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Naprapathic Manual Therapy or Conventional Orthopedic Care for Outpatients on Orthopedic Waiting Lists?

A Pragmatic Randomized Controlled Trial

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Objectives: Traditionally, orthopedic outpatient waiting lists are long, and many referrals are for conditions that do not respond to interventions available at an orthopedic outpatient department. The overall objective of this trial was to investigate whether it is possible to reduce orthopedic waiting lists through integrative medicine. Specific aims were to compare the effects of naprapathic manual therapy to conventional orthopedic care for outpatients with nonurgent musculoskeletal disorders unlikely to benefit from surgery regarding pain, physical function, and perceived recovery.

Methods: Seventy-eight patients referred to an orthopedic outpatient department in Sweden were included in this pragmatic randomized controlled trial. The 2 interventions compared were naprapathic manual therapy (index group) and conventional orthopedic care (control group). Pain, physical function, and perceived recovery were measured by questionnaires at baseline and after 12, 24, and 52 weeks. The number of patients being discharged from the waiting lists and the level of agreement concerning management decisions between the naprapath and the orthopedists were also estimated.

Results: After 52 weeks, statistically significant differences between the groups were found regarding impairment in pain, increased physical function, and regarding perceived recovery, favoring the index group. Sixty-two percent of the patients in the index group agreed to be discharged from the waiting list. The level of agreement concerning the management decisions was 80%.

Discussion: The trial suggests that naprapathic manual therapy may be an alternative to consider for orthopedic outpatients with disorders unlikely to benefit from surgery.

Key Words: orthopedic outpatient waiting lists, musculoskeletal manipulations, referral and consultation, integrative medicine

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Orthopedic outpatient waiting lists have traditionally been long and many referrals are for conditions that do not respond to surgical intervention or to the specific

competence and resources available at an orthopedic outpatient department.^{1–3} There seems to be a gap between the management skills of general practitioners and physiotherapists in primary care and those of orthopedic surgeons. When investigating the waiting lists of the orthopedic department in the county hospital in southern Sweden, where this study is conducted, the number of patients on the waiting lists who only received one single appointment with an orthopedist with “no intervention” was 46%. The same problem is observed in other studies in which the number of inappropriate referrals varies from 43% to 66%.^{1,3} There is a risk that less urgent conditions become chronic while waiting; meanwhile, patients with severe disorders have to wait unnecessarily a long time. The long waiting period for an orthopedic consultation, especially for surgery, is also an economic issue for the society.

Several general practitioners feel that they are not particularly knowledgeable about these conditions and therefore referrals not requiring an orthopedic surgeons’ management are often made.^{2,4,5} Studies show that clear guidelines for defining appropriate referrals are often missing and that of more importance for a referral or not is who makes the referral and who the patient is rather than the symptoms themselves.^{6–10} The main option for the general practitioners regarding the majority of patients with musculoskeletal problems coming to an orthopedic clinic is referring them to a physiotherapist. The majority of physiotherapists are educated in rehabilitation through physical exercises, but they are not qualified in manual treatment.^{3,11} It seems that some disorders wander around in the healthcare system; disorders that are too specialized for the general practitioners, not cured by exercises with a physiotherapist, yet not surgical cases.

Conclusions have been made in conventional medicine that it is possible to take care of orthopedic outpatients at another care level.^{1,3,11–13} Results from studies in integrative medicine, a complement to the traditionally most common way to take care of musculoskeletal problems (with general practitioners, physiotherapists, and orthopedic surgeons), have also shown that it is possible to have better treatment effects and decreased waiting periods as well as patient satisfaction.^{14–19} A British project introduced acupuncture, homeopathy, and osteopathy within a hospital and established referral indicators. Statistical differences in scores were found between a treatment and a control group on all short form (SF)-36 scales except for physical function regarding health status favoring integrative medicine.^{15,16} In addition in the UK, a musculoskeletal clinic with osteopathy and acupuncture was set up in a general practice. Thirty-nine percent of the patients had an

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appointment within 2 weeks. After 1 year, the number of specialty referrals for rheumatology and physiotherapy departments as well as the number of referrals to orthopedic specialists were lower than the national figures would have predicted.¹⁸ When using a team approach with reconfiguration of the roles of the orthopedic surgeon and rheumatologist and extending the roles of nurses, physiotherapists, and podiatrists, the waiting time decreased by about 50%.¹⁹ A Swedish inventory study for the use of complementary and alternative medicine among patients seeking hospital care showed that the most frequent complaint was musculoskeletal disorders (63%). Ninety-five percent of the patients stated that they were helped with alternative or complementary medicine.¹⁴

When comparing the effectiveness of different manual therapies combining more than one manual therapy technique with specific exercise training has been shown to be effective.¹⁷ The naprapathic profession is comparable with that of chiropractors and they are equally old (about 100 y). Naprapathy emerged as a reaction to the chiropractic theory that vertebrae could be subluxated as the basis of disease. Instead, the soft and connective tissues were believed to be the cause. Naprapathic manual therapy is a combination of different manual techniques like massage, stretching, treatment of myofascial trigger points, mobilization, and manipulation combined with physical exercises. A naprapathic treatment lasts for 30 to 45 minutes and naprapaths work under their own diagnostic and clinic responsibility. The naprapathic profession since 1994 is a part of the Swedish health and medical care system, licensed by the National Board of Health and Welfare, for treating patients with musculoskeletal pain and pain-related disability. Naprapaths constitute the largest profession within the field of specialized manual medicine in Sweden. They are also common in Norway and Finland and in some states in the United States. As naprapaths are not employed in hospitals, they are not available to a large group of patients. When the effects of naprapathic manual therapy were compared with evidence-based care provided by a physician for unspecific back and neck pain in an earlier published trial, significant more improvement regarding pain, disability, and perceived recovery was found.²⁰

To our knowledge, no published randomized trial has evaluated the effects of manual treatment on patients on orthopedic outpatient waiting lists. The overall aim of this trial was to investigate whether it is possible to reduce orthopedic waiting lists through integrative medicine. Specific aims were to compare the effects of naprapathic manual therapy with conventional orthopedic care for outpatients with different kinds of nonurgent musculoskeletal disorders unlikely to benefit from surgery regarding pain, physical function, and perceived recovery. The number of patients who were discharged from the waiting lists after the naprapathic treatment in the index group, and the levels of agreement between the naprapaths and the orthopedists' management decisions were also measured.

MATERIALS AND METHODS

This pragmatic randomized controlled trial, called the Dance Study, was approved by the Ethics Committee of the Lund University (Diary No. H4 514/2006).

Setting and Participants

The source population consisted of patients on the waiting lists at the Department of Orthopedic Surgery at Blekingesjukhuset, the province hospital in Karlskrona, in the south of Sweden, between June 2006 and June 2007. The patients were referrals from all general practitioners in the province, 2 private orthopedic surgeons, different departments in the hospital, company health services, and "own referrals." Inclusion of patients in the study was based on discussions between the naprapath, the orthopedic surgeons, and orthopedic nurses concerning "nonurgent referrals" (ie, no disc protrusions, suspected tumors or conditions requiring surgery within 6 wk). Decisions about eligibility were made through a dialog (based on the referral letters) and appropriate information available in the hospital's information system (eg, results from an x-ray, sick leave, previous surgery, etc). Inclusion criteria for the study were patients between the age of 18 and 65 years, without an explicit need for an x-ray (according to orthopedic opinion when selecting the referrals), or suggestion for diagnosis (from the general practitioner, in the referral letter). Exclusion criteria were referrals regarding "trigger fingers," numbness in the hand with only 2 or 3 fingers involved, meniscal tears, obvious or suspected acute prolapsed disc or disc injury, tumors, specific rheumatic diseases, and patients with contraindications for spinal manipulation. The contraindications are: prolapsed disc, neurologic signs (radiating pain/paresthesia, weakened reflexes, muscle weakness, and sphincter disturbance), fracture, malign tumors, infection in the spinal column, disc or skeleton, pronounced osteoporosis, rheumatic pathologic process in the cervical spine, pathology in the arteria vertebralis or arteria carotis, and L'hermitte-paresthesia. If there was an explicit wish for orthopedic judgment expressed in the referral letter, it was also excluded. Further, patients with inability to understand Swedish, patients on 100% sick leave due to the reason of the referral, pregnancy, positive radiography connected to the patients' symptoms (as this may indicate a need for surgery), recent surgery in the painful area, spinal stenosis, or spondylosis were excluded.

Randomization and Interventions

Two nurses chosen by the manager of the department subsequently randomized the 98 patients included in the study into 2 groups. They also scheduled the study participants and administered the required information, but they were not involved in determining the study participants' eligibility. The random allocation was made in blocks to keep the sizes of the 2 treatment groups similar, and also the workload level for the naprapath. The randomization was performed at 6 different occasions, as soon as there were at least 10 (or a higher number divisible by 2) eligible patients.

Together with information about the study, a time reservation for an appointment with the orthopedist or the naprapath and baseline questionnaire and a formulary for informed consent to be returned were sent to the potential study participants. Persons who had been randomized to the control group were requested not to tell the doctor that they participated in the trial. Patients randomized to the index group were informed that they still had the right to see an orthopedic surgeon in case the naprapathic treatment had not been successful. Except for this, the information was exactly the same for both groups. There was no

information to the study participants about the number of treatments offered in either group. The treatments in both groups were conformed to the patients' conditions and performed at the orthopedic outpatient clinic in the hospital, and the patients were charged a standard rate for each visit, equal in both groups. The treatments lasted from January 2007 to November 2007.

Naprapathic Manual Treatment (Index Group)

A maximum of 5 treatments within 5 weeks were given by one well-experienced naprapath. Time setting for the first appointment was 45 and 30 minutes for the following appointments. A naprapathic treatment consisted of: massage, treatment of myofascial trigger points (through pressure), therapeutic stretching, manipulation/mobilization of the spine or other joints, and—if required—electrotherapy (TNS or therapeutic ultrasonic waves), combined with home exercises.

Licensed naprapaths normally work with their own clinic responsibility. Consequently, diagnostic and management decisions as well as treatments were performed only by the naprapath, without any second opinion from an orthopedist.

Orthopedic Consulting (Control Group)

Thirteen well-experienced orthopedic surgeons were in charge of the control group, according to their specialty and allocation schedule. The consultation/treatment was conventional orthopedic judgment ("care as usual") as, for example, advice, medicine prescriptions, steroid injections, referrals for radiography, referrals for physiotherapy, or different investigations or surgery, with as many appointments/measures/steps as needed. The consultations were conducted in the way they are normally conducted at the department.

Outcomes and Follow-ups

Follow-up was performed after 12, 24, and 52 weeks after the inclusion by mailed questionnaires.²¹ All documentation in both groups, visits, examinations, treatments, surgery, other referrals, and telephone calls, was carried out in the hospital's information system, and international diagnostic codes (ICD10) were used.

Primary Outcomes

The primary outcomes of pain and physical function were measured by the SF-36 survey²² and pain intensity when at its worst the last 2 weeks was measured by the Visual Analog Scale (VAS)²³ with the anchors "no pain at all," respectively, or "worst imaginable pain."

Secondary Outcomes

Secondary outcomes were perceived recovery, the number of patients being discharged from the waiting list, and the level of agreement concerning management decisions between the naprapath and the orthopedists.

Perceived recovery is a retrospective assessment considered to have great value in trials like this.²⁴ Retrospective measures are more sensitive to change than measures at different points in time. A retrospective assessment is also more strongly correlated with patients' satisfaction with change and might increase the comprehensiveness of information and its accord with clinical practice. Perceived recovery was measured by a question in the questionnaire where the patients were asked to judge how their symptoms

had changed as the trial started by choosing from "much worse," "a little worse," "no change," "a little better," and "much better." On the basis of this scale, a dichotomized outcome was defined as a little better or much better versus no change, a little worse, or much worse.²⁰

The number of patients in the index group being discharged from the waiting list (after the naprapathic manual therapy was finished) was recorded as a measure of the effectiveness of the treatment.

Patients in the index group who were not discharged from the waiting list had their appointment with an orthopedic surgeon after the first follow-up in the trial, not to confound the results of the trial. The judgment for consultation was no significant change of pain measured by the VAS, the naprapath's opinion of the need for surgical intervention, injection, or an orthopedic opinion and the patient's own wish. When patients had a significant decrease in pain and the naprapath could not find any reason for orthopedic consultation, but the patient still wanted a consultation, this desire was always satisfied. To assess the level of agreement between the orthopedists and the naprapath, the management decisions were compared for these patients.

Statistical Analysis

Power analyses based on the primary outcomes were performed in advance to determine the sample size. The analyses were based on results from a trial of naprapathic manual therapy.²⁰ A total of 80 patients indicated a power of 80% to detect a relative risk (RR) of 1.2 to 1.3²⁵ for a clinically important improvement in pain and physical function.²⁶ A 20% to 30% improvement was the threshold for a clinically important improvement in pain (VAS).²⁶ All 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.²⁷ Changes in mean scores of pain at follow-up compared with baseline were tested using the Wilcoxon signed rank test, and the differences in changes between the groups were calculated by the Mann-Whitney *U* test. Statistic significance was equal to $P < 0.05$. Differences between the groups at baseline were tested using χ^2 tests. One-way analysis of covariance was used to test the statistical significance of differences between groups, adjusted for baseline differences in age, pain (VAS), and body localization. To compare the groups regarding the dichotomized outcomes, RR and risk differences together with corresponding 95% confidence intervals (CI) were calculated.

In summary, presentation and statistical analysis of the outcomes were managed by the University of Gothenburg and the Research and Development Department at the hospital in Blekinge. All data registration was handled by an assistant and a statistician who were not involved in the project.

RESULTS

From a source population of 1973 patients, 199 were selected, 98 were randomly assigned, and finally baseline data from a total of 78 patients was collected. The assigned patients had a mean age of 42 years and 51% were women. The most common site of pain was leg/foot and shoulder/arm. Duration of pain was more than a year for 75% of patients. Eleven (14%) patients (4 in the index group and

7 in the control group) had not had any earlier intervention. The flow of participants through the trial and details about dropouts are shown in Figure 1.

Baseline demographics, clinical characteristics, and earlier interventions in the groups are shown in Table 1. Diagnostic codes are shown in Table 2.

Primary Outcomes

Figure 2 shows group mean values of pain (VAS) and sum scores of physical function and bodily pain (SF-36) with 95% CI over time. There are differences between the groups at the follow-ups favoring the index group, but none were statistically significant, as illustrated by the overlap of the 95% CI. Figure 2 indicates that the index group had more severe symptoms at baseline.

Table 3 shows the baseline mean values for physical function (SF-36), bodily pain (SF-36), the worst pain for the groups (VAS), and the changes in the mean values at 12, 24, and 52-week follow-ups, respectively, compared with baseline. There were statistically significant changes within the index group compared with baseline at all follow-ups, but only for bodily pain at all follow-ups in the control group. There were statistically significant differences in changes between the groups at all 3 follow-ups favoring the index group. Additional analyses with analysis of covariance showed no confounding results from the items that differed between the groups at baseline [pain (VAS), age, and body localization].

Secondary Outcomes

The proportion of patients who were little or much recovered regarding the question of “perceived recovery” was clearly higher in the index group (75% at 24 wk and 64% at the 52-wk follow-up) than in the control group (37% at 24 wk and 28% at the 52-wk follow-up). The differences between the groups were statistically significant both in absolute difference (risk difference = 38%; 95% CI: 18-59 at 24 wk and 36%, 95% CI: 15-58 at the 52-wk follow-up) and in terms of RR (RR = 2.0, 95% CI: 1.3-3.2 at 24 wk, respectively, RR = 2.3, 95% CI: 1.3-4.1 at 52-wk follow-up).

Twenty-five out of 40 patients (63%) in the index group agreed to be discharged from the waiting lists. Taking into account the number of crossover patients where the naprapath and the orthopedists agreed on no intervention, the number of patients discharged from the waiting lists would have been altogether 32 (80%).

Crossover Patients and Level of Agreement

A total of 15 patients (38%) in the index group also got orthopedic consultations. The naprapath considered 4 of these candidates for surgery and 2 for opinion/intervention. The remaining 9 patients were not considered either as candidates for surgery or in need of any orthopedic intervention by the naprapath, but they wanted to see an orthopedist anyway.

The orthopedists agreed with the naprapath in all surgical cases and there was one additional case that was

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

TABLE 1. Previous Interventions and Prognostic Indicators

	Index Group (n = 40)	Control Group (n = 38)
Mean age, y	38	45*
Women %	42	60
Location of the worst pain, %		
Foot/leg	32	23*
Shoulder/arm	20	19
Knee	13	18*
Back	14	17
Elbow/hand	13	11
Head/neck	3	7*
Pelvis/hip	5	5
Duration of pain, %		
< 3 mo	5	5
3-12 mo	30	29
> 12 mo	65	66
Earlier interventions, %		
Doctor†	40	38
Physiotherapist	40	34
X-rays	50	55
Injection	20	18
Medicine‡	52	45
Other§	25	18
Average pain		
VAS; 1-100: 100 = worst	77	62*
SF-36		
Bodily pain (P-value: 0.205)	37.3	43.8
Physical function (P-value: 0.230)	70.4	73.3

*Statistically significant differences between the groups ($P < 0.05$).

†Apart from the referral consultation: GP, orthopedist or emergency visit.

‡Medicine requiring prescription only.

§Chiropractor, osteopath, acupuncture, CRP/Borreliosis/SR, orthosis, surgery.

||Higher value indicates less pain/better physical function.

not diagnosed until an electromyography (EMG) was performed. The orthopedists also agreed concerning the 2 patients referred from the naprapath for opinion/intervention, who had an x-ray plus orthosis, respectively, a steroid injection. One additional crossover patient from the

TABLE 2. Diagnostic Codes (ICD 10) Documented by Naprapath, Respectively, Orthopedist at First Visit

Location	Index	Control
Neck		
M530, M531, M542	1	2
Shoulder/arm		
M190, M191B, M244C, M294B, M653, M750, M751, M754, M770/771, M796B, S435, G560, G562C	13	11
Back		
M544, M545, M549, M626, Z039	5	7
Pelvis/hip		
M244	2	—
Knee		
M171, M222, M255, M626, M705, S837, Z039	5	7
Leg/foot		
M626, M628, M768/769, M201, M214 M242H, G576 M722, M766, M773, M775, M796H	14	11
Summary	40	38

index group had a steroid injection in the shoulder without the naprapaths' referral. Of the remaining 7 crossover patients, 4 had a decrease of pain (VAS) with 40% or more after the naprapathic treatment and were not referred by the naprapath but still wanted to have an orthopedic consultation. The results from these consultations were different radiographies. None of them had any management decision. The remaining 3 had one visit but no intervention made at all. The level of agreement between the naprapath and the different orthopedists concerning the crossover patients was 80%.

As only 8 of the 15 crossover patients had any orthopedic management, another 20% from the index group could have been discharged from the waiting list.

Naprathic Manual Treatment (Index Group)

Four of the patients were considered candidates for surgery by the naprapath and 2 were referred to an orthopedist for advice.

Two patients in the index group were false included: one because of recent surgery in the affected area and one because of a positive x-ray connected to the patient's pain.

Adverse reactions were reported in 12 cases (30%) after the first treatment session: pain (n = 9), tiredness (n = 4), stiffness (n = 2), and headache (n = 1).

Orthopedic Consultation (Control Group)

Two patients in the control group were false included as they were on sick leave.

The orthopedic interventions at the first, second, and third visits are listed in Table 4, according to how many visits and interventions with an orthopedist each of the patients received. Seven of the patients were candidates for surgery. Adverse reactions were not measured in the control group.

Interventions and Cointerventions

Interventions (Treatments/Consultations, Physiotherapy, Surgery, and Different Investigations Included in the Study)

In the index group, each patient had an average of 4.1 naprapathic treatments (164), 1 patient had 2 sessions with a physiotherapist (2), and 15 patients had an orthopedic consultation (15). Eight of these patients only had radiography and/or no intervention at all, some had several interventions performed. Two of these patients were referred for: physiotherapy (28), radiography (6), orthotics (2), EMG (1), surgery (1)* = a total of 219 interventions.

In the control group, each patient had an average of 1.4 consultations with an orthopedist (53) and 13 patients were referred for: physiotherapy (242), surgery (7), radiography (15), orthotics (6), blockades (2), EMG (1), electrofores (1) = a total of 327 interventions.

The number of injections is not reported in either group, as the injections were part of some of the orthopedic consultations.

Cointerventions (Treatments Chosen by the Patients Themselves)

In the index group, 5 of the patients had cointerventions after having finished the naprapathic treatments: 1 had massage (46), 2 visited the emergency department (2), 1 had physiotherapy (1), and 1 had naprapathic treatment (1). Both patients who visited the emergency department wished to have different radiographs quickly. None of them

PF		Mean	Lower Bound		Upper Bound	
Control	Baseline	73.3333	65.88	7.45	80.79	7.45
	3 months	77.1637	70.13	7.03	84.20	7.03
	6 months	76.2281	67.76	8.47	84.70	8.47
	12 months	76.997	69.33	7.67	84.66	7.67
Index	Baseline	70.4306	64.53	5.90	76.33	5.90
	3 months	83.25	78.32	4.93	88.18	4.93
	6 months	84.875	79.75	5.13	90.00	5.13
	12 months	83.2456	76.78	6.46	89.71	6.46

BP		Mean	Lower Bound		Upper Bound	
Control	Baseline	43.8158	35.62	8.19	52.01	8.19
	3 months	52.8421	43.79	9.06	61.90	9.06
	6 months	54.7105	45.55	9.16	63.87	9.16
	12 months	54.7838	45.67	9.11	63.89	9.11
Index	Baseline	37.25	31.70	5.55	42.80	5.55
	3 months	56.425	47.75	8.67	65.10	8.67
	6 months	62.1	53.98	8.12	70.22	8.12
	12 months	65	56.04	8.96	73.96	8.96

VAS		Mean	Lower Bound		Upper Bound	
Control	Baseline	62.18	54.24	7.94	70.13	7.95
	3 months	45.84	34.45	11.39	57.24	11.40
	6 months	48	37.61	10.39	58.39	10.39
	12 months	54.0833	43.49	10.59	64.68	10.59
Index	Baseline	76.92	71.84	5.08	82.01	5.09
	3 months	42.68	32.93	9.75	52.42	9.74
	6 months	39.22	29.13	10.09	49.32	10.10
	12 months	50.3421	39.54	10.81	61.15	10.81

FIGURE 2. A, SF-36, PF. B, SF-36, bodily pain (BP; higher value indicates less pain). C, The worst pain measured with VAS. A to C, The mean scores of PF and pain measured with SF-36 (higher estimation indicates less pain), respectively, and pain measured with a VAS (lower estimation indicates less pain) over 1 year. Control indicates control group; patient, index group; PF, physical function; VAS, Visual Analog Scale.

had any management decision. Altogether, there were a total of 50 cointerventions.

In the control group, 6 patients had cointerventions after their orthopedic consultation. Four patients were treated by a chiropractor (29) and 2 patients had additional

orthopedic consultations (2). Altogether, there were a total of 31 cointerventions.

At 52 weeks, the total number of interventions (naprapathic treatments, respectively, orthopedic consultations, additional treatments (physiotherapy), and all the

TABLE 3. Baseline Values for the Index and Control Groups, Changes in the Mean of the Outcomes for Patients Taking Part in the Follow-ups at 12, 24 and 52 wk, Respectively (Compared With Baseline for These Persons), and the Difference in Changes Between the Groups

	Baseline		12 wk		24 wk		52 wk	
	Baseline Value (95% CI)	Change (95% CI)	Difference in Change (95% CI)	Change (95% CI)	Difference in Change (95% CI)	Change (95% CI)	Difference in Change (95% CI)	
Worst pain (VAS)			<i>P</i> *: 0.015		<i>P</i> *: 0.001		<i>P</i> *: 0.005	
Index group	76.9 (71.8-82.0) n = 40	34.3 (24.1-44.4) n = 40	17.9 (3.6-32.2)	37.7 (27.0-48.4) n = 40	23.5 (9.5-37.5)	28.0 (17.7-38.3) n = 38	20.5 (6.2-34.6)	
Control group	62.2 (54.2-70.1) n = 38	16.3 (5.9-26.8) n = 38	—	14.2 (4.9-23.4) n = 38	—	7.5 (−2.6-17.7) n = 37		
Bodily pain (SF-36)			<i>P</i> *: 0.043		<i>P</i> *: 0.015		<i>P</i> *: 0.003	
Index group	37.3 (31.7-42.7)	19.2 (1.2-26.4)	10.1 (0.9-19.4)	24.9 (17.4-32.3)	14.0 (4.0-23.9)	28.2 (20.8-35.7)	17.6 (7.3-27.9)	
Control group	43.8 (35.6-52.0)	9.0 (3.0-15.1)		10.9 (4.1-17.7)		10.6 (3.3-18.0)		
Physical function (SF-36)			<i>P</i> *: 0.003		<i>P</i> *: 0.005		<i>P</i> *: 0.002	
Index group	70.4 (64.5-76.3)	12.8 (6.8-18.8)	9.0 (1.6-16.3)	14.4 (8.5-20.4)	11.6 (3.5-19.6)	13.1 (5.9-20.2)	10.2 (1.9-18.4)	
Control group	73.3 (65.9-80.8)	3.8 (−0.5-8.1)		2.9 (−2.7-8.4)		2.9 (−1.5-7.3)		

Worst pain measured by VAS (Worst imaginable pain = 100), bodily pain and physical function measured with SF-36, with 95% Confidence Intervals (95% CI).

**P*-value corresponds to the difference in changes between the groups.

different investigations and analyses included in the study, plus the cointerventions massage, chiropractic treatment, physiotherapy, naprapathic treatment, etc chosen by the patients themselves) was altogether 269 (2 patients still having treatments) in the index group, respectively, 358 (13 patients still having treatments) in the control group.

DISCUSSION

This trial suggests that integrated medicine in the shape of naprapathic manual treatment at an orthopedic

outpatient department may be effective for patients with nonurgent musculoskeletal disorders not likely to benefit from surgery. At the 52-week follow-up, statistically significant differences between the groups were found regarding decrease of pain and improved physical function compared with baseline, and regarding perceived recovery, favoring the index group. Sixty-two percent of the patients in the index group agreed to be discharged from the waiting lists. A total of 80% from the index group could have been discharged from the waiting list according to the orthopedists' opinions about the crossover patients.

TABLE 4. Orthopedic Interventions

Total 38 Patients	1 Visit (26 Patients)	2 Visits (10 Patients)	3 Visits (2 Patients)
10 patients	Advice (10)		
	Medicine (4)		
16 patients	Plain X-ray (7), MRT (1)*		
	Physiotherapy (8)		
	Orthotics (1)		
	Injection (5)		
	Medicine (3)		
	Surgery (2)		
10 patients		Plain X-ray (1), MRT† (4)	
		Physiotherapy (3)	
		Orthotics (2)	
		Other investigations (2)	
		Injection (1)	
		Medicine (2)	
		Surgery (3)	
2 patients			Physiotherapy (2)
			Injection (2)
			Medicine (1)
			Surgery (2)

Horizontally according to the number of visits and vertically to the total number of interventions made in the three respective groups.

*Neck.

†Knee (2), shoulder (1), lower back (1).

The findings in this trial correspond to a randomized controlled trial by Skillgate et al,²⁰ comparing naprapathic manual therapy with evidence-based care provided by a physician, for patients with unspecific neck and back pain. In that trial, naprapathic manual therapy was considered an effective treatment.

In an earlier study by Oldmeadow et al,³ 62% of referred patients with nonurgent musculoskeletal conditions could have been managed by a physiotherapist without a need to see a surgeon. The agreement between the orthopedists and the physiotherapists were 74% of the patients having both treatments. These results also correspond to the results of our trial.

Strengths of our trial were the setting of integrative medical approaches at the boundary of traditional health care in the everyday practice, which included the pragmatic approach, reflecting the “real world” of an outpatient orthopedic department.²⁸ The differences between the groups regarding changes of pain at 52 weeks compared with baseline were clinically important.²⁶ The majority of the patients had long-lasting pain and was carefully examined before being referred to the Orthopedic Department. This indicates that the included patients were suffering from conditions of considerable concern for the patients and for the society. The included patients were chosen in a dialog between caregivers working in the same premises, with similar administration, and patients’ fee. In addition, the sample was proportional to the whole waiting list, concerning the location of the disorders, sex, and waiting time. Further, a power calculation was performed in advance, the compliance was acceptable in both groups, there were very few dropouts and the long-term effects of the interventions were also recorded. Altogether, we think the trial has a good internal and external validity.

There are some weaknesses in the trial. The sample may be considered as limited regarding the number of referrals included. This was the result of the inclusion and exclusion criteria. Most of the excluded patients were above 65 years of age. Concerning the patients on sick-leave, it was not possible to read the length of the sick leave in the referral letter. That is the reason why we did not include any patients on sick leave, even though referrals on short-term sick leave might have been suitable for inclusion.

The randomization was carried out before the study participants gave their informed consent and the baseline questionnaire was filled in. The reason for this was that the majority of the patients had been on the waiting lists for about 36 weeks and assumedly did not want to have an appointment only for information about the trial and to give the informed consent before being scheduled for a consultation. Theoretically, there is a risk that the participants rated their pain and physical function differently in the way we administered the study, than if the baseline questionnaires would have been administrated before randomization. We considered that very small, as that would not have implied any advantage for the patient.

Owing to practical reasons, there was only one naprapath managing all the patients in the index group, as in other studies.^{1,11} This might be considered a weakness, but the content in the interventions and their distribution are very similar to interventions given in the trial by Skillgate et al,²⁰ where 8 different naprapaths participated.

Almost 40% of the patients in the index group also wanted to have an orthopedic consultation. This may seem a considerable amount, but given one of the stipulations in

the study (all the patients in the index group had the right to see an orthopedic surgeon no matter the outcome of the naprapathic manual treatment), that number does not really mirror the need. For validity reasons, we waited until after the first follow-up (at 12 wk) before the patients were scheduled for an orthopedic consultation, which makes the first follow-up “clean” (only orthopedic, respectively, naprapathic interventions in the respective groups).

There were few orthopedic interventions as a result of the orthopedic consultations; 8 of the crossovers (53%) only had radiography or no intervention at all. The level of agreement between the naprapath and the different orthopedists about all of the crossover patients were 80%. In addition, there was only one of the 5 patients considered as candidates for surgery that—for different reasons—finally had an operation. We also analyzed the outcomes of the crossover patients separately and compared the result with the result of the rest of the index group. This was carried out at the 24-week follow-up and did not indicate any differences in results. Not to jeopardize the objectives of this trial, no crossover was carried out in the opposite direction; patients in the control group who were not helped by the orthopedists were not offered a naprapathic treatment. It would have been interesting, although, and in everyday practice probably the most efficient way to achieve best treatment results.

Many of the patients on orthopedic outpatient waiting lists have health conditions that are not of pathologic but of dysfunctional character. Working with integrative medicine where the conventional and the complementary treatments are given in the same premises is probably of benefit for the patients as they can have both treatments in a safe setting where, and if needed, further investigations can be offered. The integrative setting also offers possibilities to a creative dialog between conventional and former complementary health professionals, to get even better results and higher satisfaction for everybody involved. Earlier studies state that communication is central and working in the same premises is the most successful way to achieve quicker and better outcomes at a lower cost.^{4,5,16,19,29–32}

To our knowledge, this is the first trial that has evaluated the effects of combined manual therapy performed under own diagnostic, treatment and management responsibility, for patients with musculoskeletal disorders in outpatient orthopedic waiting lists. Further research is required to establish clinical guidelines for different musculoskeletal disorders and to investigate to which extent manual therapy may reduce orthopedic outpatient waiting lists and to perform cost analyses.

CONCLUSIONS

It is plausible that naprapathic manual therapy may reduce orthopedic waiting lists. Compared with conventional orthopedic care, naprapathic manual therapy resulted in a larger improvement in pain, increased physical function, and perceived recovery to a larger extent for orthopedic outpatients with nonurgent musculoskeletal disorders not likely to benefit from surgery.

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