Costs and Utilities of Manual Therapy and Orthopedic Standard Care for Low-prioritized Orthopedic Outpatients of Working Age

A Cost Consequence Analysis

Stina C. Lilje, DN, Ulf B. Persson, PhD,† Stine T. Tangen, DN,‡ Stine Kåsamoen, DN,‡ and Eva Skillgate, PhD§*

Objectives: Treatment for musculoskeletal disorders in primary care in Sweden is generally initiated with advice and medication. Second-line therapy is physiotherapy and/or injection and radiography; third-line therapy is referral to an orthopedist. Manual therapy is not routine. It is a challenge to identify patients who benefit from treatment by different specialists. The current referral strategy probably contributes to long waiting lists in orthopedic departments, which is costly and implies prolonged suffering for the patients. The aim of this health economic evaluation was to compare costs and outcomes from naprapathic manual therapy (NMT) with orthopedic standard care for common, low-prioritized, nonsurgical musculoskeletal disorders, after second-line treatment.

Materials and Methods: Diagnose Related Groups were used to define the costs, and the SF-36 was encoded to evaluate the outcomes in cost per quality adjusted life years gained.

Results: Results from a 12 months' follow-up showed significantly larger improvement for the NMT than for orthopedic standard care, significantly lower mean cost per patient; 5427 SEK (*Price level 2009; 1 Euro = 106,213 SEK; 1 US Dollar = 76,457 SEK) (95% confidence interval, 3693-7161) compared to14298 SEK (95% confidence interval, 8322-20,274), and more gains in outcomes in cost per quality adjusted life years per patient (0.066 compared with 0.026). Thus the result is "dominant."

Discussion: It is plausible that improved outcomes and reasonable cost savings for low-prioritized nonsurgical outpatients would be attainable if NMT were available as an additional standard care option in orthopedic outpatient clinics.

Key Words: cost effectiveness, cost utility, QALY, DRG, musculoskeletal disorders

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Standard care for the treatment of musculoskeletal pain and disorders in Sweden varies and is not very well defined. However, for many health care providers the first-line treatment is advice from a general practitioner and medication. Second-line treatment is physiotherapy and/or steroid injections, and/or diagnostic radiography. Third-line treatment is an appointment with an orthopedic surgeon in the hospital's outpatient department. There is a perceived gap in the competence between primary and secondary care[1]: many general practitioners feel that they are not particularly knowledgeable about musculoskeletal disorders; the majority of physiotherapists are educated in physical exercises for rehabilitation, not in manual therapy; and orthopedic surgeons are specialized in surgery.[2–6] Many of the referrals to orthopedic departments concern disorders unlikely to benefit from surgery.[7–9] The waiting lists become long and apart from prolonged suffering for the patient, this is also time consuming and costly. Moreover, when the "low priority patients" have an appointment with an orthopedic surgeon, in an attempt to help the patients, many different but not necessarily the most appropriate, interventions are made[1] such as rereferrals to physiotherapy, medication, injections, different kinds of tests and analysis, radiography, orthotics, and even surgery. Even though there is evidence for the positive effect of manual treatment for musculoskeletal pain,[10] few health economic evaluations have been carried out, and specialized manual therapy is not routine within the health care system.

In Sweden, manual therapy providers are mainly registered naprapaths, chiropractors, and physiotherapists. Naprapaths and chiropractors in Sweden have a 4 to 5 years of full-time specialist education in manual therapy for treatment of disorders in the musculoskeletal system. Physiotherapists have a broader 3-year full-time education focusing on rehabilitation. Physiotherapists with a 2-year additional education in manual therapy have similar skills in manual treatment as naprapaths and chiropractors, but those constitute only a few percent of all physiotherapists in Sweden. Manual therapy may include musculoskeletal manipulations such as massage, stretching, manipulation (a specific adjustment of 1 particular joint performed with high velocity and a thrust), and mobilization (a low velocity adjustment, without thrust, performed to either 1 specific joint or more generally, to several joints at a time), as well as exercises/advice. Both the initiative to pursue, and the costs for specialized manual therapy remain with the patient.[5]

Previous studies have been performed on patients in first-line treatment in primary care, with a focus on patients with neck pain and low back pain. When comparing physiotherapy and manual manipulation performed by chiropractors for low back pain in Sweden, no differences in costs or outcomes were found.[11] In the United Kingdom

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From the *Blekinge Institute of Technology, Gräsvik, Karlskrona; †The Swedish Institute for Health Economics, Lund; ‡Scandinavian College of Naprapathic Manual Medicine, Kräftriket; and §Karolinska Institutet, Stockholm, Sweden.

The authors declare no conflict of interest.

Reprints: Stina C. Lilje, DN, Blekinge Institute of Technology, Department for Health Sciences, SE-371 79 Karlskrona, Sweden (e-mail: titti.lilje@bth.se).

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manual manipulation added to best care for low back pain has proved to be cost effective,[5] and in a trial performed on patients with neck pain in the Netherlands, manual therapy was more effective and less costly than physiotherapy or care by a general practitioner.

The problem concerning waiting lists caused by inappropriate referrals for common but nonsurgical orthopedic disorders (the leg/knee and shoulder/arm being the most common) is well known.[1,7–9] This has been successfully approached before, for example when experienced and specially trained physiotherapists have acted as gate keepers for orthopedic outpatients, and when comparisons of the physiotherapists' and the orthopedists' diagnostic skills have been compared, but the different treatment effects in the context of a clinical trial have not been compared.[7–9] To our knowledge, no health economic evaluation in the context of a randomized controlled trial (RCT) on manual therapy for the subgroup of low-prioritized orthopedic outpatients (patients with nonurgent and non-malignant muculoskeletal disorders, with no explicit need for surgery, and without a diagnosis) in second-line treatment has been published. Such knowledge is important for the attempt to shorten the waiting lists.

In Sweden, naprapathy is the largest profession within the field of specialized manual medicine. Naprapathy is defined as a system for specific examination, diagnostics, and manual treatment of soft and connective tissues, aiming to increase the function and to decrease pain and disability in the musculoskeletal system.[12] It is common that naprapaths in Sweden work with specific groups with high demands on physical performance, such as the dancers in the Royal Ballet School, and the Swedish Royal Ballet, where naprapaths have been employed for >30 years. The most frequent pain locations among the dancers are the same as in many orthopedic outpatient departments; the foot and knee.

In 2 earlier trials naprapathic manual therapy (NMT) was compared with evidence-based care in patients with nonspecific back and neck pain, and to orthopedic standard care on orthopedic outpatients with different kinds of musculoskeletal disorders. The results from both trials were in favor of the NMT.[1,13,14]

Cost effectiveness (costs and grade of effects), and the utility of an intervention (quality adjusted life year [QALY]) are interesting and important factors when comparing different interventions.[15] Usually, an intervention that is more effective is also more expensive. If an intervention is more effective and less costly than its comparators, it is said to be "dominant."[16] To perform a full economic evaluation of the interventions compared in our previously published trial (index group: NMT and control group: orthopedic standard care)[1] this study aimed to compare both the costs and utilities for working-age patients in second-line treatment, not eligible for surgical intervention. We also intended to specify the amount and types of interventions, both interventions that were part of the trial and self-elected, made in the 2 treatment arms during the follow-up.

MATERIALS AND METHODS

Data from a pragmatic RCT[1] were used to compare the cost and utilities of NMT and orthopedic standard care. Eligible participants in the trial were patients between 18 and 65 years old, considered as "low priority," and not candidates for surgery. The patients were selected and randomized to one of the 2 interventions. Primary outcome measures were pain and physical function. SF-36[17] measured bodily pain and physical function, and the pain intensity at its worse in the previous 2 weeks was measured with a Visual Analogue Scale, at baseline, 3, 6, and 12 months after inclusion. Secondary outcome was perceived recovery, measured at the 6- and 12-month follow-up. The trial was performed "per protocol" with no crossover until after the first follow-up. For ethical reasons, patients in the index group were then offered orthopedic consultation, if the patient needed or wished it. Thus, as a secondary outcome, the number of patients who agreed to be discharged from the waiting lists directly after the NMT was recorded. Both the interventions performed in the trial and self-elective treatments in both groups were also recorded during the follow-up time, and calculated as a part of the total costs.

The source population consisted of referrals to the Orthopedic Department of the hospital in Blekinge province, Southern Sweden. The referrals concerned patients who had been selected as "low priority" before the trial was planned. Patients who were on full-time sick leave, had different contraindications for manipulation, or an explicit wish for an orthopedic opinion expressed in their referral letter were excluded. Details about exclusion criteria, etc. are published elsewhere.[1] The patients in the index group received a maximum of 5 naprapathic treatments, within 5 weeks. (The time set for a naprapathic appointment is 30 to 45 minutes, and the treatment consists of massage, stretching, manipulation, and mobilization of the spine and peripheral joints, electrotherapy if needed, and home exercises and/or restrictions). The patients in the control group received standard care from orthopedic surgeons, with as many appointments as required. Standard care consisted of advice, drug prescriptions, steroid injections, referrals to physiotherapy, radiography, different examinations, analyses, or surgery. The consultations were conducted the way they are normally conducted at the department, and the orthopedists did not know which patients were participating in the study.

Statistics

A total of 80 patients provided a power of 80% to detect a relative risk of 1.2 to 1.3 for a clinically important improvement in pain and physical function. Differences between the groups at baseline regarding baseline characteristics were tested using analysis of variance. The differences in changes between the groups were tested and calculated by using the Wilcoxon signed-rank test and the Mann-Whitney *U* test at follow-up. To compare the groups regarding the dichotomized outcome perceived recovery, relative risks and risk differences together with corresponding 95% confidence intervals (95% CI) were calculated. For the health economic evaluation, the encoding of QALYs was made in Data Analysis and Statistical Software (STATA) and Statistical Package for the Social Science (SPSS). The gains in QALYs and the costs, presented as individual mean costs per month and year, and as total costs per year, were made in Excel. Data from the participants who withdrew from the trial were used until the time of withdrawal.

Diagnostic Related Groups (DRG)

"Prices and compensations for the health region in the south of Sweden" was used. DRG is used on groups to define interventions and costs in hospitals, related to a

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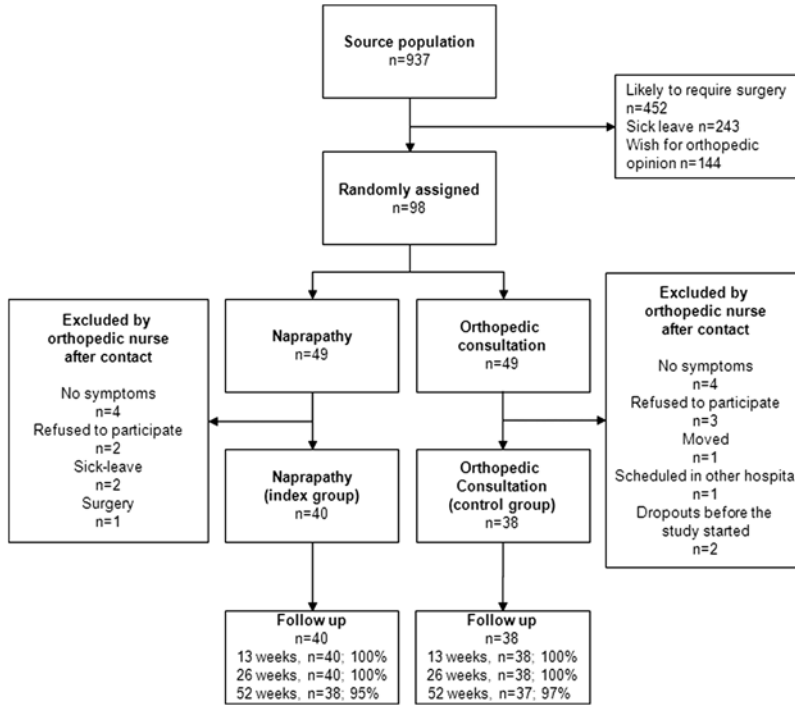

FIGURE 1. Flow chart describing the progress of patients throughout the trial.

diagnosis. This system has detailed information on prices for different interventions. Central variations for the DRG classification are: diagnosis, procedure, sex, age, and discharge status.[18] DRG was used to substantiate each effort in the RCT and was documented for all interventions in both the groups.[1]

SF-36, SF-6D

To perform a health economic evaluation that includes cost utilities, using QALYs, it is necessary to convert the health surveys SF-36 and EQ5D. The SF-36 health survey that was used in the previously performed RCT consists of 36 questions on 8 dimensions: physical function, role function, bodily pain, general health, vitality, social function, emotional role function, and mental health. A cost utility analysis may be performed by encoding the SF-36 to SF-6D, which is a specially condensed version of SF-36. In the SF-6D, a 6-dimensional health state classification system is used. The dimensions general health and emotional role function are withdrawn, and the questions are reduced from 36 to 9.[19] To estimate the cost utility in the health care, QALY has been developed.[20] It combines longevity with quality of life; the time an individual exists in a certain health condition is weighed against a value corresponding to the health-related quality associated with that actual condition. Every question in the SF-36 is converted into a common index of full health (this index is between 0 and 1, where 1 is equal to a year in full health and 0 is death). A summary health utility score may thus be derived, to evaluate QALYs and the results are modeled to estimate a scoring algorithm for deriving a single index (the SF-6D). When calculating the QALY gains the mean QALY values per person in the groups at baseline and at all the different follow-ups were used to calculate the area under the curve. The difference between the groups at baseline was adjusted to avoid bias.

RESULTS

Seventy-eight participants were included, and randomly assigned to the index group (40 participants) and to the control group (38 participants). Altogether, 96% completed the 1-year follow-up measurements (Fig. 1). Statistically significant differences between the groups were found regarding pain intensity, increased physical function, and perceived recovery, favouring the index group at 12-, 26-, and 52-week follow-up. After the 26-week follow-up, 62% in the index group agreed to be discharged from the waiting lists after the NMT. The total cost for the index group (n = 40) during the 12-month follow-up was 216,820 SEK and for the control group (n = 38) 538,754 SEK. The cost per patient in the index group ranged from 630 SEK to 24,387 SEK compared with 2000 SEK to 86,907 SEK in the control group. The mean cost per patient was 5427 SEK (95% CI, 3693-7161) in the index group, and 14,298 SEK (95% CI, 8322-20,274) in the control group. Altogether the index group received 275 interventions compared with 379 interventions in the control group. The most common intervention in the control group was physiotherapy (n = 13), and the most expensive intervention was surgery (n = 7).

Table 1 shows prices for each intervention in the RCT and Table 2 shows types, numbers, and costs for all the interventions. In Table 3, the individual mean cost per month as well as the total mean cost per treatment group are shown. The distribution and median of quality-of-life values in each group at different follow-up periods are shown in Figure 2. The individual mean quality-of-life values at baseline were lower in the index group compared with the

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TABLE 1. Price Per Intervention (SEK: Price Level 2009)

Interventions	Price	Interventions	Price
Naprapathic manual therapy	630	Drugs, prescription	93
Orthopaedic Consultation	2000	Massage	350
Physiotherapy	738	Chiropractic treatment	630
Orthotics	1382	Acute orthopedic consultation	2267
Magnetic resonance tomography	3530	Company health services	1420
Ultrasound	640	M75.0 adhesive capsulitis*	53,832
Plain x-ray	609	G56.0 Carpaltunel Syndrome*	10,922
Scintigraphy	2632	M23.2 arthroscopy knee*	15,069
Blockade	3079	T93.0 wound*	4334
Borealis analysis (lyme disease)	144	M21.4 Pes planus*	72,726
Electrophoresis	159	M62.8 bilateral compartment syndrome*	12,340
Electromyography	1255	M19.0 impingement GH-joint*	15,278
Bone density	1500	M19.1B AC-joint*	15,278
Steroid injection	762		

*Codes for surgery according to the International Codes of Diagnosis-10 (ICD-10).

control group. This difference was adjusted when calculating the QALY gains to avoid bias. The utility gains per patient measured in QALYs calculated as "area under the curve" for the index group was 0.066 and for the control group 0.026, as shown in Figure 3. A QALY gain of 0.04 corresponds to the value of 15 days in full health, or assuming the willingness to pay about €2000 (0.04 × €50,000) based on 1 QALY in the magnitude of €50,000 (which is a reasonable threshold value used for a health condition of medium degree of severity by TLV, [The Swedish Dental and Pharmaceutical Benefits Agency; Tandvårds- och Läkemedelsverket]). Applying a conservative value of 1 QALY in the region of £30,000, which as is the widely cited threshold value used by The National Institute for Health and Clinical Excellence in England,[21] results in a value of the health gain in the magnitude of £1200.

Sensitivity Analysis

A sensitivity analysis was made to investigate uncertainty in cost drivers. The largest fraction of cost offset is attributable to a difference in surgery (171,099 SEK); 6 patients undergoing surgical procedures in the control group were compared with 1 in the index group. The types of surgical interventions for the control group (n = 6) were: Carpal Tunnel Syndrome (CTS), arthroscopy of a knee, impingement of the glenohumeral joint, resection of the acromioclavicular joint, correction of a Pes planus, wound in a foot, and adhesive capsulitis. The diagnoses for the patients in the index group who were referred to surgery (n = 4) were: Pes planus, CTS, arthroscopy of a knee, and a bilateral compartment syndrome (the latter underwent surgery). When subtracting surgery the control group had almost 70% higher costs compared with the index group.

DISCUSSION

Principal Findings

Previously published results show improvements in both the groups with regards to pain, physical function, and perceived recovery; however, the NMT therapy was more effective than standard care for this sample of low priority and nonsurgical working-age outpatients on the orthopedic waiting lists. This health economic evaluation shows that the gains in QALYs were higher for the NMT than for orthopedic standard care, and the costs were lower, thus the NMT strategy for this patient population is dominant.

Strengths and Weaknesses

Our health economic evaluation is unique because it is the first based on low-prioritized patients on the waiting list randomized to manual treatment or orthopedic standard care. The RCT design with very few dropouts and standard care as the comparator, that is, an active treatment, is one of the strengths of our analysis. Compliance was also acceptable in both groups; all patient-initiated and doctor-initiated treatments were documented and resulted in both higher total costs and in individual differences. This appeared equally in both groups (4 participants in each group) and may not have an influential effect on the final outcomes in the study. The control group received standard care alone and the index group received only NMT per protocol until the first follow-up, and there was no

TABLE 2. Types and Number of Consultations, Tests, and Procedures and Costs for Different Interventions in Each Group

			Total Cost in SEK	
Type of Intervention	Control Group	Index Group	Control Group (n = 38)	Index Group (n = 40)
Naprapathy	—	166 (40)	—	104,580
Physiotherapy	242 (13)	31 (2)*	178,596	22,878
Orthotics	6 (6)	1 (1)*	1650	630
Orthopaedics	53 (38)	15 (15)*	106,000	30,000
Radiography/tests	20 (19)	12 (6)*	37,346	19,197
Surgical procedures	7 (6)	1 (1)*†	187,439	16,340
Drugs/injections	18 (18)	3 (3)*	6933	3141
Other treatments‡	33 (5)	46 (5)	20,790	20,054
Total	379 (38)	275 (40)	538,754	216,820

Figures in brackets indicate number of patients receiving actual intervention.
*Cross over patients from the index group.
†1 of the 4 patients referred to surgery in the index group underwent surgery.
‡Self-elective treatments; chiropractic, massage, orthopedic consultation, and company health service.

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TABLE 3. Individual Mean Cost Per Month for Different Follow-up Periods and Total Mean Cost Per Group (SEK)

	Baseline-3 mo		4-6 mo		7-12 mo		Total Mean Cost
Control group	n = 38	2827	n = 38	651	n = 37	644	14,298
Index group	n = 40	987	n = 40	686	n = 38	68	5427

crossover between the groups before the first follow-up, at 3 months. During this period both the treatment effects and the QALYs improved in both groups, but the improvement was much larger in the index group, meanwhile the costs were significantly higher in the control group. The standard care was carried out as normal, and the orthopedists at Blekinge hospital were not aware of whether or not the patient they were treating was a participant in the trial, which is positive for the external validity.

There are several weaknesses in our study. First, the RCT that our health economic evaluation is based on is small and performed only in 1 particular hospital in a medium-sized town in Sweden. Second, in this trial standard care and DRG's from the Blekinge hospital were used, and they may vary compared with other Swedish or international hospitals, which may limit the external validity and be considered a weakness. Information on costs was limited to a health care provider perspective and indirect costs for lost production due to absence from work were not included. Yet more interventions were made in the control group compared with the index group (379 compared with 275), and therefore we can expect a larger loss of working hours for the participants in the control group. The RCT was planned on nonsurgical cases but, because of missing information and indistinct referrals, it ended in 8 cases of surgery. This may be considered a weakness, as the trial was planned for nonsurgical cases, but the chance of a larger improvement in the control group would therefore also be higher. Physiotherapy—not orthopedics—was the most common intervention in the control group, which may be considered a weakness, but physiotherapy for the selected sample of patients is a common procedure in orthopedic standard care, hence it reflects the real world, which is considered a strength. The trial was performed "per protocol" until the 3-month follow-up (only NMT in the index group, and standard orthopedic care in the control group, respectively). During this period most activities/interventions happened, particularly in the control group, hence the costs were the highest in that group.

At the 6-month follow-up, most patients in both groups had been discharged, so the costs decreased significantly in both the groups. The control group received many more interventions than the index group, but the outcomes were not better, and the effects in the index group may be considered as clinically relevant; only 3 patients still had some kind of treatment/intervention, compared with 18 patients in the control group at the 12-month follow-up. The values for the index group were higher at all 3 follow-ups, and the results in the index group improved even at the last follow-up. A graphical presentation indicates an increase in QALYs in the index group that is more than twice as high in the control group, although not significant (Fig. 3). The difference at baseline (the index group graded more severe symptoms) had been adjusted in the statistical analyses, and the number of patients who were "a little better" or "much better" was more than double as high in the index group compared with the control group. Altogether there is consistency in the results and we think that they are robust, even though not significant.

Previous Studies

The RCT by Skillgate and colleagues that compared NMT for patients with neck and low back pain with evidence-based care by a general practitioner, and the RCT that this health economic evaluation is based on both concluded that NMT is effective in the short and long term.[1,13,14] An earlier trial by Skargren et al[11] compared the costs and effects of chiropractic treatment and physiotherapy treatment on patients with back pain. The results in that trial showed no differences between the groups with regards to costs and effectiveness, but did not include the aspect of QALY. It also differed from our study regarding the kind of disorders and the treatment modalities. Another economic evaluation by Korthals de-Bos et al[6] comprised general practitioner, physiotherapy, and manual therapy. Manual therapy was more effective and less costly, and

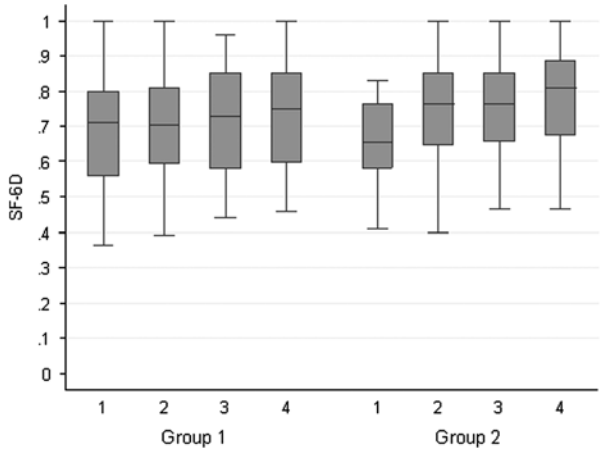

FIGURE 2. Distribution and median quality of life values per group at baseline, 3-, 6-, and 12-month follow-up.

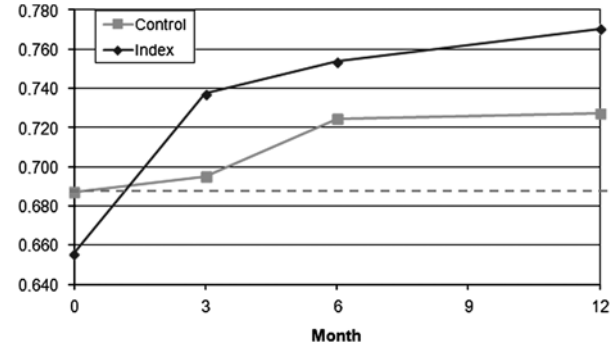

FIGURE 3. Average quality of life measure per person in index and control groups measured at baseline, 3, 6, and 12 months.

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yielded a significantly faster improvement as in our study, but was a first-line treatment for patients with neck pain only.

Implications

There are few published trials on manual treatment, and to our knowledge there is none on the subgroup of low-prioritized patients on orthopedic waiting lists with common musculoskeletal disorders, even though this is of great concern as the longest waiting lists are often seen for orthopedic patients.

Almost half of all the study participants had already had physiotherapy before they were included in the trial. Almost one third of the participants in the control group were referred to physiotherapy and their sessions were not completed at the time of the last follow-up, hence they continued to incur costs. Physiotherapy constituted 242 of all (379) interventions in the control group and was the second most expensive intervention after surgery. Physiotherapy is a common intervention but may not be the most appropriate and cost effective, for all kinds of musculoskeletal disorders.[1]

Communication between health care professionals working on the same premises is the most successful way to achieve faster and better outcomes at lower costs,[22–25] and "doing the right things from the beginning" is essential in quality assurance.[26] The characteristics of the reports of professional ballet dancers in Sweden are similar to those in many orthopedic outpatient departments. By changing the routines for managing musculoskeletal disorders so that the dancers are firstly examined by the employed naprapath and secondly, if necessary, they are referred to the consulting orthopedist, the often too long waiting lists for an orthopedic consultation are shortened. It would be of great value to perform further trials to develop clinical guidelines to define when manual treatment, surgery, or exercises, respectively, is the most appropriate intervention.

Surgery is a major cost for society, and has no guarantee of a successful result. Interestingly, the orthopedists referred altogether 4 of the participants in the index group to surgery, but only one of them agreed to undergo surgical intervention. One of the most expensive surgical interventions in the control group was for adhesive capsulitis (29% of the total costs for surgery), which was successfully treated with NMT after completion of the trial.[27]

It would be interesting to explore the cost consequences of NMT compared with surgery, for patient populations with conditions such as adhesive capsulitis, impingement of the shoulder, epicondylitis, CTS, and Achilles tendinitis among others, and to further investigate the impact on referrals to surgery and physiotherapy. These diagnoses were included in our study but were too few to analyze separately.

Cost consequence analyses based on real-world trials are valuable for health policy—makers and for patients, as they detect the effects and costs of already existing interventions. They are also valuable not least for the patients, as they may indicate if the patients are offered the most appropriate care, particularly when adding a new treatment method.

NMT resulted in lower health care costs and achieved larger gains in quality of life than orthopedic standard care for low-prioritized orthopedic outpatients of working age. Thus, the result is dominant. The study indicates that improvement in health outcomes for patients with common musculoskeletal disorders unlikely to require surgery, and reasonable cost savings would be plausible if specialized manual therapy like NMT were available as an additional option in treatment at orthopedic outpatient clinics. The results of this study add important knowledge to the body of evidence required to fully implement NMT into the financed health care system.

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