0-1.7) n = 122	0.5 (0.1-0.9) —	3.2 (2.8-3.5) n = 92	1.5 (1.2-1.8) n = 90	0.9 (0.4-1.4) —
Control Group	3.0 (2.7-3.4) n = 134	0.9 (0.6-1.2) n = 116	— —	3.0 (2.6-3.4) n = 80	0.6 (0.3-1.0) n = 73	— —

*The difference in the group mean of the outcomes at follow-up compared with baseline.

studied is very frequent, enabling a generalization of the results to a large proportion of the population. One could claim that the differences between groups concerning frequency and length of treatment sessions are a limitation, but the intention was to compare these treatments as they work in everyday practice, even though recruiting by advertising may have included a group that normally does not seek care for their pain/disability.

The fact that all outcomes were self-reported could be considered a limitation, but research shows that a self-administrated examination may be used in studies of relationships between exposure and disorders in the musculoskeletal system.[39] The patient's opinion is considered to have a great value when "observer-based performance measure" does not exist.[16] The difference between groups was most pronounced for perceived recovery, a retrospective assessment of different aspects of health. It mirrors pain and disability as well as patient satisfaction and expectations of the assigned treatment and is an important compliment to pain and disability measurements whenever the results are to be applied in clinical practice.[28,40] The 5 grades of pain in CPQ proposed by von Korff were not created in this trial because of the modified time spans in the items.

We did not measure the patients' expectations of the interventions before the trial started, because a detailed explanation of the control intervention would have been like exposing all to this intervention. An initial question about why they considered participating showed that 60% of all assigned wanted to see a naprapath, which may indicate an expectation bias.

The present trial is a unique scientific evaluation of naprapathy, and more trials are needed to confirm the results. We plan to report on the long-term effects as observed in the present trial, when results from the 6-month and 12-month follow-ups have been analyzed. The naprapathic manual therapy is a combination of manual techniques for common but often nonspecific disorders in the musculoskeletal system. There is a great need for the development of more detailed diagnostic skills and for trials evaluating the effect of manual therapies on subgroups of these patients.

CONCLUSIONS

Compared with evidence-based care provided by a physician, naprapathic manual therapy implied a greater improvement in pain and disability and also a higher success rate of recovery. The trial adds to the knowledge that recommending a combination of manual therapies, as naprapathic manual therapy, may be an alternative to consider in primary healthcare for patients with back and neck pain.

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