

Aspects of musculoskeletal pain interfering with normal life and naprapathic manual therapy from a health technology assessment perspective

Abstract

INTRODUCTION

Musculoskeletal pain is one of the most common reasons for seeking health care. If a patient's disorders remain after conventional primary care, a referral to secondary care (orthopaedics) is often made, yet many referrals on the waiting lists concern patients who are not in need of surgery. Manual therapy has a lot of "proved experience" but is not routine in the Swedish national health care system today, and there is a lack of scientific evidence for its treatment and cost effects.

AIM

The overall aim of this thesis was to increase the knowledge of musculoskeletal pain that interferes with normal life. Specific aims were to investigate if musculoskeletal pain interfering with normal life in older adults is associated with heavy physical and negative psychosocial workloads through life, and to deepen the knowledge of the treatment and cost effects of naprapathic manual therapy (NMT), and of older adults' experiences of reminders of home exercises through text messaging.

METHODS

Study I is a cross sectional study (n=641) that investigates associations between musculoskeletal pain interfering with normal life in older adults and different physical and psychological loads through life. Study II is a randomised controlled trial (n=78) that compares NMT with standard orthopaedic care for “low priority” orthopaedic outpatients. Study III (n=1) is a case study that describes the treatment effects of NMT in a patient diagnosed with adhesive capsulitis. Study IV is a cost consequence analysis (n=78), where the costs and the health economic gains in study II were analyzed. Study V is a qualitative interview study (n=8) exploring older adults’ experiences of SMS:s as reminders of home exercises after NMT for recurrent low back pain.

RESULTS

The results in Study I were that psychosocial and physical work loads are associated with musculoskeletal pain that interferes with normal life in older adults. NMT for low priority patients on orthopaedic waiting lists yielded significantly larger improvements in pain, physical function and perceived recovery compared with standard orthopaedic care (Study II). NMT for the acromio-clavicular joint, for adhesive capsulitis resulted in significant pain relief and perceived recovery, decreased sleeping disorders and medication (Study III). The health gains for naprapathy were higher compared with standard orthopaedic care, and the costs significantly lower (Study IV). Study V concluded that the use of SMS:s as reminders of home exercises after NMT were appreciated by the patients, and stimulated them to practice memorising and to create their own routines for continued compliance.

CONCLUSION

This thesis suggests that pain in older adults is associated with heavy physical and negative psychosocial workloads through life. NMT may be cost effective for low priority orthopaedic outpatients of working age with musculoskeletal disorders that are not likely to benefit from orthopaedic surgery, and was effective in a patient diagnosed with adhesive capsulitis. Text messaging used to remind older adults of home exercises after NMT stimulates the patients to create their own routines for continued compliance.

List of publications

Lilje, S., Anderberg, P., Skillgate, E., & Berglund, J. (2015). Negative psychosocial and heavy physical workloads associated with musculoskeletal pain interfering with normal life in older adults: Cross-sectional analysis. *Scandinavian Journal of Public Health*, 43; 5:453-459.

Lilje, S. C., Friberg, H., Wykman, A., & Skillgate, E. (2010). Naprapathic manual therapy or conventional orthopedic care for outpatients on orthopedic waiting list? A pragmatic randomized controlled study. *Clinical Journal of Pain*, 26, 602-610.

Lilje, S., Genberg, M., Aldudjaili, H., & Skillgate, E. (2014). Pain relief in a young woman with adhesive capsulitis after manual manipulation of the acromioclavicular joint for remaining symptoms after mobilisation under anaesthesia. *BMJ Case Reports*, 9. Doi:10.1136/bcr-2014-207199.

Lilje, S. C., Persson, U., Tangen, S.T., Kåsamoen, S., & Skillgate, E. (2014). Costs and utilities of manual therapy and orthopedic standard care for low prioritized orthopedic outpatients of working age: a cost consequence analysis. *Clinical Journal of Pain*, 30, 730-736.

Lilje, S., Anderberg, P., Olander, E., Skillgate, E., & Berglund, J. (2015). Appreciation, reflection and creation: older adults experiences of a technical device for adherence to home exercises after specialized manual therapy for low back pain. A qualitative study. *Manuscript*.

Abbreviations and definitions

HTA: Health Technology Assessment

NICE: National Institute for Health and Care Excellence

NIHR: The National Institute for Health Research

WHO: World Health Organization

TLV: The Dental and Pharmaceutical Benefits Agency

SBU: Statens beredning för medicinsk utvärdering

EBM: Evidence Based Medicine

RCT: Randomised Controlled Trial

NMT: Naprapathic Manual Therapy

TNS: Transcutan Neuromuscular Stimulation

CAM: Complementary and Alternative Medicine

OMT: Orthopaedic Manual Therapy

SNAC: Swedish National Study on Ageing and Care

SNAC-B: Swedish National Study on Ageing and Care - Blekinge

Older adult: 60 – 78 years

SF 36: The Swedish health survey Short Form 36

SF 12: The Swedish health survey Short Form 12

VAS: Visual Analogue Scal

AC: Adhesive capsulitis

GHJ: Glenohumeral joint

LBP: Low back pain

STC: Systematic Text Condensation

SEK: Swedish krona

DRG: Diagnose Related Group

QALYs: Quality Adjusted Life Years

YLD: Years lived with disability

SMS: Short Message Services

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INTRODUCTION

The aims of this thesis are to explore factors through life associated with musculoskeletal pain that interferes with normal life, to evaluate the treatment and cost effects of NMT for low priority orthopaedic outpatients with such pain, in a province hospital and to explore how older adults experience text messaging as reminders of home exercises after NMT. The perspective is that of health technology assessment (HTA)

There is a clinical background to this thesis emerging from my work as a naprapath at the Swedish Royal Ballet School, in Stockholm. For more than 30 years (i.e. before the naprapathic profession was licensed), this professional dance education has had its own naprapaths employed by Stockholm City Council, who work closely with a school nurse and a consulting orthopaedic surgeon. The students are between 9-20 years of age, and from the age of 13 they practice dance several times and hours each day, six days a week. Their numerous injuries are mostly located in the lower extremities, and of both acute and chronic character. A naprapath is employed in the school, and a consulting orthopaedist holds receptions in co-operation with the naprapath and a school nurse, every second week. If a student needs supervised rehabilitation exercises, such as barre practice in water, the orthopaedist consults a physiotherapist specialised in dance injuries in a hospital or a privately practising physiotherapist. Initially, there was a lack of routine in time scheduling for the orthopaedist, and of knowledge of the competence and skills of the orthopaedist and the naprapath. Neither the director of the school, the students nor their teachers knew when to consult the orthopaedist and when to consult the naprapath. Many students with musculoskeletal disorders were therefore sent to the orthopaedist by their dance teacher, and there was a constant overload of scheduled students. Few of the students actually required such specific competence and, consequently, many of them were therefore not helped, which made them frustrated. Furthermore, the overload of students scheduled for an appointment did not leave much time for professional discussions between the orthopaedist, the naprapath and the nurse. Hence, this way of organizing the work was not effective. A common opinion (mainly from the dance teachers) was that the best thing was to see the doctor, whilst the students' opinion was that they "only wanted to get rid of their pain". Though, the common goal for everybody was that the dance students would "be on stage" without pain or dysfunction. As a consequence, guidelines on how to handle different disorders

were implemented, by the health care professionals. The guidelines implied that the students firstly, had an appointment with the naprapath, and secondly, if needed, an appointment with the orthopaedist (e.g. students in need of an injection, medication requiring prescription, referral to radiography, surgery, physiotherapy or a second opinion). These guidelines were communicated both to the principal of the school, and to all the dance teachers and students. With the new guidelines the treatment outcomes improved, the student were more satisfied and the health professionals more secure, and there was even some time left over for discussing preventive interventions. The employment of a naprapath, the implementation of new routines with the naprapath as a gatekeeper, and knowledge of musculoskeletal disorders in the ballet dancers have many similarities with theories from implementation science, where research has shown that an organisation's ability to change is associated with a high level of specialization, decentralised decision processes, good communication and managers who are positive to changes (Grol, Wensing, Eccles, 2005). Specific individuals, to a larger extent than the organisation as a whole, have influence over specific changes. There are also similarities between the organisation of musculoskeletal disorders in the ballet school and that of orthopaedic waiting lists in Swedish county councils, both in terms of the location of the most common disorders (i.e. the leg, knee and foot), the problems with long waiting lists, and the fact that many disorders on the waiting lists are not in need of an orthopaedic surgeon's competence. If patients are not given the most appropriate care, their suffering is prolonged and it is also costly. The reason for employing naprapaths in the Swedish Royal Ballet School, the Royal Ballet corps and Philharmonic Orchestra, by the municipality of Stockholm was "proved experience". Licensed naprapaths in Sweden have health care agreements in two thirds of all counties, but they are not employed in hospitals. More scientific evidence for the effects of naprapathy is required for their acceptance as integral members of a hospital team. The way treatment of musculoskeletal pain and disorders in the Royal Swedish Ballet School was organised, and its effects, strongly inspired the writing of this thesis.

BACKGROUND

MUSCULOSKELETAL PAIN

Musculoskeletal pain constitutes one of the most common reasons for seeking primary care (Gerdle, Björk, Henriksson & Bengtsson, 2004; SBU, 2006; Jordan, Kadam, Hayward, Porcheret, Young & Croft, 2010; Månsson, Nilsson, Strender & Björkelund, 2011). There is a progressive increase in chronic musculoskeletal pain complaints with age, and correlations with heavy physical workload, psychosocial factors and higher body weight, particularly in women (Bergman, Herrström, Högström, Petersson, Svensson & Jacobsson, 2001; Bennett, 2004; Jacobs, Hammerman, Rozenberg, Cohen & Stessman, 2006; Gnudi, Sitta, Gnudi & Pignotti, 2008). Individuals with musculoskeletal pain easily develop concomitant pain that interferes with normal life, pain that is associated with sleeping disturbances and depression (Bair, Wu, Damush, Sutherland & Kroenke, 2008). In these circumstances pain easily develops into a chronic condition and becomes a public health problem (Thomas, Peat, Harris, Wilkie & Croft 2004; Becker, Bondegaard, Olsen, Sjögren, Bech & Eriksen, 1997; Bennett, 2004). Several studies have been conducted on musculoskeletal pain in the working population, where associations between low back pain (LBP) and neck pain, and heavy physical workload, work in bent positions, low educational level and different psychological factors were found (Bergenudd, 1994; Andersson, 2004). The global prevalence of musculoskeletal disorders others than osteoarthritis, rheumatoid arthritis, neck pain, LBP and gout is 8,4%. The rates of Years lived with disability (YLD) increase with age (Smith, Hoy, Cross, Vos, Naghavi, Buchbinder & Woolf, 2014) and due to the ageing of the global population, health systems in most parts of the world will need to address the needs of the rising numbers of individuals with musculoskeletal disorders that cause disability (Vos et al., 2012), and it has been suggested that specific musculoskeletal disorders others than neck and LBP should be considered separately to enable more explicit estimates of their burden in future iterations of The Global Burden of Diseases (Smith et al., 2014). Still, there is little research on musculoskeletal disorders others than neck and LBP.

TREATMENT OF MUSCULOSKELETAL PAIN AND DISORDERS IN SWEDEN

Treatment of musculoskeletal disorders in primary care in Sweden is generally initiated with advice and medication. According to guidelines and evidence-based reviews from a general practitioner, for neck and LBP, it may be defined

as support and advice on staying active and on pain coping strategies (Nachemson & Jonsson, 2000; Wadell & Burton, 2001). The general practitioner may also prescribe medication and/or recommend sick leave, and exclude possible pathological conditions, why referrals for extended examinations may be performed.

Second-line therapy may consist of physiotherapy, and/or injection, and/or radiography, and/or intervention with surgery. Physiotherapists use physical movements to promote health, and physiotherapy is based on physical exercises (Sjukvårdsupplysningen 1177, Legitimerade Sjukgymnasters Riksförbund, 2015). Its basic education may be extended with specialization in, for example, physical impairments, the elderly, patients with psychiatric and psychosomatic, neurologic or circulatory disorders, and in pain and disorders in the musculoskeletal system. In Sweden today, a few percent of physiotherapists are specialized in orthopaedic manual therapy (OMT) (i.e. biomechanic treatment, including high velocity manual manipulations), and work in private clinics, generally not in primary or secondary care (Legitimerade sjukgymnasters riksförbund, 2015). Other professions such as naprapaths, chiropractors and osteopaths, educated in biomechanic manual therapy, are not employed in hospitals and sparsely in primary care, thus biomechanic manual therapy is not mainstream in the Swedish national health care system.

If a patient's condition does not improve after treatment from a general practitioner or a physiotherapist, third-line therapy is a referral to an orthopaedic surgeon. There are different reasons for making a referral, and they may be prompted, and even performed by the patient ("self-referral"). Many referrals on orthopaedic waiting lists concern patients who are not in need of the specific competence and resources available in an orthopaedic clinic (Weale & Bannister, 1995; Cathain, Froggett & Taylor, 1995; Oldmeadow, Bedi, Burch, Smith, Leshy & Goldwasser, 2007), and research has found that no interventions are made for 30-66% of all patients on the waiting lists (Harrington, Dopf & Chalgren, 2001; Lövendahl, Hellberg & Hanning, 2002; Samsson & Larsson, 2013). The same problem is observed in other studies in which the number of inappropriate referrals varies from 43% to 66% (Oldmeadow, 2007). The etiology of and treatment and cost effects for common musculoskeletal disorders like Adhesive capsulitis, Coccygodynia and Patellfemoral pain, for example, are not well known (Maund et al., 2012; Howard, Dolan, Falco, Holland, Wilkinson & Zink, 2013; Witvrouw et al., 2014), and orthopaedic surgery for other common disorders in orthopaedic outpatient clinics (i.e. epicondylitis,

distorsions and achilles tendinitis) is unusual, or lacks convincing results (personal conversation Håkan Friberg, May, 2014; Landstinget i Halland, 2006). Eighty-six percent of all patients who sought hospital care for pain in the musculoskeletal system in the county where the studies in this thesis were performed, also sought different kinds of complementary and alternative medicine (CAM) for their conditions (Krona, 2005). The prevailing routines imply prolonged suffering both for low priority patients and for those with more severe disorders in need of surgery, and they are also time consuming and costly. Meanwhile, clinical experience from naprapathic clinics for NMT is that many patients who improve with naprapathy are already referred to an orthopaedist by their primary or company care physician, thus on the waiting lists for an appointment with an orthopaedic surgeon. A basic and central theme in quality assurance is "doing the right thing from the beginning" (Plsek, Solberg & Grol, 2004). Treatment effects and costs would be related to each other, in that an appropriate treatment for a specific condition would be less costly than its opposite.

A large proportion of patients on orthopaedic waiting lists consists of patients older than 65 years (statistics from the orthopaedic outpatient department of Blekingesjukhuset in Karlskrona), and in the general population of Blekinge the most common intervention for elderly with pain is medication (Sandin Wrangler, Rennemark, Berglund & Elmståhl, 2014). Little research has been performed on musculoskeletal pain on populations above working age, and on musculoskeletal pain defined as interfering with normal life, hence it is of interest to scientifically investigate if the use of biomechanic treatment techniques and of mobile health (mHealth) technique may be cost effective contributions in the treatment of non-surgical musculoskeletal pain that interferes with normal life.

HEALTH TECHNOLOGY

The term health technology covers a range of methods used to promote health, prevent and treat disease, and improve rehabilitation and long term care (The National Institute for Health Research, 2013).

“Health technology is the application of organized scientific knowledge and skills in the form of devices, medicines, procedures and systems developed to solve a problem in healthcare and disease prevention, and to improve quality of lives” (Kristensen, 2009; World Health Organization, 2015). Health technologies include:

Medicinal products

Medical devices

Diagnostic techniques

Surgical procedures or other therapeutic techniques

Therapeutic technologies other than medicinal products

Systems of care

Screening tools (NICE, 2013).

Applied health technology

The subject Applied health technology is defined as an interdisciplinary research area that in different ways investigates and explores how health directly and indirectly may be related to the use and the effects of technique. The research wants to show how technical science may be combined with research within health care science, public health care science and medicine, in order to enable a good life (Blekinge Institute of Technology, 2015). Health technology is a multi-disciplinary research area, which makes it broad, and the definition of health technology varies. This research subject at Blekinge Institute of Technology (BTH) is relatively new, and earlier theses have been written in the area of digital health, with subjects, such as supported health promotion in primary health care, the use of information communication technology use by older adults, implementation of information systems in health care and video conferencing in discharge planning sessions (Mahmud, 2013; Berner, 2014; Nilsson, 2014; Hofflander, 2015). The health technology focus of this thesis is biomechanical treatment techniques in the shape of NMT, and exploration of patients' experiences of mHealth, in receiving mobile text messaging aimed to increase the adherence to home exercises after NMT.

Digital health and gerontechnology

Digital health is an umbrella term for all healthcare related applications, technologies and delivery systems that make use of interconnected technologies for healthcare providers, consumers and researchers. It is an encompassing field used at BTH, which includes sub-specialties such as telemedicine, eHealth, mHealth, electronic medical record/electronic health record (EMR/EHR), personal genomics, big data and health IT (WHO, 2011; Topol, 2013; Adibi, 2015). Mobile technologies in mHealth include devices such as mobile phones,

tablets, personal digital assistants and wireless infrastructure, for policymakers in health and information technology, to reduce unnecessary referrals and to improve quality of care (Adibi, 2015). Because of the increasing numbers and percentages of older people the term gerontechnology has emerged.

Gerontechnology strives to harmonise the increasing number of older people - a product of our ageing society - and the technological innovation of products and services, referred to as the digital area (Bouma, Fozard, Bouwhuis & Taipale, 2007). *ibid*: A combination of insights into processes of ageing individuals and ageing societies, and insights into new technological options, constitutes the field of gerontechnology, where technological innovations are directed to the ambitions, purposes and needs of ageing people. Musculoskeletal disorders that cause disability increase with age (Vos et al., 2012) and physical inactivity is a leading health risk factor for mortality worldwide. (Buchholz, Wilbur, Ingram & Fogg, 2013).

Patient participation

Patients' knowledge about their pain and disorders and their participation in rehabilitation by individualised home exercises are believed to play an important role for the improvement in pain and dysfunction, according to the naprapathic concept (Skillgate, Arvidsson, Ekström, Hilborn & Mattsson-Coll, 2009), and behaviour change is an important part of improved self-management in chronic health disorders (Vlaeyen & Linton, 2000). Clinical experience often shows that the patient's pain is the reason for performing his or her exercises, so when the pain decreases the home exercises are easily forgotten, and it seems of importance for patients to be reminded of their exercises in other ways than through recurrent pain. Information technology in the shape of mHealth; through text messaging via short message services (SMS:s) may be used for different purposes, such as reminders of medication and appointments in clinics, and for pain assessment (Hughes, Done & Young, 2011; Stinson et al., 2013). Reviews have provided an overview of studies on behavior change interventions for disease management and prevention, and of clinical and healthy behaviour interventions, delivered through text messaging, (Lewis & Kershaw, 2010; Militello, Kelly & Melnyk, 2011; Wei, Hollin & Kachnowski, 2011; Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car & Atun, 2012). The majority of studies in this field are conducted in special health care settings and the most frequently studied patient groups are smokers, people with diabetes, and mental health disorders (Valerie & Menachemi, 2011). The outcomes of the studies are mostly

positive, and text messaging has also been appreciated by the participants, but its evidence base is not yet conclusive (Wei et al., 2011). Text messaging has also been used to collect data on LBP outcomes in clinical trials, and with regard to monitoring the clinical course of LBP in patients seeking manual therapy (Axén et al., 2012; Macedo, Maher, Latimer, & Mc Auley, 2012). As regards physical interventions there is evidence supporting its positive effects especially when used together with other delivery approaches, such as face-to-face (Lau, Lau, Wong & Ransdell, 2011), but text messaging with the aim to promote physical activity has only been studied by a small group of researchers (Buchholz et al., 2013). Research on smartphone interventions for people with chronic pain in general, and for LBP in particular, is very limited (Macedo et al., 2012). Qualitative studies of the experiences of patients receiving reminders about their home exercises via SMS after manual treatment has, to the best of our knowledge, never been described before.

Reminders of home exercises may also be given through/via written information, e-mails, a web site, or an application on a smartphone. Mobile applications have extended functions, such as audio recorded treatment sessions, the ability to record completed home work exercises, to review home work adherence, and to track symptom severity over time. The app may also schedule home work directly in the app and present a visual display of symptom improvement (Reger, Hoffman, Riggs, Rothbaum, Ruzek & Holloway, 2013) but to create an app for individualized messages, like those following a session of manual therapy treatments, is much more resource and time consuming than, for example, text messaging. Using a Web-enabled mobile phone makes it possible for patients to keep some form of record of their emotions and behaviour in real time and questions may be answered, which is positive since it may support self-monitoring (Kristjansdottir, Fors, Eide, Finset, van Dulmen, Horven & Eide, 2011). Using a web site or an app might stimulate more health literacy and empowerment than text messaging, since a variety of exercises and information may be given, and feed-back may be required. In this case the patient has to be more active as compared to when receiving a text message initiated by a care giver. Still, an app may send wrong information, and there is also the issue about security and privacy, when transmitting information (Elabd S, 2013). Text messaging has both technical and clinical implications in that it is simple, user-friendly, and cheap, and people of all ages have access to a mobile phone today.

The messages may, just like web sites, apps and e-mails, be given in real time, and they are easily individualized.

Biomechanics

Biomechanics as a conception may be explained as the interaction between anatomy and the impact of different physiological laws on our movements. Biomechanics is the study of the action of external and internal forces and analyses of mechanical principles within biological systems, such as the living body, especially of the forces exerted by muscles and gravity on the skeletal structure. (The American Heritage Stedman's Medical Dictionary, 2002). Aristotle wrote the first book about the subject: *De Motu Animalium*. (Biomechanics, 2015, 18 August). He did not see the animals' bodies as mechanical systems, but posed questions about the physiological differences between the theoretical description of the performance of a movement, and the concrete action when performing a movement. (**ibid**). This approach is central to biomechanics and is the basis for mechanical laws used in order to study what impact forces have on living tissues. Leonardo da Vinci analyzed muscle forces as acting along lines, and he studied joint function. He also intended to mimic some animal features in his machines.

Different forces

Different forces and moments affect how the human body works and acts. A force is an action which causes a body (a mass) to deform or to move. Newton's mechanical laws (the laws of inertia, acceleration, and reaction) describe how objects are affected by external forces, and are the origin of biomechanics (Georgia State University, 2015). The force of gravity or gravitation is the dominating universal force. It is a vector quantity with a magnitude, i.e. the size of the force, and a direction. The force of gravity is defined as the product of the mass of an object (kg) and acceleration by the formula $F=m \times a$. The acceleration on earth is on average approximately 9,82 m/s, thus the force of gravity for a person who weights 75 kg is: $F = 75 \times 9,82 \Rightarrow 736,5$ Newton (N). A force may be compressive, tensile, shear, bending and torsional, and can be represented by two components, usually acting at right angles to each other. Forces that act in different directions at various speeds may be added together and the component forces summed, in order to reconstruct a "resultant" of the two original forces (Adams, Bogduk, Burton & Dolan, 2006).

Manual manipulations and mobilizations

In order to stretch connective soft tissues and/or muscles and to normalise the function of a patient's back and extremities contact made is made, by the hands, towards a chosen point of contact in relation to the joint that is to be treated. If it is the spinal vertebra that is to be treated, the therapist creates a rotation of the segments above and under the vertebra that is to be manipulated, in order to create as much tension as possible. Thereafter, a quick movement (an impulse or a thrust) is performed, which reaches beyond the physiological movement of joint, though without exceeding the anatomical end point. The manipulation may be performed with large, general contact points (the whole hand, both hands, the forearm, leg or elbow), or with as small contact points as possible (the fingers or a part of the hand). In both cases the movement is performed with high speed velocity, a minimal range of motion, and with minimal force amplitude (Skillgate et al., 2009).

NAPRAPATHIC MANUAL THERAPY (NMT)

History

In Sweden manual therapists are mainly naprapaths, chiropractors, osteopaths and physiotherapists, but naprapaths, chiropractors and osteopaths are employed sparsely in primary care and not employed at all in specialized care in hospitals. Few physiotherapists employed in the Swedish national health care system are specialized in high velocity manual manipulations (Legitimerade Sjukgymnaster Riksförbund), why (specialized) manual therapy is not routine within the Swedish health care system today. Thus, the initiative to pursue, and the costs for specialized manual therapy most often remain with the patient. The naprapathic profession is comparable with that of chiropractors and the professions are equally old (about 100 years). Naprapaths are also common in Norway, Finland, and in the United States. Naprapathy emerged as a reaction to the chiropractic theory that vertebrae could be subluxated as the basis of disease (Smith, 1919; Smith, 1932). Instead, pain and dysfunction in the musculoskeletal system is believed to originate from the soft and connective tissues, their impact on, and interaction with the neuromusculoskeletal system (Skillgate et al., 2009). The naprapathic treatment is thus oriented towards, and has greatest impact on those structures. Pain is often of compensatory character and naprapaths treat the symptoms and strive to find the origin of the pain. A naprapathic treatment is a combination of different manual techniques like massage, stretching, treatment of myofascial trigger points, mobilizations, electrotherapy and high and low

velocity manual manipulation, combined with physical exercises. A naprapathic treatment lasts from 30-45 minutes, and naprapaths work under their own diagnostic and clinic responsibility. The profession is a part of the Swedish health and medical care system, and since 1994, licensed by the National Board of Health and Welfare for treating patients with musculoskeletal pain and pain related disability. Today two thirds of the counties in Sweden have medical care agreements with naprapaths, and institutions like the Swedish Royal Ballet and the Opera, the Swedish Royal Ballet School and Stockholm Philharmonic Orchestra have their own naprapaths, employed by the central government and by the municipality of Stockholm. However, as naprapaths are not employed in hospitals they are not easily available to a large group of patients. Before the naprapathic profession was licensed, naprapathy was considered as Complementary and Alternative Medicine (CAM). Even today, although it constitutes the largest profession within the field of specialized manual therapy in Sweden, it is still sometimes considered as CAM.

Research on manual therapy

As regards CAM therapies there has been a lack of high quality research on their treatment and cost effects and studies with long term follow-ups (Robinson, Donaldson & Watt, 2006) and a lack of policies, which is believed to be the reason why they are not mainstream in health care systems (Pelletier, Marie, Krasner & Haskell, 1997; Pelletier, Astin & Haskell, 1999; Cohen, Penman, Pirota & Da Costa, 2005; Mootz, Hansen, Breen, Killinger & Nelson, 2006). Myburgh et al. (2008) concluded that professions acting “in contested niche areas” cannot rely on legislated position alone, but need to develop more subtle “secondary legitimization strategies”. Naprapaths treat all kinds of musculoskeletal disorders and the evidence for its “proved experience” is large. However, the profession needs to be scientifically evaluated in order to be fully implemented in the Swedish national health care system.

There is evidence for the positive effects of manual treatment for musculoskeletal pain, and one biomechanic treatment technique at a time has been investigated and evaluated before, with a focus on neck and LBP. Systematic reviews have found that massage is an effective treatment for LBP (Furlan, Brosseau, Imamura & Irvin, 2002; Cherkin, Sherman, Deyo & Shekelle, 2003). Manipulation and mobilization are effective and could be recommended for adults with acute, subacute and chronic LBP, for migraine, cervicogenic headache, cervicogenic dizziness and several extremity joint conditions.

Thoracic manipulation has proved to be effective for acute and subacute neck pain (Bronfort, Haas, Evans & Bouter, 2004; Bronfort, Haas, Evans & Bouter, 2010). Evidence also supports the effects of some manual therapy techniques in chronic low back and knee pain (Bokarius & Bokarius, 2010), and in thoracic and shoulder pain (Stochkendahl, Christensen, Vach, Høilund-Carlsen, Haghfelt & Hartvigsen, 2012; Tsertsvadze, Clar, Court, Clarke, Mistry, & Sutcliffe, 2014). When comparing the effectiveness of different manual therapies for back and neck pain, combining more than one manual therapy technique with specific exercise training has shown to be effective (Sran, 2004). This has also been concluded when investigating NMT, for neck and LBP (Skillgate, Vingård & Alfredsson, 2007; Skillgate, Bohman, Holm, Vingård & Alfredsson, 2010), where naprapathy was considered an effective treatment both in the short and in the long term.

Cost effects

In an economic evaluation made alongside a randomised controlled trial, manual therapy was considered a cost effective alternative when compared with physiotherapy and care by a general practitioner for the management of neck pain. However, high velocity, low amplitude manipulations were not used (Korthals-de Boes, 2003). Another study that added spinal manipulation, exercise, or manipulation followed by exercise, to "best care" in general patients with LBP concluded that spinal manipulation was a cost effective addition (UK BEAM, 2004). A recent systematic review concluded that chiropractic manipulation was less costly and more effective than either physiotherapy or GP care in improving neck pain (Tsertsvadze et al., 2014). The aim of that review was to evaluate the cost effectiveness and/or cost utility of manual therapy techniques for reducing spinal, shoulder and ankle pain, and it concluded that manual therapy was more cost-effective than usual care by a general practitioner, spinal stabilisation and brief pain management, for improving low back and shoulder pain. Another study on back pain found no differences in costs when comparing physiotherapy and chiropractic for back pain (Skargren, Carlsson & Öberg, 1998). The manual treatment techniques in different studies are not standardised, or described in detail, and there is a paucity of evidence of cost effectiveness and health utilities from manual therapy interventions. Further methodological and reporting quality improvements of health economic evaluations of manual therapy are needed in order for policy makers, health care practitioners and patients to be able to make evidence-based decisions (Tsertsvadze et al., 2014).

In the national health care system musculoskeletal pain and disorders are taken care of in primary and/or in secondary care. The majority of patients on orthopaedic waiting lists suffer from disorders in the upper and lower extremities, these waiting lists are among the longest, and a considerable number of the referred patients are not in need of surgery (Weale & al., 1995; Cathain & al., 1995; Oldmeadow et al., 2007). Biomechanical manual therapy is not main stream in the Swedish national health care system, meanwhile approximately 1,5 million (privately financed) naprapathic treatments are performed by licensed naprapaths each year (The Swedish Naprapathic Association, 2015). Research on a combination of treatment techniques, such as those in naprapathy, for the variety of common musculoskeletal disorders found in primary care and on waiting lists for secondary care has to our knowledge never been performed.

HEALTH TECHNOLOGY ASSESSMENT (HTA)

Health technology assessment may be performed from an individual or a multidisciplinary scientific perspective, asking important questions about these technologies, and answering these questions by investigating four main factors:

whether the technology works

for whom

at what cost

how it compares with the alternatives

(The National Institute for Health Research; NIHR, 2013).

HTA is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technique. Its aim is to “inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value” (Kristensen, 2009). HTA covers all interventions and procedures in healthcare, such as diagnosis and treatment, medical equipment, pharmaceuticals, rehabilitation, disease prevention and organizational and supportive systems. The Swedish Council on Health Technology Assessment performs scientific assessment of health technology and is known internationally by its Swedish acronym SBU. Health Technology is given a broad definition by SBU, and focuses more on methods than on products. The main task for SBU is to critically examine the methods for prevention, diagnosis and treatment in health care (SBU, 2006).

Four main streams of applied research methodology have contributed to the development of HTA:

- policy analysis
- evidence based medicine (EBM)
- health economic evaluation (QALYs)
- social and humanistic sciences

(Kristensen, 2009).

Policy analysis

Policy analysis is "determining which of various alternative policies will most achieve a given set of goals in light of the relations between the policies and the goals"-(Nagel, 1999). Policy analysis it has its roots in systems analysis as instituted by United States Secretary of Defense during the Vietnam War (Radin, 2000), and is frequently deployed in the public sector. Policy analysis forms a general framework for policymaking in HTA/in HTA, while EBM and health economic evaluation form the methodological frames for the analyses carried out as part of an HTA. A majority of European Union member states have public sector HTA agencies that provide information for decision-making and policy-making at regional or national levels (Battista & Hodge, 1995). In Sweden it is called the Swedish Council on Technology Assessment in Health Care: SBU.

Evidence based medicine

Evidence based medicine (EBM) derives from the Scottish physician and epidemiologist Archibald Cochrane (Cochrane, 1972). Cochrane claimed that many treatments and methods used in healthcare lacked proved effects. He wanted medical and caring interventions to be based on the outcomes of high quality scientific trials (Cochrane, 1972). Cochrane was one of the first within the medical field who recommended randomized controlled trials (RCT), to evaluate the effects of different treatments. In his opinion such trials were more reliable than others, in that the researcher was able to control for most factors that could possibly affect the results. Cochrane also pleaded the importance of systematic reviews of well-performed clinical studies and his endeavour led to an international collaboration of systematic summaries of scientific results, "The Cochrane Collaboration", in 1993. The collaboration is an independent scientific network in which researchers cooperate to elaborate and continuously update and publish systematic reviews. EBM was first described in 1992, by "the

Evidence-Based Medicine Working Group”, as a support for clinical decision making in healthcare. Different guidelines for EBM have also been established, which have probably had a great impact on how evidence is defined, and how the concept has been interpreted and used (Oxman, Sackett & Guyatt, 1993).

Definition of the concept EBM:

“The practice of evidence-based medicine means integrating individual clinical experience with the best external clinical evidence from systematic research”.

EBM should be regarded as an integration of knowledge in clinical decision making, where scientific evidence is one of three aspects; the two others being clinical ability and the patient’s valuations and priorities (Sackett, Rosenberg, Gray, Haynes & Richardson, 1996; Grol & Grimshaw, 2003).

Health economic evaluation

There are several kinds of health economic analyses, and a key issue for decision making with regard to which programmes and interventions to fund, is cost-effectiveness analysis. In a cost-effect analysis one or several treatments regarding costs and health outcomes are compared. Depending on the patient population and the treatment method, the effect measures vary between different studies. The cost effects of, for example, lost kilos in a diet program, and gained life-years after major surgery are difficult to compare (Bartha, Carlsson & Kalman, 2005). Also, it is not evident that the described health effects correctly mirror the patient’s own experienced state of health. (Henriksson & Bjurström, 2006). For those reasons the Quality Adjusted Life Year (QALY) was developed in the middle of 1980, with the aim of trying to weigh the quantity and the quality of health into a common health state utility (Brazier, 2008). The QALY reflects changes in health-related quality of life, and when combined with an evaluation of the costs required for this change, the cost for a QALY may be calculated. (Bravo, Vergel & Sculpher, 2008).

Social and humanistic sciences

HTA also includes methodologies from social sciences and humanistic research. There is interdependence and division of work between research-based assessment and decision-making (Velasco-Garrido, Zentner & Busse, 2008), and “the role of HTA has been compared with that of a bridge between research and decision-making” (Battista et al., 1995). Social and humanistic sciences are important in HTA in that they supports its practical application in health systems. More research on their relation to health policy is needed (Kristensen F,

2009). Also, social and humanistic research is important in striving for sustainability in health; it is of importance to support and to encourage people to gain control of their daily life and of their health, and social and humanistic sciences comprise methodologies such as empowerment and health literacy. The point of departure for empowerment is that neither individuals, nor communities can reach good public health if the individuals cannot rule the conditions that decide our health (Naidoo & Wills, 2000). Regarding health literacy, the interest in the relationship between poor literacy skills and health status is well recognized, and has led to the emergence of the concept of health literacy (Nutbeam, 2008).

AIMS OF THE THESIS

The present thesis comprises five studies. The first study is an epidemiological cross sectional study that examines associations between musculoskeletal pain interfering with normal life in older adults, and physical and psychosocial workloads through life. It serves as a background to the other studies, of which three comprise technique in the shape of NMT, its cost effects and utilities. In the fifth study the experiences of patients receiving text messages via mHealth technique, in order to enhance the compliance with home exercises after NMT, are explored.

The overall aim of this thesis was to increase knowledge of musculoskeletal pain that interferes with normal life, and from a HTA perspective to investigate the treatment and cost effects of the concept NMT, and patients' experiences of mHealth used for reminders of home exercises. The specific aims were:

To investigate if musculoskeletal pain interfering with normal life in older adults is associated with heavy physical and negative psychosocial workloads through life.

To compare the treatment effects of NMT versus orthopaedic standard care, for low priority orthopaedic outpatients with musculoskeletal pain and disorders.

To describe the treatment effects of manual manipulation of the acromio-clavicular joint for Adhesive capsulitis in a young woman for persisting pain after mobilization of the gleno-humeral joint under anaesthesia.

To compare the consequences in terms of quality adjusted life years (QALYs) and costs (DRG), for low priority orthopaedic outpatients of working age, after NMT and orthopaedic standard care.

To explore older adults' experiences of text messaging for adherence to home exercises after NMT for recurrent LBP.

METHODS

MATERIALS AND METHODS OF STUDY I

Study population

The sample in Study I derives from a longitudinal study, the Swedish National study on Aging and Care (SNAC). The participants were included in the study and participated in baseline examinations performed between 2001 and 2003. SNAC is a large, longitudinal, multidisciplinary study, integrating population, care and social services data. The study provides information from different aspects: health status, functional and cognitive ability,

social and economic situation, perceived quality of life, use of drugs, received formal and informal care, services and living conditions, etc. The study participants in SNAC were randomly selected from 10 age cohorts representing the older adult population of Sweden. . Data were collected by structured interviews, medical examination, and questionnaires. These were undertaken by trained research staff. Detailed information about the source population and how the participants were randomly selected has been described previously (Lagergren et al., 2004). The source population of the present study is one of the four main areas of the SNAC study, the Karlskrona municipality in Blekinge county (SNAC-B). The area has 61,000 inhabitants and is defined as a suburban region, in southern Sweden, typical of similar sized regions in northern Europe. The study population in the present study derives from the baseline survey of the four youngest age cohorts in SNAC-B. Inclusion criteria were Swedish men and women aged 60, 66, 72, and 78 years at baseline who had filled out the questions regarding pain in the musculoskeletal system. In an attempt to define physically impairing, non-pathological musculoskeletal pain, subjects with the worst pain in the head/face, chest, abdomen, or genitals, and subjects with diagnosed, pain-related cancer or inflammatory joint disease were excluded (Figure 1).

Pain interfering with normal life

Musculoskeletal pain was explored by three questions. The first question was: (1) "Have you experienced ache/pain during the last four weeks?" with answers "Yes" or "No". (2) The quality of life survey EuroQol 5 Dimensions (EQ5D) (Shaw, Johnson & Coons, 2004), the pain item "Pain/disorders," with answer alternatives: (a) "I do not have either pain or disorders," (b) "I have moderate pain and disorders," and (c) "I have severe pain and disorders". (3) The Swedish

Health Survey Short Form-12 (SF12) questionnaire (Gandek et al., 1998) the pain item: “How much, during the past 4 weeks, has ache or pain interfered with your normal life/work?” with answer alternatives: (a) “Not at all,” (b) “A little,” (c) “Moderate,” (d) “Much,” and (e) “Very much”. Participants who answered Yes to the first question, answered either (b) or (c) to the second question and scored positively (c–e) on the item in the third question were considered to have musculoskeletal pain interfering with normal life. Other participants were considered not to have musculoskeletal pain interfering with normal life. To locate the pain the participants were asked: “Where is your pain located?” with answer alternatives: (a) head/face/mouth; (b) neck/throat; (c) back (upper back, lower back, pelvis); (d) joints; (e) shoulders/arms/hands; (f) leg/knee/foot; and (g) chest, (h) abdomen, and (i) genitals. It was possible to fill out several pain locations. To locate the worst pain the participants were asked: “In which part of your body is the pain/ache worst?” The answer alternatives were the same as mentioned above. Participants who scored (a), (g), (h), or (i) for the part with the worst pain were not included in the study.

Physical and negative psychosocial workloads

Since earlier studies have found associations between musculoskeletal pain and both physical and psychological factors (Andersson, 2004; Tuomi, Seitsamo & Huuhtanen, 1999), two main independent variables were chosen: physical workload and bodily and/or mentally perceived negative work burden. In the logistic regression models eight background covariates considered to influence the outcomes were also used: age, gender, growing-up environment, educational level, obesity, smoking, living alone or not, and physical leisure activity. The variables were re-coded for analysis as follows.

Main covariates

(1) *Physical workload*. The participants were asked: “To what degree did your main profession include physically hard work?” With answer alternatives (a) “Very light” – Sitting work (e.g., driving a vehicle, reading, office work), (b) “Light” – Standing with light muscle activity (e.g., feeding, washing up, precision-tool work, teaching), (c) “Moderate” – Muscle work with moderate intensity (e.g., lifting/carrying less than 5 kg, washing, cleaning, taking care of children), (d) “Heavy” – Quite high-intensity muscle work and increased respiration (e.g., maintenance, lifting/carrying/turning patients in health care, heavier garden work, shipping goods), (e) “Very heavy” – High-intensity

muscular activity with much increased respiration (e.g., bricklaying, carpentry, construction work, lifting/carrying more than 25 kg).

The variable was dichotomized into “heavy physical workload” (d, e) and “not heavy physical workload” (a–c) (Lagergren et al., 2004).

(2) *Negative psychosocial workload.* The question read as follows: “Do you find that your occupation has been organized so that it has implied a great burden, bodily and/or mentally, which has had a negative impact on your life or your health?” The answer alternatives were “Yes” or “No” (The Swedish Work and Environmental Inspection). In order to avoid overlap of question (1) and (2), this variable was adjusted for heavy physical workload in the logistic regression analysis.

Background covariates

(1) *Urban/rural living.* Growing up in the country, being forced to daily, varying, physical activity is different to growing up in a city. The question read: “Where did you grow up?” The answer alternatives were: (a) “in the country,” (b) “in a community with at least 500 inhabitants,” (c) “in a small town” (at least 10 000 inhabitants), (d) “in a medium-sized town,”

and (e) “in a big city.” According to national recommendations the alternatives (a) and (b) were recoded to “in the country side” and (c–e) to “in a city” (SKL, 2005).

(2) *Education.* The question read: “Have you completed elementary school.” The answer alternatives (“Yes” or “No”) were scored “Elementary education” and “Lower education,” respectively (SCB, 2011).

(3) *Living alone.* The question read: “Do you live alone?” with the answer alternatives; “Yes” or “No.”

(4) *Smoking.* The question “Do you smoke” had the following answer alternatives: (a) “Yes, I smoke regularly,” (b) “Yes, I sometimes smoke,” (c) “No, I have stopped smoking,” and (d) “No, I have never smoked.” The answer alternatives were dichotomized in (a–c) = “Smokers” and (d) = “Non smokers.”

(5) *Obesity.* Body mass index (BMI) was measured by dividing the weight in kilograms by the square of the height in meters (kg/m²). BMI values of more than 30 were scored positively; as “obesity,” all others were scored negatively (WHO, 1995).

(6) *Physical leisure activity*: The question read: "For leisure, do you normally, during the last 12 months or earlier: (a) done garden work, (b) picked mushrooms, (c) walked in the forest, or (d) gone hunting or fishing?" The answer alternatives were "yes" or "no" for each of the items, and a new variable was created and scored positively if at least one of the items or more were answered with "yes." If none of the variables were scored, the item was scored negatively.

Statistical analysis

Statistical comparison of differences between subjects with and without musculoskeletal pain interfering with normal life was made by the chi-square test. Multiple (binary) logistic regression analysis with backward selection was used to estimate which independent variables predicted the tested domain and to calculate the odds ratio (OR) at 95% confidence interval (95% CI). The model was adjusted for background factors that could confound the results: age, gender, educational level, growing-up environment, obesity, smoking, if living alone or not, and physical leisure activity. Data were analyzed using SPSS for Windows (PASW, version 19).

MATERIALS AND METHODS OF STUDY II

Study population

The source population in Study II consisted of patients on the waiting lists at the Department of Orthopaedic Surgery at Blekingesjukhuset, the province hospital in Karlskrona, in southern Sweden, between June 2006 and June 2007. The patients were referred from general practitioners in primary care in the whole province, two private orthopaedic surgeons, different departments in the hospital, company health services, and "own referrals". The referrals concerned patients who had been selected as "low priority" and "non-urgent referrals" according to orthopaedic specialist classification before the trial was planned. Referrals concerning patients without suspected disc protrusions, tumours or conditions requiring surgery within six weeks had been selected as low priority. Inclusion criteria for the study were patients between the age of 18 and 65 years, without an explicit need for radiography, surgery or suggestion for diagnosis expressed in the referral letter. Referral letters with an explicit wish for an orthopaedic opinion were withdrawn. Exclusion criteria were "trigger fingers",

numbness in the hand with only two or three fingers involved, meniscal tears, obvious or suspected acute prolapsed disc or disc injury, specific rheumatic diseases, and patients with contraindications for spinal manipulation. Further, patients unable to understand Swedish, patients on 100% sick leave (due to the reason of the referral), pregnancy, findings on 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. Decisions about eligibility for the remaining patients were based on the referral letters, and appropriate additional information available in the hospital's medical records (e.g. results from radiography, sick leave, previous surgery, etc.). See flow chart, Figure 2.

Randomization and Interventions

Two nurses chosen by the manager of the department subsequently randomized the remaining 98 included patients (from 199 potential study persons) into two 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 two treatment groups similar, as well as the workload level for the naprapath. The randomization was performed on six different occasions, as soon as there were at least 10 (or a higher number divisible by two eligible patients). Together with information about the study, a time reservation for an appointment with the orthopaedist or the naprapath, a baseline questionnaire and a form 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 had the right to be scheduled to an orthopaedic surgeon, according to their referral letter, in case they did not want to participate in the trial, or, if they chose to participate, and the naprapathic treatment had not been successful, they could also have an appointment with an orthopaedist. Except for this, the information was the same for both groups. There was no information sent to the study participants about the number of treatments offered in either group. All treatments in both groups conformed to the patients' conditions and were performed at the orthopaedic outpatient clinic in the hospital, and the patients were charged a standard rate for

each visit, equal in both groups. The treatments were carried out from January 2007 to November 2007.

Naprapathic manual therapy (index group)

A maximum of five treatments within five weeks were given by one well-experienced naprapath. The time set for the first appointment was 45 and 30 minutes for 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 from their own clinics, responsible for diagnostic and management decisions as well as treatments. Consequently, this was performed the same way in the orthopaedic clinic, without any second opinion from an orthopaedist.

Standard orthopaedic care (control group)

Thirteen well-experienced orthopaedic surgeons were in charge of the control group, according to their specialty and allocation schedule. The consultation/treatment was

conventional orthopaedic judgment ("care as usual") as, for example, advice, medicine prescriptions, steroid injections, surgery, referrals for radiography, physiotherapy, or other different investigations, with as many appointments, measures or steps as needed. The consultations were conducted in the way they are normally conducted at the department (i.e. "orthopaedic standard care")

Outcomes and Follow-ups

Follow-up was performed after 12, 24, and 52 weeks after the inclusion by mailed questionnaires. All documentation in both groups, visits, examinations, treatments, surgery, other referrals, and telephone calls, was carried out in the hospital's medical records and international diagnostic codes (WHO, 2015) were used.

Primary Outcomes

The primary outcomes of pain and physical function were measured by the SF-36 survey (Sullivan & Karlsson, 1998). Pain intensity when at its worst the last 2 weeks was measured by the Visual Analogue Scale (VAS) (Lundeberg et al., 2001) with the anchors "no pain at all", 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 orthopaedists, for the cross-over patients. Perceived recovery was measured by a question in the questionnaire at follow-up after 24 and 52 weeks, respectively, 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" (Fischer, Stewart, Bloch, Lorig, Laurent & Holman, 1999). 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 (Skillgate et al., 2007). 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 judgement 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 orthopaedic 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 (Skillgate et al., 2007). A total of 80 patients indicated a power of 80% to detect a relative risk (RR) of 1.2 to 1.32 for a clinically important improvement in pain and physical function. A 20% to 30% improvement was the threshold for a clinically important improvement in pain (VAS) (van Tulder, Malmivaara, Hayden & Koes, 2007). 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 (Hollis & Campbell, 1999). Differences between the groups at baseline were tested using χ^2 tests and One-way analysis of covariance (ANCOVA) was used to test the statistical

significance of differences between groups, adjusted for baseline differences in age, pain (VAS), and body localization. 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 $P < 0.05$. To compare the groups regarding the dichotomized outcomes, RR and risk differences together with corresponding 95% confidence intervals (CI) were calculated. Statistical analysis of the outcomes were managed by a statistician without knowledge of the group assignment.

MATERIALS AND METHODS OF STUDY III

Study participant

The case in Study III - a 29-year-old woman - derived from Study II, where she was randomised to the control group. She experienced a dull, deep pain in her right shoulder, and increasing difficulty lifting her arm, without any definable cause. She had a stressful job at a computer terminal in an office, had a two-hour daily commute, and experienced difficulties while working at her computer terminal and while performing household tasks such as vacuuming, doing dishes, washing and braiding her hair. The ache made sleeping difficult and she could no longer sleep in her preferred (prone) position. She usually woke up several times a night and seldom slept for more than three hours at a stretch, and was frequently troubled with headache. Vacation and rest made no improvement on her condition. In addition to the symptoms associated with AC the patient also experienced radiating pain and numbness in her right arm, hand and fingers. First, the patient had an appointment with a general practitioner (three months after onset). The general practitioner prescribed medication, set the patient on sick leave, gave a steroid injection and referred her to radiography and physiotherapy. The patient had physiotherapy for five months, with only minor improvement, which was why she was referred to an orthopaedic outpatient department. After some time on the waiting lists she was asked if she wanted to participate in the clinical trial described in Study II, and was randomised to the control group (standard orthopaedic care). When included in the trial, the patient had mobilization under anaesthesia, followed by additional physiotherapy and additional medication. The patient's mobility improved but not her pain, sleeping disorders or radiations. At the last follow-up in the trial, after 52 weeks, her mobility was still improved, but not the pain and sleeping disorders.

Therefore, a naprapath was consulted. The naprapath performed a manual manipulation to the patient's center of pain: her right acromio-clavicular joint. It was a high velocity, low amplitude manipulation with a thrust, performed in a cranial/lateral direction. Due to the design of the study, the data was descriptive, including the worst pain (VAS), bodily pain and physical function (SF36), range of motion (degrees of elevation of the affected arm), medication, sleep pattern and perceived recovery. The measurements were performed at baseline (i.e. at the 52-week follow-up in Study II), and at one and 52 weeks after the NMT.

MATERIALS AND METHODS OF STUDY IV

Study population

The same study population as in Study II were used to compare the utilities and costs of NMT and orthopaedic standard care. 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 orthopaedic consultation, if the patient needed or wished it. Thus, as a secondary outcome, the level of agreement between the naprapath and the orthopaedists was recorded, as was the number of patients who agreed to be discharged from the waiting lists directly after the NMT. Both the interventions performed in the trial and self-elective treatments in both groups were recorded during the follow-up time, and calculated as a part of the total costs.

Diagnose Related Groups (DRG)

"Prices and compensations for the health region in the south of Sweden" (Helsedirektoratet, 2011) based on DRG, was used to define interventions and costs in hospitals related to a diagnosis (**ibid**).

This system has detailed information on prices for different interventions. Central variations for the DRG classification are: diagnosis, procedure, sex, age, and discharge status. DRG was used to substantiate each effort in the RCT and was documented for all interventions in both the groups. 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 (Brazier, Roberts, Deverill, 2002). 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. To estimate the cost utility in the health care, QALY has been developed (Brazier, 2008). 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 (Brazier et al., 2002)). When calculating the QALY gains the mean QALY values per person in the groups at base-line 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.

MATERIALS AND METHODS OF STUDY V

The study population in Study V consisted of eight older patients (four women, four men), aged 67 - 80, who were consecutively treated with NMT, for recurrent LBP in a Naprapathic clinic. The patients had sought this treatment method themselves. It was privately financed and the participants were treated with as many sessions as their condition required in order to be free from pain and related symptoms. They were asked for participation in the study at their last treatment session and recruited consecutively through purposive sampling, which was accomplished when it was possible to identify themes in the material. One or two exercises were given, individualized and adapted to the patients' conditions (e.g. stretching of the ilio-psoas and/or quadratus lumborum muscles, and/or stretching of the glutei muscles, and/or breathing technique). The home exercises were thought to help the patients/participants to avoid recurrent pain, and followed normal clinical procedures, to aid the transferability of the study. The stretching exercises took a couple of minutes each time, whilst the breathing technique was supposed to be performed at intervals throughout a whole day. The messages were individual for each patient, and were sent to them through SMS:s to their mobile phone, since it was perceived to be the quickest way for the participants to pick them up. They were sent every third day for three weeks, then once a week for another two weeks, and the interviews took

place one week after the last treatment session (i.e. when the SMS reminder would normally arrive)

The participants were asked two broad questions (Cresswell, 2013):

1. “What have you experienced in terms of the phenomenon `SMS reminders for home exercises?’“

and:

2. “What contexts or situations have typically influenced or affected your experiences of the phenomenon?”

Follow up questions were guided by the conversations (Kvale & Brinkmann, 2009). Examples:

“What do you mean by that?”

“If I have understood you correctly . . . ”

“Could you tell a little more about . . . ?”

Data analysis: To gain an understanding of how patients experience the phenomenon of home exercise reminders via SMS after NMT, a phenomenological approach with Systematic text condensation (STC) according to Malterud was used (Malterud, 2012). STC derives from Giorgi’s principles of psychological phenomenological analysis (Giorgi, 2009). Phenomenological research can be described as a way to understand the lived relations that human beings have to their world and to human beings. The reality is comprehended through individual, embodied experience and perception, searching for the essence of a phenomenon, from the perspective of how it is experienced. It strives to find the participants’ common experience of a phenomenon, and significant statements are valuable (Cresswell, 2013). STC is an elaboration of Giorgi’s principles, including four steps of analysis with specified shifts between decontextualization and recontextualization of data (Malterud, 2012). A limited number of participants provides sufficient data for analysis, where the researcher is bracketing his or her presuppositions of the object and moves between identification with, or bracketing, during the different steps of the analysis process (Giorgi, 2009).

ETHICAL CONSIDERATIONS

The protection of a participant's health, rights and privacy are an essential element when conducting research on human beings ("WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects" 2013). The studies in this thesis were performed in accordance with the law of Ethical Review of Research Involving Humans in Sweden (SFS 2003:460) and the Declaration of Helsinki.

The participants had all signed an informed consent. The right to withdraw from the study at any time, without having to state a reason, was stressed. All participants were informed about the confidential treatment of their data and their anonymity status when presenting results.

Approval for the studies in this thesis were obtained from the Regional Ethical Review Board in Lund, Sweden (LU 605-00, LU 744-00, H4 514/2006)

RESULTS

STUDY I

Fifty-four percent of the selected sample in Study I were women. In total, pain (n=411) was reported by 64.0% of the study population (95% CI: 60.3–67.7) and musculoskeletal pain interfering with normal life (n=151) by 23.6% (95% CI: 20.3–26.9). A flow chart describing the population is shown in Figure 1. For demographics of the participants see Table 1.

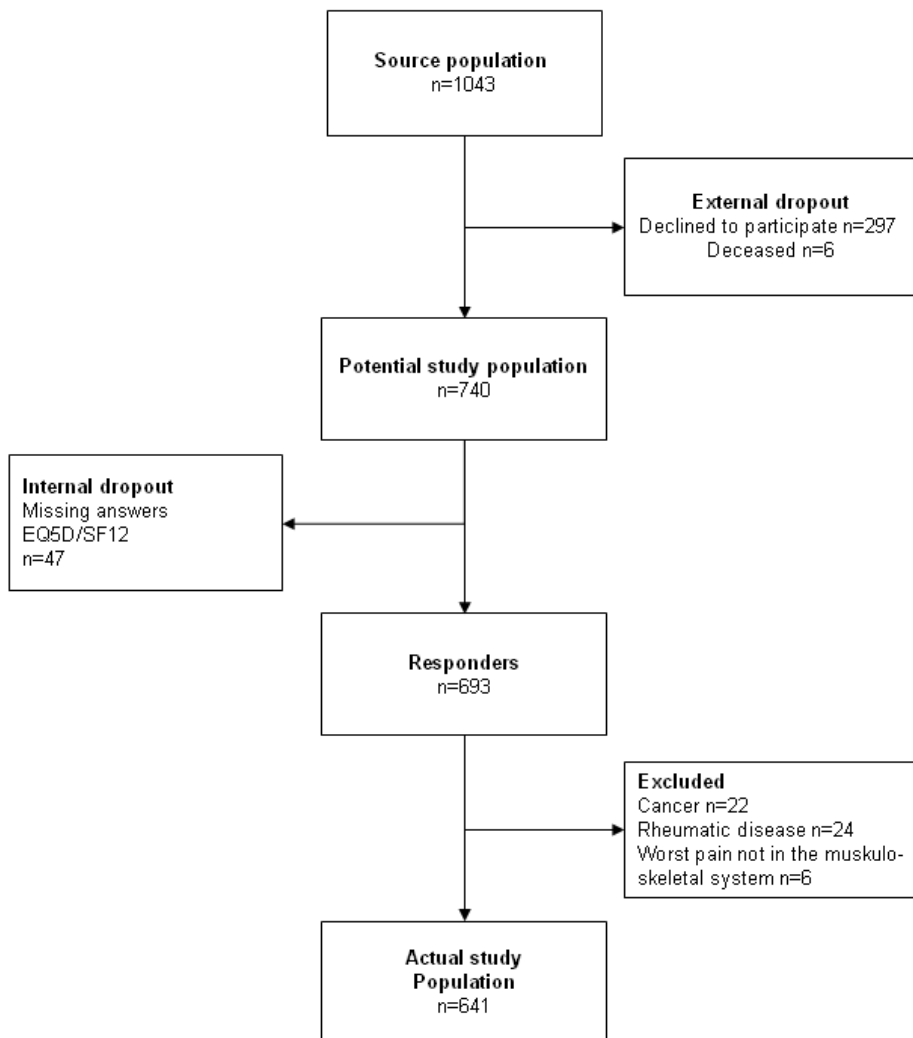


Figure 1. Flow chart describing the study population in a study on musculoskeletal pain interfering with normal life among older adults (60–78 years).

Note: Information how the source population was randomly selected in the first step is described elsewhere (Lagergren et al., 2004).

Table 1: Demographics of the participants comparing subjects with and without musculoskeletal pain interfering with normal life.

Variable	p-value	Pain:	No pain:
Gender (n = 641)	p=0,013		
Women:		95 (27%)	252 (73%)
Men:		56 (19%)	238 (81%)
Age (n=641)	p=0,612		
60 y:		37 (22%)	134 (78%)
66 y		42 (23%)	139 (77%)
72 y:		35 (22%)	121 (78%)
78 y:		37 (28%)	96 (72%)
Living alone (n=641)	p=0,213		
Yes:		45 (28%)	113 (72%)
No:		106 (22%)	376 (78%)
Educational level (n=635)	p=0,010		
Lower:		35(17%)	172 (83%)
Elementary:		112(26%)	316 (74%)
Smokers (n=632)	p=0,097		
Smokers:		89 (26%)	251 (74%)
Non smokers:		60 (20%)	232 (80%)
BMI >30 (n=636)	p=0,022		
Obese:		50 (29%)	121 (71%)
Not - “ -:		96 (21%)	369 (79%)
Growing-up environment (n=624)	p=0,440		
Urban:		36 (22%)	130 (78%)

Rural:		113 (25%)	345 (75%)
Physical workload (n=595)	p=0,008		
Not heavy:		87 (20%)	341 (80%)
Heavy:		51 (30%)	116 (70%)
Perceived negative work burden (n=635)	p= 0,000		
Yes:		69 (45%)	85 (55%)
No:		78 (16%)	403 (84%)
Physical leisure activity (n= 633)	P= 0,010		
Yes:		73 (20%)	299 (80%)
No:		74 (28%)	187 (72%)

Note: Corresponding p-values referring to the distribution of pain in the different independent variable

The most common site of pain was the leg, knee, and/or foot (70,2%), followed by upper/lower back (60,3%), joints (57,6%), shoulder/arm/hand (55,6%), and neck (43,0%). The most common number of pain sites was four (24,3%), followed by two (20,0%), five (19,3%), three (18,6%), and one (17,8%). The logistic regression analyses showed that the negative psychosocial and heavy physical workloads were independently associated with musculoskeletal pain interfering with normal life in older adults (adjusted OR: 4.44, 95% CI: 2.84–6.92), and (adjusted OR: 1.88, 95% CI: 1.20–2.93), respectively (Tables 2 and 3).

Table 2: Crude and adjusted logistic regression analysis (OR 95% CI) describing factors related to musculoskeletal pain interfering with normal life in older adults. Negative psychosocial work load is analysed in a crude and an adjusted analysis, including heavy physical work load.

Variables:	Crude; (n=591) Cases=136	Adjusted; all (n=560) Cases=125
Negative psychosocial work load	4,19 (2,81-6,25)	4,44 (2,84-6,92)
Heavy physical work load		1,40 (0,86-2,27)
Physical leisure activities		0,38 (0,18-0,82)
Age		
Female gender		1,79 (1,15-2,79)
Growing-up environment		
Living alone		
Educational level		1,62 (1,01-2,61)
Smoking		
Obesity		

Table 3: Crude and adjusted logistic regression analysis (OR 95% CI) describing factors related to musculoskeletal pain interfering with normal life in older adults. Heavy physical work load is analysed in a crude and an adjusted analysis, with negative psychosocial work load not included.

Variables:	Crude; (n=591) Cases=136	Adjusted; all except for negative psychosocial work load (n=564) Cases=127
Negative psychosocial work load		N.a.
Heavy physical work load	1,72 (1,15-2,58)	1,88 (1,20-2,93)
Physical leisure activities		
Age		
Female gender		1,99 (1,29-3,07)
Growing-up environment		
Living alone		
Educational level		
Smoking		
Obesity		

STUDY II

The flow of patients through the trial is shown in Figure 2. The index group in study II (NMT) were younger, had more pain intensity at baseline and their pain locations differed from the control group regarding the foot/leg (more common when compared with the control group) and knee (fewer when compared with the control group; see Table 4), why an additional analysis of covariance (ANCOVA) was made. It showed no confounding effects of these differences on the association between treatments and the main outcome. There were differences in pain and physical function between the index group that received NMT treatments and the control group receiving orthopaedic standard care, favouring the index group, but none were statistically significant. The changes in physical function and bodily pain measured with SF 36, and for the worst pain measured with VAS, within the index group were statistically significant compared with baseline at all follow-ups, but only for bodily pain at all follow-ups in the control group. There were also statistically significant differences in changes between the groups at all outcomes, at all follow-ups, favouring the index group. The proportion of patients who were little or much recovered regarding the question of "perceived recovery" was 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 weeks and 28% at the 52-week follow-up). These differences were statistically significant both in absolute difference (risk difference = 38%; 95% CI: 18-59 at 24 weeks and 36%, 95% CI: 15-58 at the 52-week follow-up) and in terms of RR (RR=2.0, 95% CI: 1.3-3.2 at 24 weeks, respectively, RR=2.3, 95% CI: 1.3-4.1 at 52-week 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 orthopaedists agreed on no intervention, the number of patients who would have been discharged from the waiting lists was altogether 32 (80%). The average number of naprapathic treatment sessions was 4,1. The orthopaedic interventions for the control group are shown in Table 5.

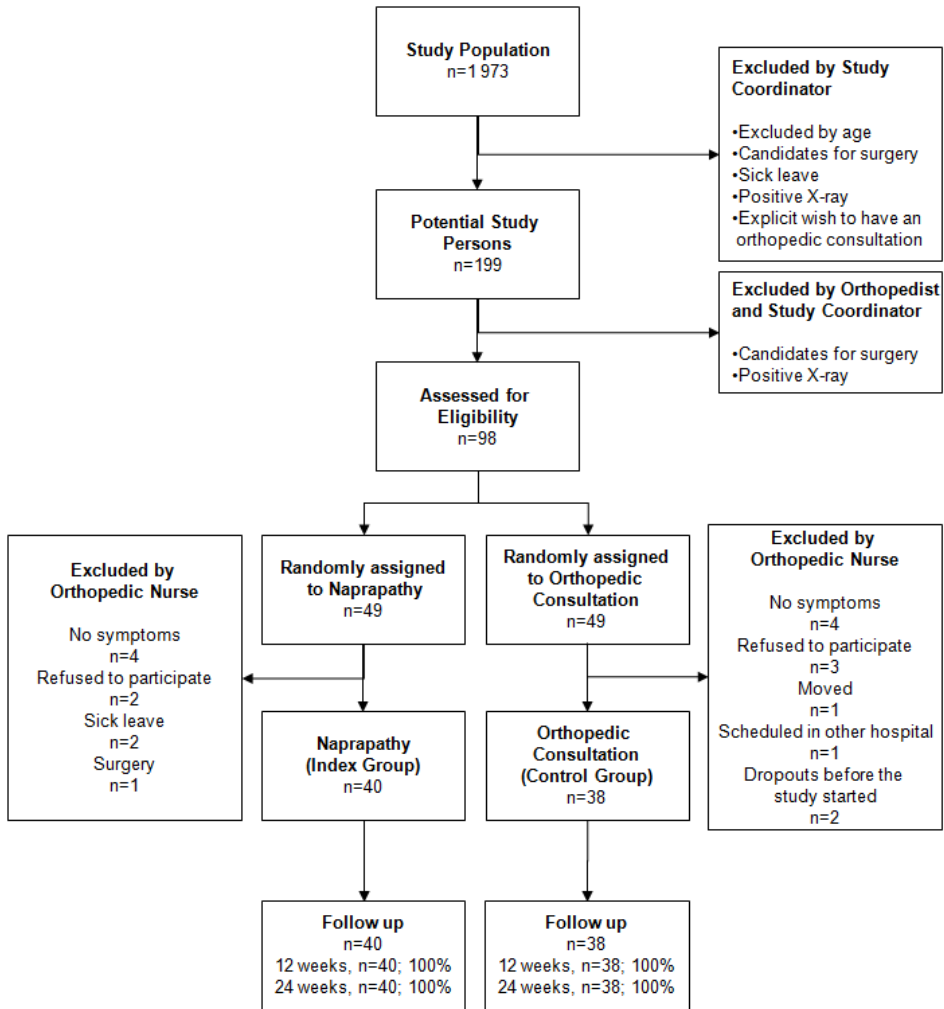


Figure 2. Flow chart describing the progress of patients throughout the trial.

Table 4: Previous interventions and prognostic indicators for all study participants before inclusion.

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

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

\dagger Medicine requiring prescription only.

\ddagger Chiropractor, osteopath, acupuncture, CRP/ Borrelia/SR, orthosis, surgery.

§ Higher value indicates less pain/better physical function.

α Statistically significant differences between the groups (p<0.05).

Table 5: Orthopaedic interventions. Horizontally according to the number of orthopaedic appointments and vertically to the total number of interventions made as a result from these appointments, distributed in the three respective groups.

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)

* Neck

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

STUDY III

The case in the study is a young woman (aged 29) who suffered from increased pain in her right shoulder, distinctly restricted movement and “electric chock sensations”, without any definable cause. Conventional primary care (an appointment with a general practitioner) for the patient resulted in a steroid injection, medication, referral to physiotherapy, and sick-leave. During physiotherapy the mobility of the affected shoulder varied over time, but the pain and sleeping disorders persisted. When included in the trial in Study II the patient had mobilisation under anaesthesia, which resulted in increased active abduction, but the pain, electric sensations and sleeping disorders persisted. Almost a year after the surgical intervention (23 months after onset), the patient’s mobility, pain and sleep disorders were unchanged, which is why she had an appointment with a licensed naprapath. Before treatment on the first treatment session the elevation was 70 degrees. Directly after a high velocity, low amplitude manual manipulation performed to the most painful area (the acromio-clavicular joint), the elevation was 130 degrees. At follow-up, one week later, the patient reported that she had experienced severe pain for a couple of hours directly after the manual manipulation, after which the numbness and electric sensations in her arm and hand disappeared. She was now able to move her right arm without restriction. The patient had ceased her Panocod medication, and she was able to sleep through the whole night, and to braid her hair (See Table 6).

Table 6: Outcomes of conventional and specialized manual treatment, respectively, at follow-up after 12, 24, 52, 55 and 107 weeks.

	At baseline in the RCT (11 months after onset)	12 weeks after baseline in RCT 8 weeks after manipulation under anaesthesia	24 weeks after baseline in RCT 20 weeks after manipulation under anaesthesia	52 weeks after baseline in RCT 48 weeks after manipulation under anaesthesia	55 weeks after baseline in RCT 1 week after manual manipulation	107 weeks after baseline in RCT 52 weeks after manual manipulation
VAS* (the worst pain)	100 mm	99 mm	99 mm	74 mm	25 mm	3 mm
SF36; bodily pain**	Very severe	Very severe	Severe	Severe	A little pain	No pain
SF36; restricted*** physical function	Very much	Much	Very much	Much	No restriction	No restriction
ROM; elevation external rotation	15° 30°	80° 50°	80° -	70° 40°	Unrestricted "	Unrestricted "
Perceived recovery	-	Unchanged	Slightly better	Unchanged	Much better	Much better
Medication	NSAID, sleeping pills	NSAID, sleeping pills, Gabepentin, Hexal	NSAID, sleeping pills, Gabepentin, Hexal (increased intake)	NSAID, sleeping pills, Gabepentin, Hexal,	Gabepentin, Hexal (decreased intake)	None
Sleep	Four hours sleep per night	Four hours sleep per night	Four hours sleep per night	Four hours sleep per night	No sleep disturbances	No sleep disturbances

*) A 100 mm scale, with the anchor 0 ("no pain at all"), and 100 ("worst imaginable pain"). The mean value from three different scales (the pain when at its worst, the pain at present, and the average pain for the last four weeks) were assessed.

**) The question read: "How much pain or ache have you experienced during the last four weeks"?

***) The question read: "During the last four weeks, how much has pain or ache interfered with your normal work (including both professional and domestic work)?"

STUDY IV

The results of Study IV was that the individual mean quality of life values at baseline were lower in the index group compared to the control group, which 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. A QALY gain of 0,04 corresponds to the value of 15 days in full health, or assuming the willingness to pay about €2,000 based on one QALY in the magnitude of €50,000 ($0,04 \times €50,000$), which is a reasonable threshold value used for a health condition of medium degree of severity (TLV, 2013). Applying a conservative value of one QALY in the region of £30,000, which as is the widely cited threshold value used by NICE in England (Rawlins & Culyer, 2006), results in a value of the health gain per patient in the magnitude of £1,200. The mean costs per patient and month, and the total mean costs are described in Table 8. A sensitivity analysis was made in order to investigate uncertainty in cost drivers. The largest fraction of cost offset is attributable to a difference in surgical interventions (171,099 SEK); six patients undergoing surgical procedures in the control group were compared to 1 in the index group. The types of surgical interventions for the control group (n=7) 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 to the index group (Table 7).

Table 7: Types and number of consultations, tests and procedures, and costs for the different interventions in each group.

Type of intervention:	Control group:	Index group:	Total cost in SEK:	
			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)*	1,650	630
Orthopedics	53 (38)	15 (15)*	106,000	30,000
Radiography/tests	20 (19)	12 (6)*	37,346	19,197
Surgical procedures	7 (7)	1 (1)*	187,439	16,340
Drugs/injections	18 (18)	3 (3)*	6,933	3,141
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.

***) Self elective treatments; Chiropractic, massage, orthopedic consultation and company health service.

Table 8: Individual mean cost per month for different follow-up periods and total mean cost per group (SEK).

	Baseline-3 months	4-6 months	7-12 months	Total mean cost
Control group (n=38)	2,827	(n=38) 651	(n=37) 644	14,298
Index group (n=40)	987	(n=40) 686	(n=38) 68	5,427

STUDY V

The SMS reminders of home exercises after NMT for recurrent LBP in Study V were perceived as positive by all the participants. They found that the SMS technique was easy to handle, the exercises easy to perform and that it was helpful to be reminded. The participants were pain/symptom free when the interviews took place, and they stated that therefore they didn't continue as thoroughly with the exercises; they simply forgot to perform them. This was also the case when going on a trip and staying away, overnight. All the participants were reflective about the usefulness and the value of the exercises and the fact that their pain had improved, and some of them stated that they would have wanted extended exercises.

Their experiences were that they were stimulated to memorize things, to reflect about the exercises and to create their own routines in order to continue with them, when they SMS:s would cease to come. Quite different options were mentioned, like having specific routines when going to the gym, or when warming up before a golf session, performing the exercises at the same time as a daily medication, having mobile phone alerts, and to write a diary for the exercises.

The results of the interviews were divided into three themes, each with three to four subgroups. The themes were:

1. Appreciation (subgroups: usability, stimulation for memorising).

The participants' experiences of the SMS reminders were that they were satisfied to be reminded, and they found the exercises easy to perform, since there were few and they did not require any equipment. The reminders were perceived as timely, never annoying, and it was possible to perform the exercises as soon as the SMS:s arrived.

"I thought that it was REALLY good to be reminded . . . it was such an easy exercise, compared to when I was to lay on the floor and pick up a ball and make something that took quite some time; I mean, many more exercises . . . This exercise, I could perform it when I was standing by the oven, waiting for the tea water to boil." (P3).

" . . . I thought then that ONE alternative to this would be to MAKE a list and tick it off, and . . . that you make your own list; that wouldn't be bad, because thus I'd see: "well, I didn't do anything yesterday". (P7).

" There is nothing (disturbing) about it, when it comes to such things. It is different with all the telephone salesmen . . . That is when you get upset! THIS is only positive. " (P5).

2. Reflections (subgroups: aim, value, improvement in pain)

In the last section of the interviews, the participants expressed reflections about the aim of the exercises. Firstly they reflected about the value of the exercises, and how these were useful to them. Their experiences were that the reminders were valuable and useful.

" . . . I haven't thought of it (the exercises), more than, eh, what the aim was; or whether I would feel better, or . . . then I have reflected a little about my breathing, whatsoever, HOW I breath (laughter). If I breathe through my trunk, and HOW I do that, and WHEN I do that, and when I DON'T. Well, I have had THESE thoughts . . . (you ask me to breathe like that, and then I wonder a little; how do I breath, actually?) . . . I have never reflected on that before . . . " (P2).

" . . . Well, the thing is, I believe, that it is VALUABLE to me, myself, to perform those exercises; there is something positive about it. It has only been positive." (P4).

Secondly, the participants reflected about their improvement in pain. Most participants stated that at the time being, they were free from pain, which was positive, and even surprising to them, and they reflected about whether it was because of the exercises that they were free from pain. More than forgetfulness, the fact that the participants did not suffer from pain or disability any more, was the reason they forgot to do their exercises.

" . . . I am a little SURPRISED that it, that my back doesn't protest more than it does, right now. I play extremely much golf, eh, and, sure, I am stiff and so, in the morning, like I use to be, but since I stress my back as much as I do right now, I am a little surprised that it doesn't protest any more than it does . . . " (P2).

". . . of course, one performs the exercises less often when one is not in pain . . . right now I don't have much pain in my back . . ." (P8).

Those of the participants who had been on a trip during the follow-up period, also stated that when they stayed away over night, they forgot to perform their exercises.

". . . The thing is that I've been away, and THEN it's more difficult to remember this. Well, it is quite easy when one is at home, in one's everyday life . . ." (P6)

3. Creation (subgroups: continuation, own routines; reminders)

After reflecting about the cessation of exercises, when being free from symptoms, the participants considered creating their own routines, that would make it possible to continue with their exercises at home when the SMS:s ceased to arrive. Some of the participants also requested supplementary exercises, in order to stay pain free.

" . . . one should have it as a routine, actually; a couple of times each day. One should actually have them at each time. "Well, now I have to do it". That it says "pling" and then I have to do them. Of course, this would be possible for me to arrange myself; I have an alert on, in order to take a pill, at a certain time and . . . I have it continuously, that alert, every day. So I could fix that on my own." (P5).

" . . . it would be . . . if you put it as . . . well, as a matter of fact, I have certain routines . . . if I would HAVE it as a routine, for example when BEGINNING to

play golf. Because I use to, eh, try to stretch my back before starting to hit/swing. And THERE I would think that I could perform those exercises too, at the same time. I would consider that! But not otherwise; you have to connect/associate it to/with something.” (P2).

DISCUSSION

RESULTS DISCUSSION

Summary of findings

This thesis suggests that musculoskeletal pain that interferes with normal life in older adults is associated with heavy physical and negative psychosocial workloads through life (Study I). NMT may be cost effective for low priority orthopaedic outpatients of working age with musculoskeletal disorders that are not likely to benefit from orthopaedic surgery (Studies II and III), and was effective for a patient diagnosed with adhesive capsulitis (Study IV). Text messaging in order to remind older adults of home exercises after NMT is appreciated, and stimulates reflection about pain and exercises, is an aid to memorising, and to the creation of one's own routines for continued compliance with the exercises (Study V).

Comparison with earlier studies

The strengths with all the studies in this thesis are that their outcomes are quite distinct and the studies hypothesis generating. In Study I the OR for psychosocial and for heavy physical workloads when analyzed separately and when analyzed together are slightly overlapping. It seems that psychosocial workloads are more strongly associated with musculoskeletal pain that interferes with normal life. The association with psychosocial workloads is in line with earlier research, where associations to musculoskeletal pain for people of working age were found (Bergenudd et al., 1994; Bergman et al., 2001). One of those indicated that factors others than heavy physical workload, such as psychosocial factors and neurohormonal changes, amongst others, may be of importance for the development and the preservation of chronic musculoskeletal pain (Bergman et al., 2001). Previous research is focused on working populations and their professional life, whilst research on older adults and the retired, including factors such as growing-up environment and leisure activities is unusual. Also, the start of professional life for the study population in Study I was between 1940 and 1960, and the question regarding psychosocial workloads (whether the participants' occupations had been "organized so that it implied a great burden, bodily and/or mentally, which had a negative impact on your life or your health") might not be possible to generalize to a similar age cohort in the future. What differed most of all in the results in Study I from previous studies is

that the covariates age and obesity were not associated with pain, and that education was inversely correlated. Heavy physical workloads (including obesity) preload the spinal cord though, (Adams et al., 2006) and it is more common that people with low education work with heavy physical loads. Regarding age, another previously published study concluded that measures of physical fitness may be more important predictors for functional tasks among older adults than chronological age (Topp, Mikesky & Thompson, 1998).

The effects of NMT on neck and LBP with regard to pain, physical function and perceived recovery in Study II correspond to the findings in earlier trials, where NMT was considered an effective treatment in the short and the long term, for patients with neck and back pain (Skillgate et al., 2007; Skillgate et al., 2010). Research on the effect of manual therapy performed by physiotherapists for neck and back pain has shown positive treatment effects (Korthals-de Bos et al., 2003), and studies on back and shoulder pain, back and knee pain, and thoracic pain support some manual therapy techniques (Tsertsvadze et al., 2014; Bokarius et al., 2010; Stochkendahl et al., 2012), whilst research on pain and disorders in the upper and lower extremities (being the most frequent pain locations in Studies I, II and III) are not commonly studied. The level of agreement between the orthopaedists and the naprapath concerning the cross-over patients from the index group was measured in Study II, and found to be 80%, which is in line with an earlier study on specialized physiotherapists' ability to diagnose and assess orthopaedic outpatients, where the level of agreement was 74% (Oldeadow et al., 2007).

There are similarities between Study III and previously published case studies on AC, where the majority of patients had undergone physiotherapy before the studies were performed (Polkinghorn, 1995; Vermeulen, Obermann, Burger, Kok, Rozing, & van Den Ende, 2000; Roubal & Placzek, 2008; Trachsel, 2009; Maricar, Shacklady, & McLoughlin, 2009). There were also significant changes in pain, mobility and physical function in all those studies. The most salient difference in the treatment modalities compared with the present study is the treatment techniques: previous studies have used different mobilisation techniques, which are not always defined in detail, whereas in Study III a high velocity manipulation technique with a thrust was performed. The treatment in earlier studies was also focused on the GHJ, whereas in ours the focus was on the acromio-clavicular joint. The number of treatment sessions, their duration and the cost for the NMT were also significantly lower for the case in Study III, than for previously published case studies.

The result of Study IV was ‘dominant’ (improved treatment effects and significantly decreased costs for the index group), which is unusual in health economic evaluations. One previous study has compared the costs and effects of chiropractic treatment with those of physiotherapy, on patients with back pain (Skargren et al., 1998), which did not show any differences between the groups with regard to costs and effectiveness. Another economic evaluation by Korthal de-Bos et al. (2003) that comprised general practitioner, physiotherapy and manual therapy (performed by specialized physiotherapists) for patients with neck pain, concluded that manual therapy was more effective and less costly. This study yielded a significantly faster improvement than in Studies II and IV but was a first line treatment for neck pain only.

The result from Study V (patients’ experiences of the use of a technical device as a reminder of home exercises) indicates that text messaging may be used to improve adherence to home exercises after NMT for LBP. Earlier research on text messaging mostly concern the effects of the SMS:s, in studies on mental disorders, weight control and smoking cessation. The effects are positive, and the SMS:s are appreciated (Wei et al., 2011; Buchholz et al., 2013) but few studies have focused on the experiences of the participants, and to our knowledge no study has been performed in the shape of a qualitative study. Study V also found that the participants were positive, and had improvement in pain, and that the SMS:s stimulated the participants to reflexion and creativity. Thereby, the participants internalised their exercises as a routine, which may imply increased independency and health literacy in the future for older adults with LBP.

Clinical relevance

In Studies II and IV both groups improved during the first 12 weeks, both in terms of treatment effects (pain, physical function and perceived recovery) and in quality of life (QALYs), but the increase in QALYs was not significantly larger in the index group compared with the control group. Yet, the difference in changes in treatment effects was significantly larger in the index group, and the costs were significantly lower. Sixty-two percent of the participants in the index group chose to leave the waiting lists after an average of 4,1 NMT treatment sessions per patient, and at the 12 months follow-up only 3 patients in the same group still had some kind of treatment or intervention, compared with 18 patients in the control group. Furthermore, the participants in the index group had continuing improvement at the last follow up. Thus, the results were clinically relevant.

The case in Study III had had 78 sessions of physiotherapy before being included in the clinical trial in Study II, because of remaining symptoms. The interventions performed within the trial included mobilization under anaesthesia, strong medication and additional physiotherapy sessions (including home exercises), and when summarizing all the interventions performed within the study (i.e. without including the sessions of physiotherapy preceding the clinical trial), this patient was significantly more costly than the rest of the participants, yet still suffered from pain, impaired physical function and sleeping disorders. There were five treatments with the naprapath after completion of the RCT, after which the patient was pain free, had unrestricted range of shoulder motion and did not suffer from any sleep disorders. It is not possible to draw any firm conclusions and it is not possible to generalize any results from a single case, but the effects of the NMT performed in Study III in this thesis both had clinical relevance (van Tulder et al., 2007).

The patients in Study V all had improvement in pain, and their experiences of the SMS:s were positive, both with regard to the messages and the exercises, which were easy to perform in real time. The reminders made the participants reflect and create their own routines for continued compliance. Thus, Study V had both technical and clinical relevance.

METHODS DISCUSSION

Strengths and weaknesses

The strengths of the methods of all the studies in this thesis are that they are new, and aimed to study research questions not previously studied. Except for Study V, validated health surveys (SF 36, SF 12, SF6D) were used which increases the studies' validity and compliance. Perceived recovery was also used. It is a retrospective assessment considered to have great value in trials like this (Fischer et al., 1999). Retrospective measures are more sensitive to change than measures at different points in time, since retrospective assessment is more strongly correlated with patients' satisfaction with change, and might increase the comprehensiveness of information and its accord with clinical practice. The overall weakness with all the studies, except for Study I, is that the researcher and the therapist is one and the same person, which may weaken the studies' validity. This is discussed further in the section below.

The strengths of Study I is that the population is large, randomly selected and well defined as representative for the population of a medium-sized town of northern Europe. Pain is a common reason for attending health care, and it may be of different types and of different aetiology, and many previous studies have investigated pain in general and musculoskeletal pain in particular. In this thesis it seemed important to try to define musculoskeletal pain that interferes with normal life, since clinical experience often shows that when the pain disturbs or prevents physical activity, it easily develops concomitant biomechanical problems, disorders and dysfunctions that become chronic conditions. The definition of pain in Study I was made by using the SF12 health survey and by excluding participants with pathological reasons for their pain (i.e. tumours or rheumatoid arthritis, and/or those with pain in areas such as the abdomen, the genitals or the face). Study I differs from earlier research in that covariates such as growing-up environment, physical leisure activities and living alone or not were included, in striving for encompassing the participants' entire lives. A weakness with the Study is that its cross-sectional design makes it difficult to draw any conclusions about causality, which is a weakness with the study. There is a risk that the participants' pain was present before the workloads came into effect, and there is also a risk that the participants find their workloads heavier because of pain that is already present. Also, the question in one of the main variables (psychosocial workloads) comprised two questions in one, which made it difficult to know whether it was the psychosocial or the physical workloads

that was measured. This was considered in a second step though, in the logistic regression analyses, where physical workloads were analyzed separately, and a new variable was created, in which the physical work load was adjusted for.

There are several clinical trials and health economic evaluations on manual treatment, but to our knowledge there are none on manual therapy for patients with other pain locations than the neck or back, or on the subgroup of low-priority patients on orthopaedic waiting lists with common musculoskeletal disorders. Though this is of great concern, since the longest waiting lists are often seen for orthopaedic patients. The fact that Studies II, III and IV were performed “in real life”; in the everyday life of a busy orthopaedic clinic, is a strength. The study sample in Studies II and IV is also small. For this reason a power calculation on the primary outcomes pain and physical function (SF36) was made in advance, and a total of 80 participants indicated a power of 80% to detect a relative risk (RR) of 1.2 - 1.3 for a clinically important improvement (van Tulder et al., 2007), which is a strength.

In Study III different manual techniques like massage, pressure of triggerpoints, electrotherapy, and mobilization were used, but it was one particular treatment technique (i.e. high velocity manipulation of the acromio-clavicular joint, added at the last treatment session) that made a difference. This technique has not to our knowledge been utilized in the treatment of AC before, which is also a strength. There are also weaknesses with the studies. The design of Study III makes it difficult to draw any firm conclusions or generalisations, when studying one single case, but there was no alternative design to consider. A very small number of previous studies take any notice at all, of the acromio-clavicular joint, and when doing so, they are focused on referred pain of that joint, not on its mobility (Polkinghorn, 1995; Kivimäki et al., 2007; Anakwenze, Hsu, Kim & Abboud, 2011). Many studies on the condition AC have been published, but to the best of our knowledge there are no published studies where a manual, high velocity and low amplitude manipulation directed to the acromio-clavicular joint, for remaining symptoms after manipulation under anaesthesia and physiotherapy has been performed. Since there is not sufficient evidence for the treatment and cost effects of conventional treatment, the result of the study is hypothesis generating.

The results from Study V may contribute to create a mean for improving and evaluating the long term effects after NMT, thus it may increase the body of evidence for the effects of manual therapy, which is a strength. For practical reasons the researcher, the interviewer and the therapist were one and the same

person, which is a weakness, since there is dependency between a patient and their therapist, which may cause skew the answers. However, the methods chosen for analysing the data considers the researcher's presuppositions, which increases the credibility of the study (Malterud, 2012).

EBM is one main stream of HTA. It is an integration of knowledge in clinical decision making, where scientific evidence is one of three aspects, the two others being clinic ability and the patient's valuations and priorities (Sackett et al, 1996). The best scientific evidence from systematic research is required, in terms of randomised controlled trials. Long term follow-ups, validated surveys, power calculations and several trials that indicate the same effects and conclusions are also required, which is difficult when performing research in a new area like NMT. In striving to increase the body of evidence for NMT, study II was designed as an RCT, validated health surveys (SF 36) were used, and a long-term follow-up (52 weeks) was performed. A power calculation on the study population was also performed in advance, and there was almost no "loss to follow up". The study populations in Studies II - IV are small, and performed only in one particular hospital in a medium-sized town in Sweden, which is a weakness since the routines regarding referrals might be different in a smaller than in a larger hospital, or in a university hospital. Standard care and DRG's from the region of Blekinge were used and they may vary compared to other hospitals, which limits the study's external validity. On the other hand, the problems with long waiting lists and the routines for patients on orthopaedic waiting lists have been described in earlier studies, and are similar to ours (Daker-White, Carr, Harvey, Woolhead, Bannister, Nelson & Kammeling, 1999; Reeder, Lyne, Dilip, Cucos & Cucos, 2004; Oldmeadow et al., 2007). The compliance was acceptable in both groups and there were very few dropouts, which gives the trials a good internal and external validity. No earlier clinical trial on manual therapy for orthopaedic outpatients has been published before, which is a strength, but it also makes it difficult to compare and to validate our study with others. The naprapathic treatments performed in Studies II and III were performed only by one naprapath, who is also the first author of the study, which is a weakness, since the effects in the index group might be contributed to an individual naprapath's skills more than to naprapathy in general. Still, when comparing the treatment techniques in Studies II- IV, they are similar to or the same as those performed in a previously published RCT that compares naprapathy with evidence-based care in primary care, for unspecific neck and back pain, where eight different naprapaths were involved (Skillgate et al.,

2007). Two nurses in the orthopaedic outpatient department performed the randomisation of patients in Studies II, III and IV, and collected the patient surveys at all follow-ups, and a statistician not involved in the project performed all the statistical analyses. These are all strengths, since the researcher/naprapath could not have any impact on the allocation of patients to the respective groups or on the interpretation of data. The issue of placebo may also be a weakness, in particular when being both the researcher and the clinician, but the question of placebo is also relevant when seeing a doctor, especially since all the participants in Studies II- IV had been referred to a specialist in orthopaedics before being asked to participate in the trial. Furthermore, the patient in Study III and the index group in Studies II and IV kept improving even at the last follow-up. It may be just as probable that the long-term improvements for these patients were due to the biomechanical analyses and treatment techniques that were performed, and to the patient's involvement in his or her improvement (e.g. in terms of home exercises), as to placebo effects alone. There were differences in pain between the groups at baseline and in Study II this difference was analysed, using ANCOVA, which did not yield any significant differences between the groups. In Study IV this difference was also adjusted for, before calculating the QALYs, in order to avoid confounding. For validity reasons it was not until after the first follow-up (at 12 weeks) that some of the patients were scheduled for an orthopaedic consultation (e.g. became "cross-overs"), which makes the first follow-up "clean" (only orthopaedic and naprapathic interventions, respectively, in the different groups), which is also a strength.

A weakness in Study III is that since the aetiology of the condition AC is unknown, the case described in the study might be only one type or a subgroup of AC that engages the acromio-clavicular, not the GHJ. Another weakness with the study is that it might have been the natural course, not the manual manipulation, that made the patient free from symptoms, but the patient had distinct pain relief and was free from symptoms only a couple of hours after the manual manipulation. These effects were stable at the 52 weeks follow-up, which are strengths. The case was treated in a province hospital in a small county, and it may be questioned if that reflects the routines in other hospitals. Yet her treatment followed normal clinical procedures for her condition. Before being included in the RCT there was no alternative treatment to be offered for the patient, which increases the study's validity. The case was included in the RCT (Study II) and, therefore, followed for a long period of time (two years), when different "standard care" interventions were performed and their outcomes analysed. This increases the validity of the study. There is no sufficient evidence

for the treatment or the cost effects of conventional care (physiotherapy, medication and manipulation under anaesthesia) or for the location of its treatment techniques (e.g. the GHJ) for AC today (Green et al., 2010; Maund et al., 2012). Therefore Study III is hypothesis generating.

One strength of Study V is that no qualitative research on the experience of technical devices as reminders of home exercises in the area of musculoskeletal pain has been published before.

The SMS reminders are cheap and easy to use, and seem to be very effective, which is important for the prospect of increasing the base of evidence for the long-term effects of NMT for recurrent LBP. Another strength with Study V is that it also opens up for the possibility to use SMS messages the other way around: answers via SMS:s instead of postal questionnaires for follow-ups in clinical trials, which has been evaluated in earlier research (Macedo et al., 2012; Axén et al., 2012). The messages may easily be delivered in real time, which might help to increase the validity of and evidence for the effects of NMT. The study population in Study V consisted of older adults, as opposed to most earlier studies, which may be considered a weakness, though earlier research has shown that age does not seem to affect the experience of SMS reminders (Lewis & Kershaw, 2010).

Treatment of musculoskeletal pain in the Swedish health care system

Studies II, III, IV and V were performed on patients who had sought care for their pain. Studies II, III and IV consisted of orthopaedic outpatients of working age, whilst Studies I and V included older adults (60-80 years), and participants who had not sought care for their pain (Study I). The study populations and their age are not the same in all these studies, which may be considered a weakness but, interestingly, the most common locations of pain (the lower extremities, followed by the shoulder and arm) in Studies I, II and III were the same. With regard to an increasing prevalence of pain with age (Smith et al., 2014) and to the routines for treatment of musculoskeletal pain in the Swedish national health care system, it seems probable that older adults with pain that interferes with normal life end up on orthopaedic waiting lists. Almost 50% of the population on the waiting lists consists of people older than 65 years. The majority of disorders are located in the lower and upper extremities (Statistics from the orthopaedic clinic of Blekingesjukhuset, Karlskrona, 2015) and a common intervention for elderly with pain is medication alone (Sandin Wrangler et al.,

2014). With a growing aging population it seems of importance to propose other alternatives, NMT might be one among others.

The case in Study III and almost half of all the participants in both groups in Studies II and IV had received physiotherapy before they were asked for participation; when included in the study one third of the participants in the control group were referred to a physiotherapist. Physiotherapy constituted the most common intervention and the second most expensive in the control group; at the 12-months follow-up all participants who were referred to physiotherapy, except one, still had this intervention. A few earlier studies have investigated the ability of physiotherapists' specialized in manual therapy diagnose non-urgent musculoskeletal conditions and have compared the level of agreement between their diagnoses and those of orthopaedists. The competence in diagnosing and in making treatment decisions has been positive and the level of agreement high (Weale & Bannister, 1995; Oldmeadow et al., 2007) but no comparison of orthopaedics and physiotherapy as a technique has been published. The education to become a physiotherapist in Sweden and to become a naprapath are different in lengths (i.e. three years and five years, respectively), where the naprapathic education is a specialization in musculoskeletal health and manual treatment techniques from the very beginning. For physiotherapists the basic three-year training is broad and many physiotherapists continue with a supplementary education. Specialisation in Orthopaedic manual therapy is organised as an additional education in three detached steps, distributed over a couple of years. In 2014 the number of physiotherapists who had accomplished all three steps was approximately 220 out of 16 000 licensed physiotherapists (Legitimerade Sjukgymnasters Riksförbund, 2014), of which the majority work in and around Stockholm. Thus, in Sweden today, manual therapy including high velocity, low amplitude manipulations are not routine, and according to Studies II, III and IV in this thesis it seems that this gap in treatment might be of importance when treating low priority orthopaedic outpatients, from a cost effective perspective.

It is common that the acromio-clavicular joint is examined and treated in naprapathic clinics in patients who suffer from shoulder disorders and it might be valuable to evaluate a complementing treatment method such as NMT, for diagnosis and treatment when suspecting AC. The manual manipulation of the acromio-clavicular joint was painful for the patient though, therefore, a co-operation between orthopaedists and naprapaths, in order to be able to anaesthetise, would be of great value for the patient.

CONCLUSIONS

This thesis suggests that musculoskeletal pain that interferes with normal life in older adults is associated with heavy physical and negative psychosocial workloads through life. NMT may be cost effective for low priority orthopaedic outpatients of working age with musculoskeletal disorders that are not likely to benefit from orthopaedic surgery and was effective for a young patient diagnosed with AC. Text messaging to remind older adults of home exercises after NMT was appreciated and stimulated the patients to reflect on their pain and exercises, to practice memorising, and to create their own routines for continued compliance.

IMPLEMENTATION OF MANUAL THERAPY IN SWEDISH HEALTH CARE

There seems to be a gap in knowledge of NMT and implementation of a profession such as naprapathy may be a valuable complement. This calls for evidence through large randomised trials on treatment and cost effects, research on subgroups of patients with specific but common musculoskeletal disorders and on those that may not benefit from surgery. Though, when the studies in this thesis were completed and had been published, they were every now and then met by criticism and protectionism, by ignorance of the naprapathic profession and by the differences between naprapathy and other health professions. Earlier research has found that “provider competition” is one of the most common obstacles for incorporating CAM into mainstream health care (Pelletier et al., 1997; Pelletier et al., 1999) and ignorance is believed to hamper an implementation of a new profession (Myburgh et al., 2008). There is ignorance in patients, in clinicians and policy makers, in terms of which disorders might benefit from NMT, and of the different competences of health care professionals such as general practitioners, orthopaedists, naprapaths and physiotherapists. Therefore, it is important to define manual therapy in terms of the length and in the content of its education. It is also important to perform social and humanistic research, in order to enhance an implementation of manual therapy in the reimbursed national health care system.

Innovation, evidence, health economy, policy and clinical guidelines are conceptions related to knowledge in research on implementation (Nilsen, 2010), which is in line with HTA, being the framework for this thesis. Implementation science is about how to realize ideas and plans into concrete action, which seems

important for NMT, in order to be fully implemented into the Swedish national health care system. Characteristics that decide to which extent an organisation may adopt innovations are, a high degree of specialisation, the ability to change, decentralised decision processes, good communication, leaders with a positive attitude to changes and the fact that specific individuals to a larger extent than the organisation as a whole have influence over specific changes (Damanpour 1991, Grol et al., 2005). The decision to adopt an innovation also has to be well accepted in the whole organisation (Zaltman, Duncan & Hobeck, 1973; Damanpour, 1991). This is in line with the prerequisites for carrying out Studies II-IV. These characteristics seem valuable for a future implementation and co-operation between naprapaths and different kinds of health care professionals within the Swedish national health care system. Communication is central, and working in the same premises is the most successful way to achieve quicker and better outcomes at a lower cost (Rawson, 1994; Reason, 1995; Pietroni, 1994; Emanuel, 1999; Richardson, 2001; Rymaszewski, Sharma, McGill, Murdoch, Freeman, & Loh, 2005). The two main streams EBM and health economic evaluations in HTA have been applied as methodological frames in two of the studies in this thesis. As for the other two (policy analysis and social and humanistic research), clinical guidelines that indicate which disorders that may benefit from which type of care, including NMT and implementation science, would probably facilitate a cost-effective co-operation between different health care professionals, of benefit for the patients and for the society.

ACKNOWLEDGEMENTS

SUMMARY IN SWEDISH/SVENSK SAMMANFATTNING

BAKGRUND

Muskuloskeletal smärta är en av de vanligaste anledningarna till att söka sjukvård. Om en patients besvär kvarstår efter konventionell primärvård kan en remiss till specialistsjukvård (ortopedi) göras, men många remisser på väntelistan rör patienter som inte är i behov av kirurgi. Det finns "beprövad erfarenhet" av manuell terapi, men den är inte rutin i det svenska hälso- och sjukvårdssystemet idag och det saknas forskning kring dess behandlings- och kostnadseffekter.

SYFTE

Det övergripande syftet med den här avhandlingen var att öka kunskapen om muskuloskeletal smärta som inkräktar på det dagliga livet. Specifika syften har varit att fördjupa kunskapen om behandlings- och kostnadseffekter av naprapati och om äldre patienters erfarenheter av påminnelser om hemövningar via text meddelanden (SMS).

MATERIAL OCH METOD

Studie I är en tvärsnittsstudie (n=641) som undersöker samband mellan muskuloskeletal smärta som stör dagligt liv hos äldre och olika fysiska och psykologiska belastningar genom livet. Studie II är en randomiserad kontrollerad studie (n=78) som jämför naprapati med sedvanligt ortopediskt omhändertagande för "lågprioriterade" öppenvårdspatienter som remitterats till ortoped. Studie III (n=1) är en fallstudie som beskriver behandlingseffekterna av naprapati för en patient med "frusen skuldra". Studie IV är en kostnadskonsekvensanalys (n=78), där kostnaderna (DRG) och hälsovinster (Qalys) i studie II analyserats. Studie V är en kvalitativ intervjustudie (n=8) som undersöker äldres upplevelser av SMS-påminnelser om hemövningar efter naprapati för återkommande ländryggssmärta.

RESULTAT

Resultaten i studie I var att fysisk och psykosocial arbetsbelastning var associerat med muskuloskeletal smärta som inkräktar på det dagliga livet hos äldre. Naprapati för lågprioriterade patienter i ortopedikö gav signifikant större förbättringar med avseende på smärta, fysisk funktion och upplevd förbättring jämfört med sedvanligt ortopediskt omhändertagande (studie II). Naprapati för en ung kvinna som genomgått mobilisering under narkos för en "frusen skuldra" resulterade i signifikant smärtlindring, förbättrad fysisk funktion och upplevd förbättring (studie III). Hälsovinster för naprapati var högre jämfört med sedvanligt ortopediskt omhändertagande och kostnaderna signifikant lägre (studie IV). Konklusionen i studie V var att användandet av sms som påminnelse om hemövningar efter behandling hos naprapat är uppskattat och att det stimulerar till att öva minnesträning och att skapa egna rutiner för övningarna.

KONKLUSION

. Smärta hos äldre är associerat med tung fysisk och negativ psykosocial belastning genom livet. Naprapati kan vara kostnadseffektivt för lågprioriterade patienter i ortopedikö, som inte ansetts bli hjälpta med kirurgi och var effektivt för behandling av en patient med "frusen skuldra". Påminnelser till äldre om hemövningar via SMS efter behandling hos naprapat stimulerar till att skapa egna rutiner för fortsatt följsamhet

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Negative psychosocial and heavy physical workloads associated with musculoskeletal pain interfering with normal life in older adults: Cross-sectional analysis

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Abstract

Aims: Pain is one of the most frequent reasons for seeking health care, and is thus a public health problem. Although there is a progressive increase in pain and impaired physical function with age, few studies are performed on older adults. The aim of this study was to investigate if there are associations between musculoskeletal pain interfering with normal life in older adults and physical and psychosocial workloads through life. **Methods:** The association of heavy physical workload and negative psychosocial workload and musculoskeletal pain interfering with normal life (SF 12) was analyzed by multiple logistic regression. The model was adjusted for eight background covariates: age, gender, growing-up environment, educational level, if living alone or not, obesity, smoking, and leisure physical activity. **Results:** Negative psychosocial and heavy physical workloads were independently associated with musculoskeletal pain interfering with normal life (adjusted OR: 4.44, 95% CI: 2.84–6.92), and (adjusted OR: 1.88, 95% CI: 1.20–2.93), respectively. The background covariates female gender and higher education were also associated with musculoskeletal pain interfering with normal life, and physical leisure activity was inversely associated. **Conclusions:** The findings suggest that negative psychosocial and heavy physical workloads are strongly associated with musculoskeletal pain interfering with normal life in older adults.

Key Words: Work-related disorders, heavy physical workload, aging, musculoskeletal pain, pain and disability evaluation

Introduction

Pain is one of the most common reasons for seeking medical care in Sweden, for sick-leave and disability pensions, and is hence a public health problem [1,2]. Musculoskeletal pain is more common in women than in men; the legs, shoulders, and back being the most frequent locations [3]. Several studies have been made on musculoskeletal pain in the working population, where associations to heavy physical workload, work in bent positions, low educational level, and different psychological factors have been found [4,5]. There is a progressive increase in chronic musculoskeletal pain complaints with age, with correlations between pain and heavy

physical workload, psychosocial factors, and higher body weight, particularly in women [3,4,6–9], but few studies have investigated these relationships among older people. Older patients with osteoarthritis for example, easily develop concomitant soft-tissue problems, which increase the probability of an unfavorable outcome [5,6,10–12], and joint pain has an inhibitory effect on muscle functioning and strength, which increases the risk of falling [5,13–15]. Earlier studies have focused on musculoskeletal pain, not interfering pain. The aim of the current study was to examine possible associations between musculoskeletal pain interfering with normal life in

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(Accepted 16 March 2015) [AQ: 4]

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DOI: 10.1177/1403494815580876

older adults, and physical and psychological workloads through life.

Materials and methods

Population

The sample derives from a longitudinal study, the Swedish National study on Aging and Care (SNAC). The participants were included in the study and participated in baseline examinations performed between 2001 and 2003. Detailed information about the source population and how the participants were randomly selected has been described previously [16]. SNAC is a large, longitudinal, multidisciplinary study, integrating population, care, and social services data. The study provides information from different aspects: health status, functional and cognitive ability, social and economic situation, perceived quality of life, use of drugs, received formal and informal care, services and living conditions, etc. The study participants in SNAC were randomly selected and were asked to participate. Data were collected by structured interviews, medical examination, and questionnaires, and were performed by trained research staff. The source population of the present study is one of the four main areas of the SNAC study, the Karlskrona municipality in Blekinge county (SNAC-B). The area has 61,000 inhabitants and is defined as a suburban region, in southern Sweden, typical of similar sized regions in northern Europe. The study population in the present study derives from the baseline survey of the four youngest age cohorts in SNAC-B. Inclusion criteria were Swedish men and women aged 60, 66, 72, and 78 years at baseline, who had filled out the questions regarding pain in the musculoskeletal system. In an attempt to define physically impairing, non-pathological musculoskeletal pain, subjects with the worst pain in the head/face, chest, abdomen, or genitals, and subjects with diagnosed, pain-related cancer or inflammatory joint disease were excluded (Figure 1). The study was approved by the Ethics Research Committee of Lund University (LU 605-00, LU 744-00).

Pain interfering with normal life

Dependent variable. Musculoskeletal pain was explored by three questions. The first question was: (1) "Have you experienced ache/pain during the last four weeks?" with answers "Yes" or "No." The dependent variable was pain interfering with normal life, explored by (2) the quality of life survey EuroQol 5 Dimensions (EQ5D) [17], and the pain item "Pain/disorders," with answer alternatives: (a) "I do not have either pain or disorders," (b) "I have moderate

pain and disorders," and (c) "I have severe pain and disorders." If the participants had answered either (b) or (c), the item was scored positive. (3) The Swedish Health Survey Short Form-12 (SF12) questionnaire [18], the pain item: "How much, during the past 4 weeks, has ache or pain interfered with your normal life/work?" with answer alternatives: (a) "Not at all," (b) "A little," (c) "Moderate," (d) "Much," and (e) "Very much."

Participants who scored positively (c–e) on the item were considered to have musculoskeletal pain interfering with normal life. Other participants were considered not to have musculoskeletal pain interfering with normal life.

To locate the pain the participants were asked: "Where is your pain located?" with answer alternatives: (a) head/face/mouth; (b) neck/throat; (c) back (upper back, lower back, pelvis); (d) joints; (e) shoulders/arms/hands; (f) leg/knee/foot; and (g) chest, (h) abdomen, and (i) genitals. It was possible to fill out several pain locations. To locate the worst pain the participants were asked: "In which part of your body is the pain/ache worst?" The answer alternatives were the same as mentioned above. Participants who scored (a), (g), (h), or (i) for the part with the worst pain were not included in the study.

Physical and negative psychosocial workloads

Since earlier studies have found associations between musculoskeletal pain and both physical and psychological factors [5,19], two main independent variables were chosen: physical workload and bodily and/or mentally perceived negative work burden. In the logistic regression models eight background covariates considered to influence the outcomes were also used: age, gender, growing-up environment, educational level, obesity, smoking, living alone or not, and physical leisure activity. The variables were re-coded for analysis as follows.

Main covariates

(1) *Physical workload.* The participants were asked: "To what degree did your main profession include physically hard work?" With answer alternatives (a) "Very light" – Sitting work (e.g., driving a vehicle, reading, office work), (b) "Light" – Standing with light muscle activity (e.g., feeding, washing up, precision-tool work, teaching), (c) "Moderate" – Muscle work with moderate intensity (e.g., lifting/carrying less than 5 kg, washing, cleaning, taking care of children), (d) "Heavy" – Quite high-intensity muscle work and increased respiration (e.g., maintenance, lifting/carrying/turning patients in health care, heavier garden work, shipping goods), (e) "Very

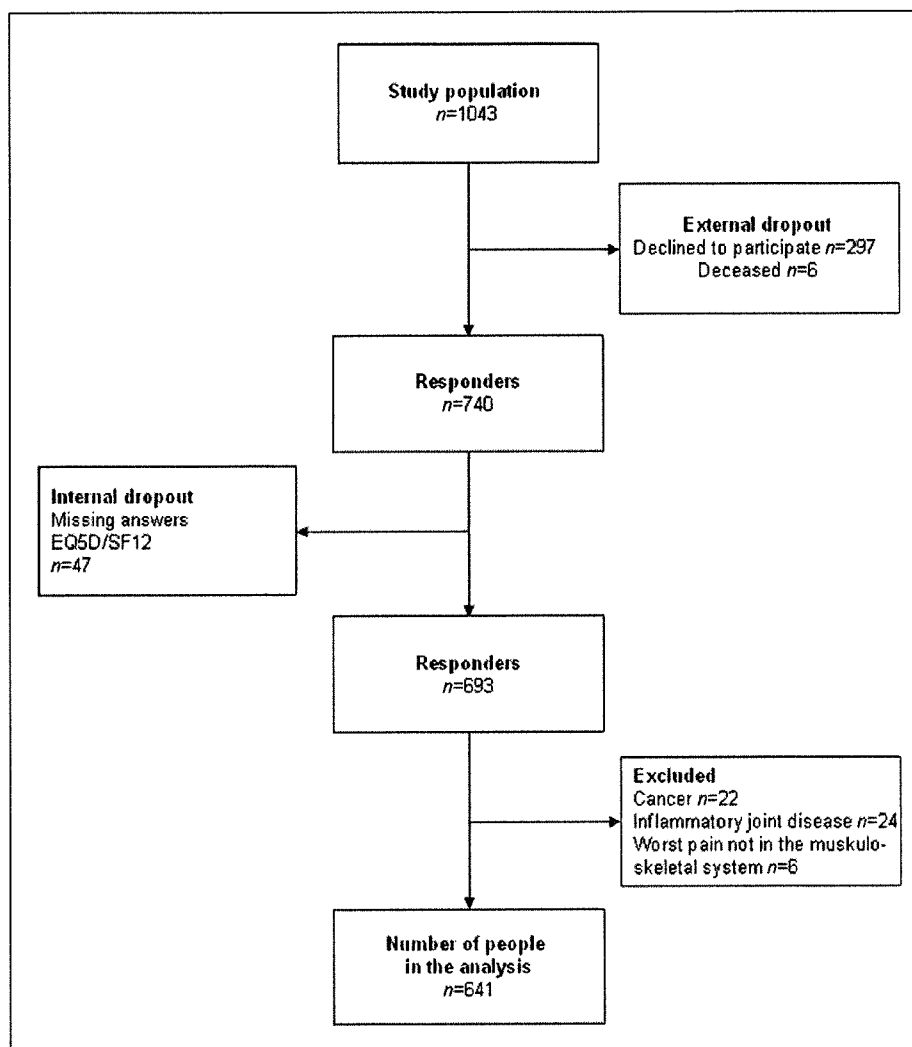


Figure 1. Flow chart describing the study population in a study on musculoskeletal pain interfering with normal life among older adults (60–78 years).

Note: Information how the source population was randomly selected in the first step is described elsewhere [16].

heavy” – High-intensity muscular activity with much increased respiration (e.g., bricklaying, carpentry, construction work, lifting/carrying more than 25 kg). The variable was dichotomized into “heavy physical workload” (d, e) and “not heavy physical workload” (a–c) [16].

(2) *Negative psychosocial workload.* The question read as follows: “Do you find that your occupation has been organized so that it has implied a great burden, bodily and/or mentally, which has had a negative impact on your life or your health?” The answer alternatives were “Yes” or “No” [20]. In order to avoid overlap of question (1) and (2), this variable was adjusted for heavy physical workload in the logistic regression analysis.

Background covariates

(1) *Urban/rural living.* Growing up in the country, being forced to daily, varying, physical activity is different to growing up in a city. The question read: “Where did you grow up?” The answer alternatives were: (a) “in the country,” (b) “in a community with at least 500 inhabitants,” (c) “in a small town” (at least 10 000 inhabitants), (d) “in a medium-sized town,” and (e) “in a big city.” According to national recommendations the alternatives (a) and (b) were recoded to “in the country side” and (c–e) to “in a city” [21].

(2) *Education.* In several former studies a low educational level has been associated with musculoskeletal pain. The question read: “Have you completed elementary school.” The answer alternatives (“Yes”

or "No") were scored "Elementary education" and "Lower education," respectively [22].

(3) *Living alone.* The question read: "Are you living alone?" with the answer alternatives; "Yes" or "No."

(4) *Smoking.* The question "Are you smoking?" had the following answer alternatives: (a) "Yes, I smoke regularly," (b) "Yes, I sometimes smoke," (c) "No, I have stopped smoking," and (d) "No, I have never smoked." The answer alternatives were dichotomized in (a-c) = "Smokers," and (d) = "Non smokers."

(5) *Obesity.* Body mass index (BMI) was measured by dividing the weight in kilograms by the square of the height in meters (kg/m²). BMI values of more than 30 were exposed and scored positively; as "obesity," all others were scored negatively [23]. (6) *Physical leisure activity:* The question read: "For leisure, do you normally, during the last 12 months or earlier: (a) do garden work, (b) pick mushrooms, (c) walk in the forest, or (d) go hunting or fishing?" The answer alternatives were "yes" or "no" for each of the items, and a new variable was created and scored positively if at least one of the items or more were answered with "yes." If none of the variables were scored, the item was scored negatively.

Statistical analysis

Statistical comparison of differences between subjects with and without musculoskeletal pain interfering with normal life was made by the chi-square test. Multiple (binary) logistic regression analysis with backward selection was used to estimate which independent variables predicted the tested domain and to calculate the odds ratio (OR) at 95% confidence interval (95% CI). The model was adjusted for background factors that could confound the results: age, gender, educational level, growing-up environment, obesity, smoking, if living alone or not, and physical leisure activity. Data were analyzed using SPSS for Windows (PASW, version 19).

Results

The selected sample included 641 participants, of which 54% were women. The different steps in the inclusion process and details about exclusion are shown in Figure 1.

In total, pain was reported by 64.0% of the study population ($n=411$; 95% CI: 60.3–67.7) and musculoskeletal pain interfering with normal life by 23.6% ($n=151$; 95% CI: 20.3–26.9). Pain was

Table I. Demographics of the participants in a study of older adults comparing subjects with and without musculoskeletal pain interfering with normal life.

Variable	Pain	No pain	<i>p</i>
Gender ($n = 641$)			$p=0.013$
Women	95 (63%)	252 (51%)	
Men	56 (37%)	238 (49%)	
Age ($n=641$)			$p=0.612$
60 years	37 (24%)	134 (27%)	
66 years	42 (29%)	139 (28%)	
72 years	35 (23%)	121 (25%)	
78 years	37 (24%)	96 (20%)	
Living alone ($n=641$)			$p=0.213$
Yes	45 (30%)	113 (23%)	
No	106 (70%)	376 (77%)	
Educational level ($n=635$)			$p=0.010$
Lower	35 (24%)	172 (35%)	
Elementary	112 (76%)	316 (65%)	
Smokers ($n=632$)			$p=0.097$
Smokers	89 (60%)	251 (52%)	
Non-smokers	60 (40%)	232 (48%)	
BMI >30 ($n=636$)			$p=0.022$
Obese	50 (34%)	121 (25%)	
Not obese	96 (66%)	369 (75%)	
Growing-up environment ($n=624$)			$p=0.440$
Urban	36 (24%)	130 (27%)	
Rural	113 (76%)	345 (73%)	
Physical workload ($n=595$)			$p=0.008$
Not heavy	87 (63%)	341 (75%)	
Heavy	51 (37%)	116 (25%)	
Perceived negative work burden ($n=635$)			$p= 0,000$
Yes	69 (47%)	85 (17%)	
No	78 (53%)	403 (83%)	
Physical leisure activity ($n= 633$)			$p= 0,010$
Yes	73 (50%)	299 (62%)	
No	74 (50%)	187 (38%)	

reported more frequently in women ($p=0.03$), as shown in Table I, and the OR for perceived negative work burden was higher in women than in men (Table II). The most common site of pain was the leg, knee, and/or foot (74%), followed by upper/lower back (63%), joints (60%), shoulder/arm and/or hand (58%), and neck (46%). The most common number of pain sites was four (24%), followed by two (20%), five (19%), three (19%), and one (18%). Baseline demographics stratified for pain interfering with normal life for all the tested variables are shown in Table I.

The logistic regression analyses showed that the negative psychosocial and heavy physical workloads were independently associated with musculoskeletal pain interfering with normal life in older adults (adjusted OR: 4.44, 95% CI: 2.84–6.92), and (adjusted OR: 1.88, 95% CI: 1.20–2.93), respectively.

Table II. Crude and adjusted logistic regression analysis (OR 95% CI) describing factors related to musculoskeletal pain interfering with normal life in older adults. Negative psychosocial workload is analyzed in a crude and an adjusted analysis, including heavy physical workload. [AQ: 3]

Variables	Crude (n=591) Cases=136	Adjusted; all (n=560) Cases=125
Negative psychosocial workload	4.19 (2.81–6.25)	4.44 (2.84–6.92)
Heavy physical workload		1.40 (0.86–2.27)
Physical leisure activities		0.38 (0.18–0.82)
Age		
Female gender		1.79 (1.15–2.79)
Growing-up environment		
Living alone		
Educational level		1.62 (1.01–2.61)
Smoking		
Obesity		

When adjusting for background factors that could confound the results, female gender was also associated with an increased OR. The results of the crude and adjusted logistic regression analyses are shown in Tables II and III.

Discussion

Summary

In this study on older adults, negative psychosocial and heavy physical workloads were independently associated with musculoskeletal pain interfering with normal life. Musculoskeletal pain interfering with normal life was reported by 23.6% of the study population, and women reported pain more frequently compared to men. The most common site of pain was the leg, knee and/or foot, and the most common number of pain sites was four.

Comparison with earlier studies. The results regarding the pain locations and also the prevalence of pain are in line with earlier published studies in general populations [3,4,5,24,25]. Associations to psychosocial workload are also known from former studies on people of working age [3,4]. One of those indicated that factors others than heavy physical workload, such as psychosocial factors and neurohormonal changes, amongst others, may be of importance for the development or preservation of chronic musculoskeletal pain [4]. What most of all differentiates the results in our study from former studies on musculoskeletal pain in middle-aged and older cohorts in Sweden is that obesity, lower education, and age were not independently associated with

Table III. Crude and adjusted logistic regression analysis (OR 95% CI) describing factors related to musculoskeletal pain interfering with normal life in older adults. Heavy physical workload is analyzed in a crude and an adjusted analysis, with negative psychosocial workload not included.

Variables	Crude (n=591) Cases=136	Adjusted; all except for negative psychosocial workload (n=564) Cases=127
Negative psychosocial workload		N.A.
Heavy physical workload	1.72 (1.15–2.58)	1.88 (1.20–2.93)
Physical leisure activities		
Age		
Female gender		1.99 (1.29–3.07)
Growing-up environment		
Living alone		
Educational level		
Smoking		
Obesity		

musculoskeletal pain interfering with normal life [3,4]. Heavy physical workloads (including obesity) preload the spinal cord though [30], and it is more common that people with low education work with heavy physical loads. Regarding age, another previously published study concluded that measures of physical fitness may be more important predictors for functional tasks among older adults than chronological age [13]. The present study didn't investigate musculoskeletal pain alone, but defined musculoskeletal pain that interferes with normal life. The results in our study indicate that there may be different mechanisms behind the two, which may be supported by the different amount of subjects reporting "pain" (n=411), as compared to those reporting "pain interfering with normal life" (n=151).

The study also indicates an inversed association between leisure physical activity and pain. Passive coping is a risk factor for disabling neck and low back pain, meanwhile self-efficacy and fear avoidance are determinants of disability in patients with chronic musculoskeletal pain [26,27]. Associations in cross-sectional studies should be interpreted cautiously, since they cannot prove causality, but it may be that people who have had an overall physically active life, including physical leisure activity and even heavy physical workload, are protected against pain interfering with daily life, in that they don't suffer from fear avoidance, and that their coping strategies and physical function (mobility, proprioception, and strength) are good.

Strengths and weaknesses. Strengths with this study are its contribution to a quite undefined research area, musculoskeletal pain interfering with normal life in older adults, and that the study sample was large, randomly selected, and population based. Pain is very common, but when pain prevents individuals from performing their daily activities it becomes a public health problem, particularly serious in older adults. Several earlier studies have examined musculoskeletal pain in older adults, but to our knowledge musculoskeletal pain related to daily, physical activity [1,3,4] has not been studied before. Our endeavor was to define physically impairing musculoskeletal pain. The number of participants in the study who stated that they suffered from pain was much higher than the number of participants stating that they had pain "interfering with normal life" (411 compared to 151, respectively). That is, 411 of the participants experienced pain, but only 151 of these experienced that their pain was disturbing or preventing them from performing their daily activities, which we interpreted as they were suffering not only from pain, but from physically impairing musculoskeletal pain. Two validated instruments (the SF12 health survey and the EQ5D quality of life survey) were used to define the dependent variable. Subjects with known inflammatory joint disease and cancer, and those with pain not in the musculoskeletal system were not included in the study. Most studies in the field of musculoskeletal pain and disorders focus on work-related pain, and when designing for that purpose it implies that a large part of life (outside work) is excluded. In our study, growing-up environment, if living alone or not and physical leisure activity were included in the analyses. There was consistency regarding the negative psychosocial and the heavy physical workloads both in the crude and in the adjusted logistic regression analyses. There are also weaknesses in our study. With a cross-sectional design it isn't possible to determine causality between pain and available exposure factors. The largest amount of dropouts was on the variable heavy physical workload, which may also be considered a weakness, since it may affect both the internal and the external validity. Also, the item "perceived negative work burden" comprised two questions in one, which makes it difficult to know whether it was the bodily or the mentally perceived burdens being measured. However, in the logistic regression model we created a variable for the mental burden, psychosocial workload, where we adjusted for the bodily burden. We have tried to define the kind of pain that we intended, by using additional questions that the participants had answered (i.e., exclusion of participants with known/diagnosed cancer, and inflammatory joint disease, as well as those with the

worst pain in areas others than the musculoskeletal). Questions about polymyalgia rheumatic and osteoarthritis for example were presumably included in "inflammatory joint disease." The reason for this is that we wanted to exclude patients with pain due to pathological conditions.

We believe that we have included both widespread and regional musculoskeletal pain interfering with normal life, but the intensity, frequency and duration of the pain are not captured by the SF12 and EQ5D surveys. Such information could have further defined the type of pain and be valuable for future studies.

Implications for future studies. Previous studies on associations between pain and physical function have focused on impaired physical function in subjects with pain [28,29]. Few studies have examined it in reverse: the development of pain in subjects with impaired physical function. Physical activities through life, both at work and at leisure, even those that imply heavy physical workload, probably enable good physical function. It might not prevent the development of musculoskeletal pain, but it may prevent that the pain interferes with normal life. In future research it would be of interest to investigate if physical function tests may predict the development of pain interfering with normal life. This would promote optimization of resources for prevention in this important public health field.

Conclusion

In this study on older adults, negative psychosocial and heavy physical workloads were independently associated with musculoskeletal pain interfering with normal life.

Acknowledgements

The SNAC (<http://www.snac.org>) is initiated and organized by the Swedish Ministry of Health and Social Affairs, and by the participating county councils, municipalities and university departments. We are grateful to the subjects and staff of SNAC-Blekinge for their engagement in the study.

Conflict of interest

None declared.

Funding

The work with this study was supported financially by research grants to the first author, from The Research Council of Blekinge County (grant no. 2011/0046). The source of funding had no influence on the design, the conduct or the reporting of the trial.

Supplementary materials

The SNAC (<http://www.snac.org>).

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CASE REPORT

Pain relief in a young woman with adhesive capsulitis after manual manipulation of the acromioclavicular joint for remaining symptoms after mobilisation under anaesthesia

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SUMMARY

Adhesive capsulitis is a painful condition with a prevalence of 2–5%. There is a lack of evidence for its aetiology and for conventional treatment and cost effects. This study describes the treatment effects of manual manipulation of the acromioclavicular joint for adhesive capsulitis in a young woman for persisting pain after mobilisation of the glenohumeral joint under anaesthesia. Primary outcomes were pain and physical function, measured by a visual analogue scale and the SF36 health survey. Secondary outcomes were sleep pattern, medication and perceived recovery. The mobility after manipulation under anaesthesia: elevation 55° and no improvement in pain. After manual manipulation: unrestricted elevation and significant pain relief. The patient no longer suffered from sleeping disorders and ceased all medication. Considering the lack of knowledge in aetiology and treatment, specialised manual examination of the acromioclavicular joint should be considered early in patients diagnosed with adhesive capsulitis.

BACKGROUND

Musculoskeletal impairments in the glenohumeral joint (GHJ) are one of the most common reasons for seeking orthopaedic medical care.¹ One of these impairments is adhesive capsulitis (AC), also known as ‘frozen shoulder’, with a prevalence of 2–5% in the general population. The cardinal symptoms of AC are decreased mobility in the shoulder girdle, an insidious onset of pain in/around the GHJ, night pain and a gradual loss of active and passive movement in all directions.² The duration of symptoms ranges from 3 to 36 months, with a mean of 15 months.³ Radiographs are typically normal, but important for eliminating other causes,² and the diagnosis is clinically verified.⁴ The condition is perceived to result from fibrosis and contracture of the joint capsule in the GHJ,² and tenderness over the acromioclavicular joint may be an associated symptom.⁵ The aetiology is unclear and poorly understood; it is common for AC to occur concurrently with other pathological conditions in the GHJ,⁶ which is why the condition is sometimes divided into primary and secondary frozen shoulder.⁷ ⁸ The progress itself is self-limiting, but the condition may persist for years and some patients never fully recover.⁶

Conventional treatments for the condition are medication, physiotherapy, steroid injection, radiography or ‘wait and watch’. Failure to obtain improvement after 6 months is a general indication for surgical intervention,² where manipulation of the GHJ under anaesthesia is the gold standard.⁸ There are inconsistencies and controversy regarding the aetiology and the treatment of AC,^{2 6 9} and no substantial evidence for the treatment or cost effects of conventional treatments.^{10–12}

The aim of this study is to describe the treatment effects of manual manipulation of the acromioclavicular joint in a patient with AC for persisting pain after conventional treatment in primary and secondary care (medication, steroid injection, radiography, physiotherapy and mobilisation under anaesthesia). The case was included in a previously published clinical trial comparing conventional orthopaedic care with manual therapy. The patient was randomised to the control group, where she had mobilisation under anaesthesia; she was not cured until she had manual therapy of the acromioclavicular joint 1 year later. To the best of our knowledge, this has never been described before. Also, a recently accepted health economic evaluation of the clinical trial found the described case to be the most expensive.¹¹

CASE PRESENTATION

The case concerns a previously healthy 29-year-old woman who experienced a dull, deep pain and increasing difficulty lifting her arm, without any definable cause. She had a stressful job at a computer terminal in an office, had a 2 h daily commute, and experienced difficulties while working at her computer terminal and while performing household tasks such as vacuuming, doing dishes, washing and braiding her hair. The ache from her GHJ made sleeping difficult and she could no longer sleep in her preferred (prone) position. She usually woke up several times a night and seldom slept for more than 3 h at a stretch, and was frequently troubled with headache. Vacation and rest made no improvement on her condition. In addition to the symptoms associated with AC the patient also experienced radiating pain and numbness in her right arm, hand and fingers. First, the patient had an appointment with a general practitioner (3 months after onset). Thereafter she had physiotherapy for 5 months,

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Accepted 24 October 2014



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To cite: Lilje S, Genberg M, Aldudjaili H, et al. *BMJ Case Rep* Published online: [please include Day Month Year] doi:10.1136/bcr-2014-207199

with only minor improvement, which was why she was referred to an orthopaedic outpatient department. By that time she agreed to participate in a clinical trial, and was randomised to the control group, (standard orthopaedic care¹), 11 months after onset.

INVESTIGATIONS

General practitioner: Three months after onset, contact with a general practitioner was initiated.

Physiotherapist: After 5 months of consecutive physiotherapy (ie, 8 months after onset) the patient also had a plain radiography performed at her cervical spine and right shoulder, which was unremarkable.

Orthopaedist (11 months after onset): The functions innervated from nervus medianus, ulnaris and radialis were normal, elevation was now 15°, and external rotation was estimated at 30° (table 1). The orthopaedist confirmed the diagnosis M.750 (AC), based on the patient's history and symptoms, and on previous medical records.

Naprapath (23 months after onset): The pain was a deep sensation in and around the right GHJ, and the acromioclavicular joint on the same side had a distinct swelling and tenderness. A swelling was also found over the scalenii muscles on the right side. Palpation on the left side's vertebrae transverse outgrowth on C6, C7 and Th1 gave a sore sensation and her right acromioclavicular joint had a ventral movement restriction. The naprapath's diagnosis was M24.4B (dysfunction of the right acromioclavicular joint) and UNS M02.9B (reactive arthritis).

TREATMENT

The general practitioner had a steroid injection made, prescribed non-steroidal anti-inflammatory drug and made a referral to a physiotherapist. At her appointment with a physiotherapist 2 weeks later, elevation in the patient's affected shoulder was 80° (external rotation was not recorded). The physiotherapy interventions consisted of laser-device treatment, stretching, massage and trigger point pressure, water-based exercises, taping, transcutaneous electrical nerve stimulation over the affected area, and acupuncture with and without electric impulses. The patient was also provided a home exercise programme focused on mobility and posture. After an additional 3 months of physiotherapy, the patient was prescribed supplementary drugs (panocod, paracetamol, codeine and sleeping pills), and was referred to an orthopaedic surgeon.

Mobilisation under anaesthesia in all movement planes was performed 5 weeks after the first appointment with the orthopaedist (12 months after onset). After the intervention the patient was informed about the importance of continuing the physiotherapy sessions, in order to be able to fully recover. Because of the radiation and 'electric shock' sensations the patient was prescribed a new medication for peripheral nerve pain and epilepsy: Gabapentin Hexal.

Because of the remaining symptoms after completion of the trial (52 weeks), the patient had naprapathic manual therapy. Naprapathic manual therapy¹ is a combination of different manual techniques such as massage, stretching, treatment of myofascial trigger points, and specific mobilisation and manipulation techniques, combined with physical exercises. Naprapaths work under their own diagnostic and clinic responsibility, and since 1994 the naprapathic profession is a part of the Swedish health and medical care system, licenced by the National Board of Health and Welfare, for preventing, evaluating and treating patients with musculoskeletal pain and pain-related disability.

During the first four sessions the naprapath performed massage around the GHJ and thoracic area and treatment of myofascial trigger points (by pressure) in the surrounding muscles. Ultrasound treatment was performed over the right acromioclavicular joint and tuberculi minoris humeri with a low dose (3.3–3.9 W) for only 3 min, as well as careful, general mobilisation of the right GHJ and acromioclavicular joint, due to the pain. The home exercises consisted of supported elevation of the right arm, self-mobilisation of the GHJ (elevating the patient's right arm with her right hand: 'climbing the wall') and the acromioclavicular joint (careful outward rotation of the right arm, in flexion), and stretching of mm. scalenii on the affected side. On the fifth session a high velocity manipulation with a thrust was performed to the right acromioclavicular joint, in a lateral/cranial direction, and a cracking sound was heard. The patient was advised only to take the antiflogistic medication, panocod, and to gradually decrease intake of her antiepileptic medication, Gabapentin Hexal, as prescribed by her doctor.

OUTCOME AND FOLLOW-UP

The general practitioner's injection and the medication had no effect on the patient's symptoms.

During physiotherapy, the mobility of the affected shoulder varied over time, but the pain and sleeping disorders persisted. After mobilisation under anaesthesia the active abduction increased, but the pain, 'electric shock sensations' and sleeping disorders persisted. For primary and secondary outcomes see table 1. Almost a year after the surgical intervention (23 months after onset), the patient's mobility, pain and sleep disorders were unchanged, which is why she had an appointment with a licenced naprapath.

Directly after the manual manipulation of the acromioclavicular joint the elevation was 130°. At follow-up 1 week later the patient reported that she had experienced severe pain for a couple of hours directly after the manual manipulation, after which the numbness and electric sensations in her arm and hand disappeared. She was now able to move her right arm without restriction. The patient had ceased the panocod medication, and was gradually decreasing her Gabapentin Hexal medication as planned, and she was also able to sleep through the night.

One year follow-up

At follow-up 1 year after the manual manipulation (36 months after onset) the patient was pain free and had ceased all medication. There was no swelling over her acromioclavicular joint or mm. scalenii, and she had no adverse sensations in her right arm. Her movements were unrestricted and she did not suffer from any sleeping disorders.

DISCUSSION

This is a case study of a 29-year-old woman with a diagnosed AC. After medication, sick leave, steroid injection, radiography and physiotherapy in primary care, with no change in symptoms, she was referred to an orthopaedist. At the orthopaedic outpatient department manipulation of the GHJ under anaesthesia was performed, followed by additional physiotherapy and medication, after which the patient's mobility improved, but not her pain or sleeping disorders. One year later the patient's condition was unchanged, which is why she had naprapathic manual therapy. After manual manipulation of the acromioclavicular joint on the affected side, there were significant improvements in pain, mobility and sleeping disorders, and the patient

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Table 1 Outcomes of conventional and specialised manual treatment, respectively, at follow-up after 12, 24, 52, 55 and 107 weeks

	At baseline in the RCT (11 months after onset)	12 Weeks after baseline in the RCT 8 Weeks after manipulation under anaesthesia	24 Weeks after baseline in the RCT 20 Weeks after manipulation under anaesthesia	52 Weeks after baseline in the RCT 48 Weeks after manipulation under anaesthesia	55 Weeks after baseline in the RCT 1 Week after manual manipulation	107 Weeks after baseline in the RCT 52 Weeks after manual manipulation
VAS* (the worst pain) (mm)	100	99	99	74	25	3
SF36; bodily pain†	Very severe	Very severe	Severe	Severe	A little pain	No pain
SF36; restricted‡ physical function	Very much	Much	Very much	Much	No restriction	No restriction
ROM; elevation external rotation	15°30°	80° 50°	80°–	70°40°	Unrestricted	Unrestricted
Perceived recovery	–	Unchanged	Slightly better	Unchanged	Much better	Much better
Medication	NSAID, sleeping pills	NSAID, sleeping pills, Gabepentin, Hexal	NSAID, sleeping pills, Gabepentin Hexal (increased intake)	NSAID, sleeping pills, Gabepentin Hexal	Gabepentin Hexal (decreased intake)	None
Sleep	4 h sleep per night	4 h sleep per night	4 h sleep per night	4 h sleep per night	No sleep disturbances	No sleep disturbances

NSAID, non-steroidal anti-inflammatory drug; RCT, randomised controlled trial; ROM, range of motion; VAS, visual analogue scale.

ceased all medication. The improvement at follow-up 1 year later was even better.

Literature review: aetiology and former studies

The aetiology of AC is unclear. In the first publication of the condition, in 1872, it was described as a scapulohumeral peri-arthritis causing stiffness around the shoulder joint.⁴

To date, a very small number of studies take notice of the acromioclavicular joint, thus focusing on the pain, and not on any treatment of that joint, but on the GHJ.^{5 13 14} Only in one previously published case study was manual manipulation of the GHJ following a failed surgical intervention (arthroscopic capsular release) described.¹⁵ To the best of our knowledge no reports exist where manual manipulation has been performed following manipulation under anaesthesia.

There are similarities with a few (5) previously published case studies in that the pain duration in those studies varies from 3 to 12 months, and the follow-up period from 6–8 weeks to 2 years, and in the majority of the studies, the patients had undergone physiotherapy before the studies were performed.^{13 15–18} Also, in all four studies containing treatment, there were significant changes in pain, mobility and physical function. The treatment in those studies consisted of translational manipulation, combined with Interscalene block, end-range mobilisation techniques, Maitland mobilisation, ‘exercises’ and mobilisation, and ‘manually adjusted force short level chiropractic adjustment’, respectively. The most salient difference in the treatment modalities compared with the present study is the treatment technique; former studies have used different mobilisation techniques, whereas in our study a high velocity manipulation technique was performed. Also, in former studies the treatment was focused on the GHJ, whereas in ours the focus was the acromioclavicular joint. The treatment duration and the amount of treatment sessions also varied (from 5 sessions for 2 weeks in the present study, compared with between 18 and 35 sessions for 12–17 weeks in previously published studies). Thus, the number of treatment sessions and their duration, as well as the cost of treatment, were much lower for the treatment described in this study, which is an

additional advantage. However, even though only during the manual manipulation, and for a couple of hours after the same, was this treatment painful for the patient, it should maybe have been performed under anaesthesia. In one former case study a treatment plan for AC is presented, yet without any evaluation.

The origin of the pain in patients with AC may be difficult to localise; it is usually the deltoid and/or the anterior or posterior part of the glenohumeral capsule, sometimes radiating to the biceps tendon.^{6–8 19} Thus, the origin for some AC may be the acromioclavicular joint, not the GHJ, and some manipulations or mobilisations of the GHJ may also affect the mobility of the acromioclavicular joint, whereas other manipulations do not. It may be that this joint is manipulated simultaneously but unintentionally, when manipulating the GHJ.

Strengths and weaknesses

The patient in the present study was included in a randomised controlled trial and in a recently published cost consequence analysis. Therefore her pain, physical function, medication,

Patient’s perspective

I have been willing to cooperate and to contribute information about my condition, as it might be of help to other patients suffering from the same condition. If there is any way that others may be helped, it is worthwhile. Although physiotherapy did not render any distinct improvement, I was happy to have been supported by my physiotherapist, with discussions about how to move on (radiography, referral to the orthopaedist, other kinds of exercises, and changing jobs, etc). I have been ‘the good patient’, who always performs her homework and seldom complains. My physiotherapist did not realise that I was in such pain, since I seldom complained. But why should I? I wonder why it had to take 2 years to be cured, when—actually—there was a method that worked. Why was this not offered to me before?

sleep pattern, perceived recovery and the costs were measured for almost 3 years, using the SF 36 survey, which is a strength. We find this case study interesting and important, as it strives to find new ways to explain and to treat AC. A weakness in our study is that the manual manipulation was painful for the patient and should have been performed under anaesthesia. Large pragmatic randomised trials including manual treatment for AC, with overall comparisons of cost-effectiveness, are warranted.

Learning points

- ▶ For this case of adhesive capsulitis (AC), manual manipulation of the acromioclavicular joint successfully improved the symptoms. Given the lack of clarity on the aetiology and the lack of evidence for the treatment and cost-effectiveness of existing conventional treatments, the following should be considered:
 - There does not necessarily have to be any 'preceding trauma' in patients who suffer from AC.
 - Some cases of AC may be a dysfunction of the acromioclavicular joint, not the glenohumeral joint.
 - In order to speed up the recovery process, and to reduce costs, specialised manual examination of patients with AC should be considered early in the healthcare chain.
 - Cooperation between orthopaedic surgeons and specialists in manual therapy should be considered in patients with suspected or diagnosed AC, in order to reduce the pain when performing manual manipulation.

Acknowledgements The authors would like to acknowledge our case for giving us permission to publish her story, the Research Council of the Swedish Orthopaedic Association for advice, Daniel Jusinski (physiotherapist) and Mattias Wharme (orthopaedic surgeon) for their professional contribution and Daniel Mustajärvi and Rowena Jansson for proofreading.

Contributors SL was primarily responsible for writing the paper, the design, coordination and drafting of the manuscript. MG and HA acquired the data, and ES has revised the final version of the manuscript. All authors have participated throughout the writing process and have read and given final approval of the version to be published.

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Competing interests None.

Patient consent Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

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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
(*Clin J Pain* 2010;00:000–000)

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

Received for publication May 7, 2009; accepted February 1, 2010.

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This study was financially supported by the Department for Primary Care and the Research and the Development Center at the county council of Blekinge, Karlskrona, Sweden, and the Swedish Naprapathic Association.

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

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

44 To our knowledge, no published randomized trial
45 has evaluated the effects of manual treatment on patients
46 on orthopedic outpatient waiting lists. The overall aim
47 of this trial was to investigate whether it is possible to
48 reduce orthopedic waiting lists through integrative medi-
49 cine. Specific aims were to compare the effects of napra-
50 pathic manual therapy with conventional orthopedic care
51 for outpatients with different kinds of nonurgent musculo-
52 skeletal disorders unlikely to benefit from surgery regard-
53 ing pain, physical function, and perceived recovery.
54 The number of patients who were discharged from the
55 waiting lists after the naprapathic treatment in the index
56 group, and the levels of agreement between the naprapaths
57 and the orthopedists' management decisions were also
58 measured.

61 MATERIALS AND METHODS

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

Setting and Participants

65 The source population consisted of patients on the
66 waiting lists at the Department of Orthopedic Surgery at
67 Blekingesjukhuset, the province hospital in Karlskrona,
68 in the south of Sweden, between June 2006 and June 2007.
69 The patients were referrals from all general practitioners
70 in the province, 2 private orthopedic surgeons, different
71 departments in the hospital, company health services, and
72 "own referrals." Inclusion of patients in the study was
73 based on discussions between the naprapath, the orthopedic
74 surgeons, and orthopedic nurses concerning "nonurgent
75 referrals" (ie, no disc protrusions, suspected tumors or
76 conditions requiring surgery within 6 wk). Decisions about
77 eligibility were made through a dialog (based on the
78 referral letters) and appropriate information available in
79 the hospital's information system (eg, results from an
80 x-ray, sick leave, previous surgery, etc). Inclusion criteria
81 for the study were patients between the age of 18 and
82 65 years, without an explicit need for an x-ray (according to
83 orthopedic opinion when selecting the referrals), or
84 suggestion for diagnosis (from the general practitioner,
85 in the referral letter). Exclusion criteria were referrals
86 regarding "trigger fingers," numbness in the hand with only
87 2 or 3 fingers involved, meniscal tears, obvious or sus-
88 pected acute prolapsed disc or disc injury, tumors, specific
89 rheumatic diseases, and patients with contraindications
90 for spinal manipulation. The contraindications are: pro-
91 lapsed disc, neurologic signs (radiating pain/paresthesia,
92 weakened reflexes, muscle weakness, and sphincter dis-
93 turbance), fracture, malign tumors, infection in the spinal
94 column, disc or skeleton, pronounced osteoporosis, rheu-
95 matic pathologic process in the cervical spine, pathology in
96 the arteria vertebralis or arteria carotis, and L'hermitte-
97 paresthesia. If there was an explicit wish for orthopedic
98 judgment expressed in the referral letter, it was also
99 excluded. Further, patients with inability to understand
100 Swedish, patients on 100% sick leave due to the reason of
101 the referral, pregnancy, positive radiography connected to
102 the patients' symptoms (as this may indicate a need for
103 surgery), recent surgery in the painful area, spinal stenosis,
104 or spondylosis were excluded.

Randomization and Interventions

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

116 Together with information about the study, a time
117 reservation for an appointment with the orthopedist or the
118 naprapath and baseline questionnaire and a formulary for
119 informed consent to be returned were sent to the potential
120 study participants. Persons who had been randomized to
121 the control group were requested not to tell the doctor that
122 they participated in the trial. Patients randomized to the
123 index group were informed that they still had the right to
124 see an orthopedic surgeon in case the naprapathic treat-
125 ment had not been successful. Except for this, the infor-
126 mation was exactly the same for both groups. There was no

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

9 Naprathic Manual Treatment (Index Group)

10 A maximum of 5 treatments within 5 weeks were given
11 by one well-experienced naprathic. Time setting for the
12 first appointment was 45 and 30 minutes for the follow-
13 ing appointments. A naprathic treatment consisted of:
14 massage, treatment of myofascial trigger points (through
15 pressure), therapeutic stretching, manipulation/mobiliza-
16 tion of the spine or other joints, and—if required—electro-
17 AQ4 therapy (TNS or therapeutic ultrasonic waves), combined
18 with home exercises.

19 Licensed napraths normally work with their own
20 clinic responsibility. Consequently, diagnostic and manage-
21 ment decisions as well as treatments were performed only
22 by the naprathic, without any second opinion from an
23 orthopedist.

25 Orthopedic Consulting (Control Group)

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

37 Outcomes and Follow-ups

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

45 Primary Outcomes

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

51 Secondary Outcomes

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

56 Perceived recovery is a retrospective assessment con-
57 sidered to have great value in trials like this.²⁴ Retrospective
58 measures are more sensitive to change than measures at
59 different points in time. A retrospective assessment is also
60 more strongly correlated with patients' satisfaction with
61 change and might increase the comprehensiveness of
62 information and its accord with clinical practice. Perceived
63 recovery was measured by a question in the questionnaire
64 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 naprathic
manual therapy was finished) was recorded as a measure of
the effectiveness of the treatment.

Patients in the index group who were not dis-
charged 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 naprathic'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 naprathic 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 naprathic, 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 naprathic
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 Gothen-
burg 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

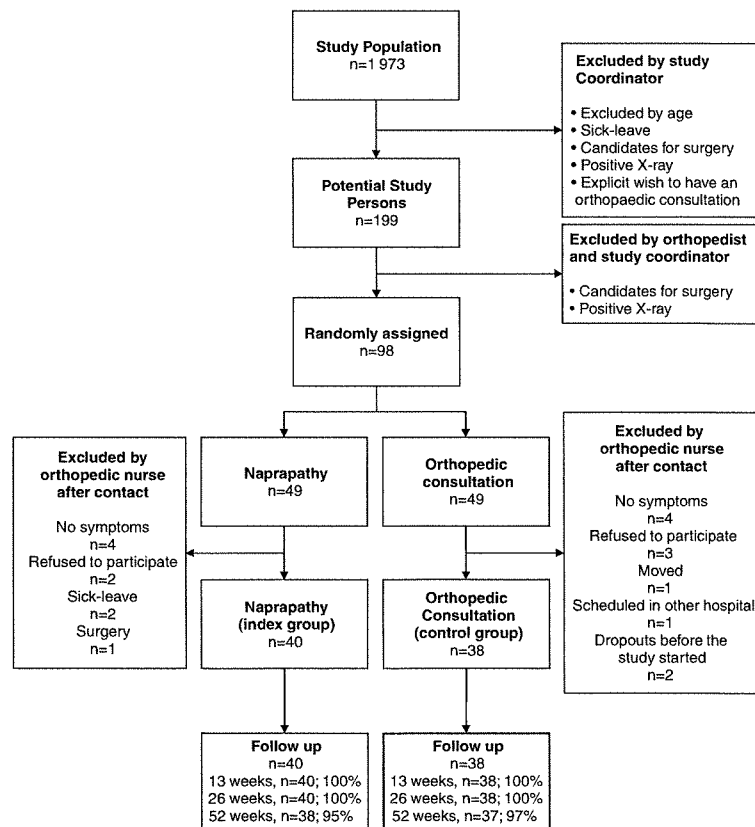


FIGURE 1. Flow chart describing the progress of patients throughout the trial.

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/Borrelia/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.

Naprapathic 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

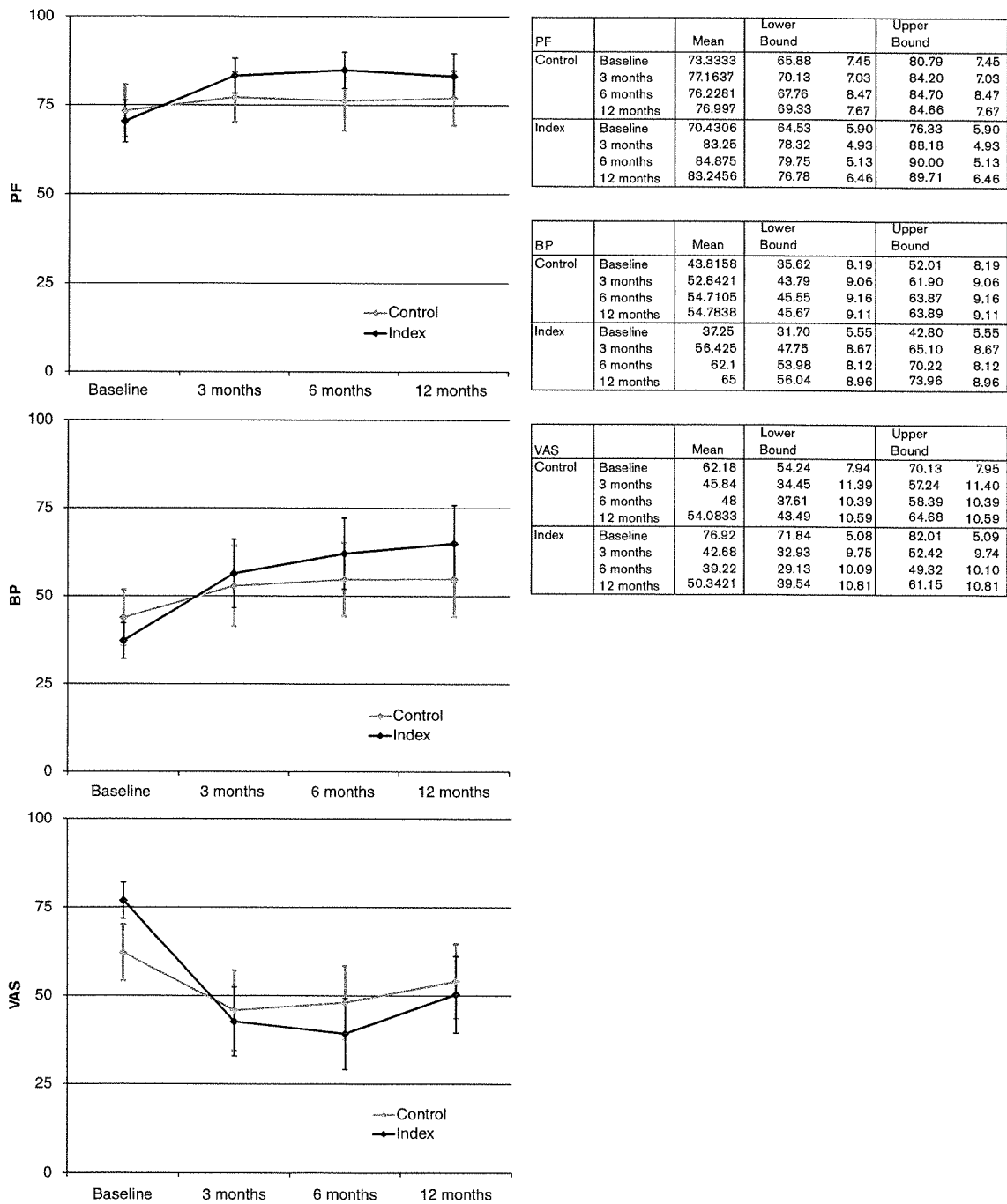


FIGURE 2. A, SF-36, PF. B, SF-36, bodily pain (BP; higher value indicates less pain). C, The worst pain measured with VAS. A to C, The mean scores of PF and pain measured with SF-36 (higher estimation indicates less pain), respectively, and pain measured with a VAS (lower estimation indicates less pain)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

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

63 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.

65 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)		
16 patients	Medicine (4)		
	Plain X-ray (7), MRT (1)*		
	Physiotherapy (8)		
	Orthotics (1)		
	Injection (5)		
10 patients	Medicine (3)		
	Surgery (2)		
		Plain X-ray (1), MRT† (4)	
		Physiotherapy (3)	
		Orthotics (2)	
2 patients		Other investigations (2)	
		Injection (1)	
		Medicine (2)	
		Surgery (3)	
			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).

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

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

15 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
 17 approach, reflecting the “real world” of an outpatient
 orthopedic department.²⁸ The differences between the
 19 groups regarding changes of pain at 52 weeks compared
 with baseline were clinically important.²⁶ The majority
 21 of the patients had long-lasting pain and was carefully
 examined before being referred to the Orthopedic Depart-
 23 ment. This indicates that the included patients were
 suffering from conditions of considerable concern for the
 25 patients and for the society. The included patients were
 chosen in a dialog between caregivers working in the same
 27 premises, with similar administration, and patients’ fee. In
 addition, the sample was proportional to the whole waiting
 29 list, concerning the location of the disorders, sex, and
 waiting time. Further, a power calculation was performed
 31 in advance, the compliance was acceptable in both groups,
 there were very few dropouts and the long-term effects of
 33 the interventions were also recorded. Altogether, we think
 the trial has a good internal and external validity.

35 There are some weaknesses in the trial. The sample
 may be considered as limited regarding the number of
 37 referrals included. This was the result of the inclusion and
 exclusion criteria. Most of the excluded patients were above
 39 65 years of age. Concerning the patients on sick-leave, it
 was not possible to read the length of the sick leave in the
 41 referral letter. That is the reason why we did not include
 any patients on sick leave, even though referrals on short-
 43 term sick leave might have been suitable for inclusion.

45 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
 47 the majority of the patients had been on the waiting
 lists for about 36 weeks and assumedly did not want to
 49 have an appointment only for information about the trial
 and to give the informed consent before being scheduled
 51 for a consultation. Theoretically, there is a risk that the
 participants rated their pain and physical function differ-
 53 ently in the way we administered the study, than if the
 baseline questionnaires would have been administrated
 before randomization. We considered that very small, as
 55 that would not have implied any advantage for the patient.

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

63 Almost 40% of the patients in the index group also
 wanted to have an orthopedic consultation. This may seem
 65 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 evalu-
 ated the effects of combined manual therapy performed
 under own diagnostic, treatment and management respon-
 sibility, for patients with musculoskeletal disorders in out-
 patient 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 conven-
 tional orthopedic care, naprapathic manual therapy re-
 sulted 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.

ACKNOWLEDGMENTS

The authors thank Hans Krona and Göran Holst for
 the contribution of a scientific background, Charles Thaft for
 the statistical analyses, Jan Resebo for help with a summary

1 of the questionnaires, Lil Carleheden-Ottosson for the docu-
 3 mentary research, Ulla Henriksson for all practical tasks at
 5 the Orthopedic Department, and all the participating ortho-
 7 pedists, nurses, and secretaries.

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

A Cost Consequence Analysis

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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 is 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 to 14298 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

(*Clin J Pain* 2013;00:000-000)

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 care¹: 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 made¹ such as referrals 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

Received for publication December 1, 2012; accepted August 13, 2013.

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

7 The problem concerning waiting lists caused by inap-
 9 propriate referrals for common but nonsurgical orthopedic
 11 disorders (the leg/knee and shoulder/arm being the most
 13 common) is well known.^{1,7-9} This has been successfully
 15 approached before, for example when experienced and
 17 specially trained physiotherapists have acted as gate keepers
 for orthopedic outpatients, and when comparisons of the
 19 physiotherapists' and the orthopedists' diagnostic skills
 have been compared, but the different treatment effects in
 21 the context of a clinical trial have not been compared.⁷⁻⁹ To
 23 our knowledge, no health economic evaluation in the con-
 text of a randomized controlled trial (RCT) on manual
 therapy for the subgroup of low-prioritized orthopedic
 outpatients (patients with nonurgent and non-malignant
 musculoskeletal 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.

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

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

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

59 MATERIALS AND METHODS

61 Data from a pragmatic RCT¹ were used to compare
 the cost and utilities of NMT and orthopedic standard care.
 63 Eligible participants in the trial were patients between 18
 and 65 years old, considered as "low priority," and not
 65 candidates for surgery. The patients were selected and

randomized to one of the 2 interventions. Primary outcome
 67 measures were pain and physical function. SF-36¹⁷ mea-
 69 sured 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
 71 months after inclusion. Secondary outcome was perceived
 recovery, measured at the 6- and 12-month follow-up. The
 73 trial was performed "per protocol" with no crossover until
 after the first follow-up. For ethical reasons, patients in the
 75 index group were then offered orthopedic consultation, if
 the patient needed or wished it. Thus, as a secondary out-
 77 come, the number of patients who agreed to be discharged
 from the waiting lists directly after the NMT was recorded.
 79 Both the interventions performed in the trial and self-elec-
 tive treatments in both groups were also recorded during the
 81 follow-up time, and calculated as a part of the total costs.

83 The source population consisted of referrals to the
 Orthopedic Department of the hospital in Blekinge provin-
 85 ce, Southern Sweden. The referrals concerned patients
 who had been selected as "low priority" before the trial was
 87 planned. Patients who were on full-time sick leave, had
 different contraindications for manipulation, or an explicit
 89 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
 91 received a maximum of 5 naprapathic treatments, within
 5 weeks. (The time set for a naprapathic appointment is 30
 93 to 45 minutes, and the treatment consists of massage,
 stretching, manipulation, and mobilization of the spine and
 95 peripheral joints, electrotherapy if needed, and home exer-
 cises and/or restrictions). The patients in the control group
 97 received standard care from orthopedic surgeons, with as
 many appointments as required. Standard care consisted of
 99 advice, drug prescriptions, steroid injections, referrals to
 physiotherapy, radiography, different examinations, anal-
 101 yses, or surgery. The consultations were conducted the way
 they are normally conducted at the department, and the
 103 orthopedists did not know which patients were participat-
 ing in the study.

105 Statistics

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

127 Diagnose Related Groups (DRG)

129 "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

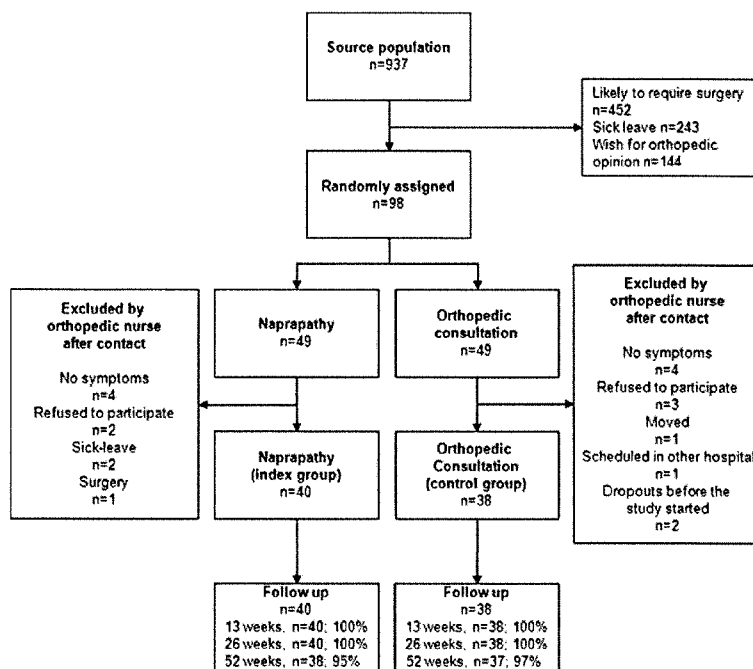


FIGURE 1. Flow chart describing the progress of patients throughout the trial.

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 distributed randomly 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 impairment in pain, increased physical function, and perceived recovery, favouring the index group at 12-, 26-, and 52-week follow-up, as reported earlier. 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

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 Carpal tunnel 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).

values at baseline were lower in the index group compared with the 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 ($0.04 \times \text{€}50,000$) 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). Applying a conservative value of 1 QALY in the region of £30,000, which as is the widely cited threshold value used by NICE in England (Rawlins and Culyer, 2006), results in a value of the health gain in the magnitude of £1200.

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

Type of Intervention	Control Group	Index Group	Total Cost in SEK	
			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 (7)	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.

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 = 7) 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. The 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 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. Firstly, 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. Secondly, 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.

Earlier 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 al¹¹ 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 al⁶ comprised general practitioner, physiotherapy, and manual therapy.

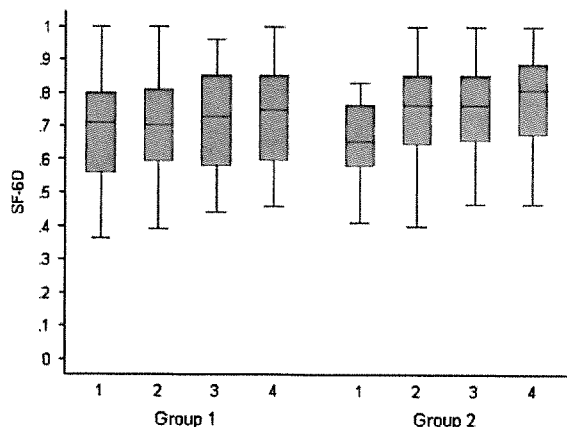


FIGURE 2. Distribution and median quality of life values per group at baseline, 3-, 6-, and 12-month follow-up.

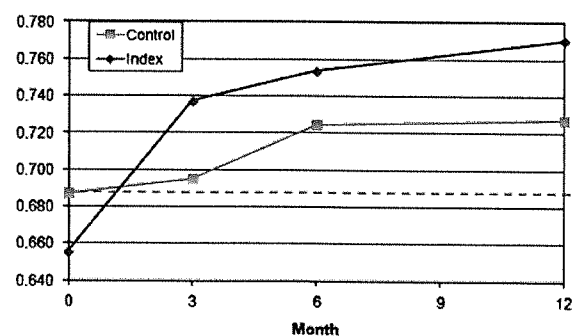


FIGURE 3. Average quality of life measure per person in index and control groups measured at baseline, 3, 6, and 12 months.

1 Manual therapy was more effective and less costly, and
 3 yielded a significantly faster improvement as in our study,
 but was a first-line treatment for patients with neck pain
 only.

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

11 Implications

13 Almost half of all the study participants had already had
 physiotherapy before they were included in the trial. Almost
 15 one third of the participants in the control group were
 referred to physiotherapy and their sessions were not com-
 17 pleted at the time of the last follow-up, hence they continued
 to incur costs. Physiotherapy constituted 242 of all (379)
 19 interventions in the control group and was the second most
 expensive intervention after surgery. Physiotherapy is a
 21 common intervention but may not be the most appropriate
 and cost effective, for all kinds of musculoskeletal disorders.¹
 23 Communication between health care professionals working
 on the same premises is the most successful way to achieve
 25 faster and better outcomes at lower costs,^{21–24} and “doing the
 right things from the beginning” is essential in quality
 27 assurance.²⁵ The characteristics of the complaints of pro-
 fessional ballet dancers in Sweden are similar to those in
 29 many orthopedic outpatient departments. By changing the
 routines for managing musculoskeletal disorders so that the
 31 dancers are firstly examined by the employed naprapath and
 secondly, if necessary, they are referred to the consulting
 33 orthopedist, the often too long waiting lists for an orthopedic
 consultation are shortened. It would be of great value to
 35 perform further trials to develop clinical guidelines to define
 when manual treatment, surgery, or exercises, respectively, is
 37 the most appropriate intervention.

39 Surgery is a major cost for society, and has no guar-
 antee of a successful result. Interestingly, the orthopedists
 referred altogether 4 of the participants in the index group
 41 to surgery, but only one of them agreed to undergo surgical
 intervention. One of the most expensive surgical inter-
 43 ventions in the control group was for adhesive capsulitis
 (29% of the total costs for surgery), which was successfully
 45 treated with NMT after completion of the trial.²⁶

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

55 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 inter-
 57 ventions. They are also valuable not least for the patients,
 as they may indicate if the patients are offered the most
 59 appropriate care, particularly when adding a new treatment
 method.

61 NMT resulted in lower health care costs and achieved
 larger gains in quality of life than orthopedic standard care
 63 for low-prioritized orthopedic outpatients of working age.
 Thus, the result is dominant. The study indicates that
 65 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.

ACKNOWLEDGMENTS

The authors thank The Research Council of Blekinge
 County, The Swedish Naprapathic Association, and The
 Swedish Institute for Health Economics.

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APPRECIATION, REFLECTION AND CREATION; OLDER ADULTS EXPERIENCES OF A TECHNICAL DEVICE FOR ADHERENCE TO HOME EXERCISES AFTER SPECIALIZED MANUAL THERAPY FOR LOW BACK PAIN A QUALITATIVE STUDY

Tidskrift: Health Information Technology J*/Health informatics journal*

Informatics for Health and Social Care*

ABSTRACT

BACKGROUND

Low back pain interfering with normal life is common in the general population (1) and positive effects from Naprapathic manual therapy have been found in clinical trials, with regards to decreased pain, increased physical function and perceived recovery, both in the short and in the long term (2-4). The Naprapathic treatment concept is pragmatic, where the patients' knowledge about their disorders, and commitment in terms of home exercises play an important role (5). If it is possible to increase patients' adherence to homework, it may have an impact on the long-term effects of the treatment, thus the independence for patients. Hence, knowledge of patients' experiences of reminders of home exercises seems important.

Communication technologies are expanding and there are many areas in health care where it may be used for different purposes, for example reminders of medication and appointments in clinics, and for pain assessment (6, 7). Smartphone applications belong to a growing field of technological inventions with positive effects, both with regards to the outcomes of different interventions, and to their feasibility and usability (8-10). The answers may be given in real time and so the analyzes, and the compliance is good. Evaluations on the effects of smartphone reminders (text messaging via short message services; SMS:s) for disease prevention, facilitation of self management of long-term illnesses, and clinic and healthy behaviour interventions are common, the outcomes are positive and the SMS:s are also appreciated by the majority of study participants (11-13). The most frequently studied patient groups are smokers, those with diabetes and mental health disorders (14, 15), meanwhile research on smartphone interventions for persons with chronic pain in general, and for low back pain (LBP) in particular, is limited (16, 17). Qualitative studies of the experiences of patients with musculoskeletal pain receiving reminders of homework via SMS, after manual treatment for such pain, has to the best of our knowledge never been described before. In striving for stable, positive long

term effects of such treatment, and in order to increase the base of evidence for the treatment and cost effects of specialized manual therapy, it seems of interest to explore how reminders of home exercises are experienced.

AIMS

The aim of this study was to explore what the experience of patients' use of a technical device in the shape of short messengers service (SMS) used in order to support adherence to home exercises after specialized manual treatment for chronic LBP in older adults.

PARTICIPANTS

Eight older patients (four women, four men), aged 67 - 80 who where treated for chronic LBP, in a clinic for Naprapathic manual therapy.

METHODS

In Sweden, Naprapathy is the largest profession within the field of specialized manual medicine. The profession is a part of the Swedish health and medical care system, since 1994, licensed by the National Board of Health and Welfare. Naprapathy is defined as a system for specific examination, diagnostics, and manual treatment (massage, stretching, treatment of myofascial trigger points, mobilization and manual manipulation, combined with physical exercises) of soft and connective tissues, aiming to increase the function and to decrease pain and disability in the musculoskeletal system. The treatment concept is pragmatic, and home exercises for the patients play an important role.

The patients/study participants had sought this treatment method themselves, and it was privately financed. In the present study one or two exercises were given, individualised and adapted to the patients' conditions (e.g. stretching of the ilio-psoas and/or quadrates lumborum muscles, or stretching of the glutei muscles, and breathing technique). The most common exercise was stretching of the ilio-psoas muscle and breathing technique. The stretching exercises took a couple of minutes each time, and would be performed once a day, whilst the breathing technique was supposed to be performed repeatedly throughout a whole day. The patients were recruited consecutively through purposive sampling, and asked for participation on their last treatment session. The recruitment was accomplished when it was possible to identify themes in the material. All the participants suffered from recurrent LBP, and were treated with as many sessions as their condition required, in order to be free from symptoms. The home exercises were thought to help the patients/participants to avoid recurrent pain, and followed normal clinical procedures, to aid the transferability of the study. The messages were individual for each patient, and were sent every third day for three weeks, then once a week for another two weeks. The interviews took place one week after the last treatment session (i.e. when the SMS reminder would normally arrive).

The participants were asked two broad questions (semi structured?):

1. *“What have you experienced in terms of the phenomenon `sms reminders for home work?’”*

and:

2. *“What contexts or situations have typically influenced or affected your experiences of the phenomenon?”*

Follow up questions were guided by the conversations (18). Examples:

“What do you mean by that?”

“If I have understood you correctly . . . ”

“Could you tell a little more about . . . ?”

Data analysis: To gain an understanding of how patients experience the phenomenon of home work reminders via SMS after Naprapathic manual therapy, a phenomenological approach with Systematic text condensation (STC) according to Malterud was used. (19). STC derives from Giorgi’s principles of psychological phenomenological analysis (20). Phenomenological research can be described as a way to understand the lived relations that human beings have to their world and to human beings. The reality is comprehended through individual, embodied experience and perception, searching for the essence of a phenomenon, from the perspective of how it is experienced. It strives to find the participants’ common experience of a phenomena, and significant statements are valuable (18). STC is an elaboration of Giorgi’s principles, including four steps of analysis with specified shifts between decontextualization and recontextualization of data (19). A limited number of participants (5-15) provides sufficient data for analysis, where the researcher is bracketing his or her presuppositions of the object, and moves between identification with, or bracketing, during the different steps of the analysis process (20).

Pre-understanding: Researchers “position” themselves in a qualitative research study. This means that researchers convey their background, how it informs their interpretation of the information in a study, and what they have to gain from a study.

In this study the first author’s pre-understanding is based on an empirical perspective; experience of 25 years of clinical work both as an employed and as a privately practicing Naprapath. Initially the patient consisted of young, elite classical ballet dancers (10-20y), and later of “ordinary people” both of working age, older adults, and elderly. The researcher has also educated quality assurance to/in the Naprapathic core, and has performed research on treatment and cost effects of Naprapathic manual therapy at the boundary of specialized care (21). STC was chosen since it strives for “presenting the experience of the participants as expressed by themselves, rather than exploring any possible

underlying meaning of what is said” (19). This seems to set aside (bracket) the author’s preconceptions as much as possible. The author’s preconceptions were that the participants in the current study would find the SMS reminders of home exercises positive, yet a little annoying, since they would disturb the participants in their everyday’s life, and in that the reminders would give them bad conscience about neglected “home work”. The preconception was also that the participants would cease to perform their exercises when the SMS’s didn’t arrive anymore.

1. Total impression – from chaos to themes:

This step includes an overview of data, where the whole transcript is read, in order to get a general impression, looking for preliminary themes associated with the research question, with our the researcher’s preconceptions bracketed. After reading the full text, the researcher lists three to six preliminary themes that relate to the study question.

2. Identifying and sorting meaning units – from themes to codes:

In the second step the transcript is systematically reviewed, to identify meaning units.. Coding implies decontextualization; the meaning units are identified, classified, sorted and coded to the three to six themes described above.

3. Condensation – from code to meaning:

The meaning units are then sorted as thematic groups, and sorted into two to three subgroups, depending on the study question and the interpretative perspectives. The subgroup is now the unit of analysis. The content of the meaning units are reduced into a condensate; an artificial quotation maintaining the terminology applied by the participants.

4. Recontextualization:

In this step it is important to make sure that the synthesized results still reflect the validity of the original context. A story about the phenomenon in the empirical data, with the quotations of relevance, and the most salient content is now to be told. Finally, data from the transcript that might challenge our conclusions are searched, and an assessment of findings compared with existent research findings and theory. We also check whether our findings challenge our preconceptions.

Results

The SMS reminders were perceived as positive by all the participants. Their experience was that the SMS’s were easy to handle, as were the performance of the exercises, and that it was helpful to be reminded. The participants also found that the reminders were valuable in that they stimulated them to memorising things. The participants were pain/symptom free when the interviews took place, and they

stated that therefore they didn't continue as thoroughly with the exercises; they simply forgot to perform them. This was also the case when going on a trip and staying away, overnight. All the participants were reflective about the usefulness and the value of the exercises, and the fact that their pain had improved, and some of them stated that they would have wanted extended exercises. Their creativity also seemed to be stimulated, in that they thought of, and planned for, the best way to keep up with the exercises when the test period was finished/over. Quite different options were mentioned, like having specific routines when going to the gym, or when warming up before a golf session, performing the exercises at the same time as a daily medication, mobile phone alerts, and to write a diary for the exercises.

The results of the interviews were divided into three themes, each with two to four subgroups.

The themes were:

Themes:

1. Appreciation (subgroups: usability, stimulation for memorising)

The SMS reminders were perceived as positive by all the participants. The participants' experiences of the SMS reminders were that they were satisfied to be reminded, and they found the exercises easy to perform, since there were few and they did not require any equipment.

"I thought that it was REALLY good to be reminded . . . it was such an easy exercise, compared with when I was to lay on the floor and pick up a ball and make something that took quite some time; I mean, many more exercises . . . This exercise, I could perform it when I was standing by the oven, waiting for the tea water to boil." (P3).

The participants also appreciated that the reminders made them practice memorising. The reminders were perceived as timely, never annoying, and it was possible to perform them as soon as the SMS's arrived. Only if driving a car, or similar, it was difficult to perform them immediately.

. . . . I thought then that ONE alternative to this would be to MAKE a list and tick it of, and . . . that you make your own list; that wouldn't be bad, because thus I'd see: "well, I didn't do anything yesterday". (P7).

" There is nothing (disturbing) about it, when it comes to such things. It is different with all the telephone salesmen. . . . That is when you get upset! THIS is only positive. " (P5).

" . . . they haven't arrived in any context where people have wondered what I am up to (laughter). I have been able to perform them right away. So it's been OK". (P2).

2. Reflections (subgroups: aim, value, improvement in pain)

In the last section of the interviews, the participants expressed reflections about the aim of the exercises. Firstly they reflected about the value of the exercises, and how these were useful to them. Their experiences were that the reminders were valuable and useful.

" . . . I haven't thought of it (the exercises), more than, eh, what the aim was; or whether I would feel better, or . . . then I have reflected a little about my breathing, whatsoever, HOW I breathe (laughter). If I breathe through my trunc, and HOW I do that, and WHEN I do that, and when I DON'T. Well, I have had THESE thoughts . . . (you ask me to breath like that, and then I wonder a little; how do I breathe, actually?) . . . I have never reflected on that before . . ." (P1)

" . . . Well, the thing is, I believe, that it is VALUABLE to me, myself, to perform those exercises; there is something positive about it. It has only been positive." (P4).

Secondly, the participants reflected about their improvement in pain. Most participants stated that at the time being, they were free from pain, which was positive, and even surprising to them. **Some of them reflected about/wondered whether it was because of the exercises that they were free from pain.** More than forgetfulness, the fact that the participants didn't suffer from pain or disability any more, was perceived to be the reason they forgot to continue with their exercises.

" . . . I am a little SURPRISED that it, that my back doesn't protest more than what it does, right now. I play extremely much golf, eh, and, sure, I am stiff and so, in the morning, like I use to be, but since I stress my back as much as I do right now, I am a little surprised that it doesn't **protest** any more than it does . . ." (P2).

. . . of course, one performs the exercises less often when one is not in pain . . . right now I don't have much pain in my back . . . (P8).

Those of the participants who had been on a trip during the follow up period also stated that when they stayed away over night, they forgot to perform their exercises.

. . . The thing is that I've been away, and THEN it's more difficult to remember this. Well, it is quite easy when one is at home, in one's everyday life . . . (P6).

3. *Creation* (subgroups: continuation, own routines; reminders).

After reflecting about (the cessation of exercises, when the participants were free from symptoms), the participants thought of creating own routines, that would make it possible to continue with their home work, when the SMS's didn't arrive anymore.

" . . . one should have it as a routine, actually; a couple of times each day. One should actually have them at each time. "Well, now I have to do it". That it says "pling" and then I have to do them. Of course, this would be possible for me to arrange myself; I have an alert on, in order to take a pill, at a certain time and . . . I have it continuously, that alert, every day. So I could fix that on my own." (P5).

. . . I thought then that ONE alternative to this would be to MAKE a list and tick it of, and .

. . . that you make your own list; that wouldn't be bad, because thus I'd see: "well, I didn't do anything yesterday". (P7).

. . . You, yourself have to see to that you are able to exercise. You could make a more time defined schedule, in order to practice different things . . . I sometimes have my ideas about going to a gym, and then one could practice not only that, but different areas (P4).

" . . . it would be . . . if you put it as . . . well, as a matter of fact, I have certain routines . . . if I would HAVE it as a routine, for example when BEGINNING to play golf. Because I use to, eh, try to stretch my back before starting to hit/swing. (And THERE I would think that I could perform those exercises too, at the same time. I would consider that!) But not otherwise; you have to connect it to something." (P2).

Some of the participants also requested additional exercises, in order to stay pain free.

" . . . one would need some more exercising. Generally speaking, exercising the back and so on . . . One would need to start doing that. Because one shouldn't need to be in so much pain, be in such pain, due to a movement that your body is not used to. If you are sufficiently well trained, then it shouldn't hurt. There are actually several exercises that strengthen the back for example. It would have been convenient with several additional exercises . . . " (P4).

DISCUSSION

Summary of findings: The main findings in this study was that SMS reminders of homework after Naprapathic manual therapy are appreciated; the study participants find that it is positive and valuable to be reminded of the exercises that they had been given. It is also appreciated to practice memorising. This was very obvious when the interview took place, when most participants didn't suffer from pain or disability, and therefore stated that they easily forgot to continue to perform their home work. (This was also the case when going on a trip, and staying overnight, something that is also often recognized in clinical situations).

All the participants' pain had improved, or some of them were pain free, and the exercises are perceived as usable, in that they were few and easy to perform, since no equipment was needed. The exercises are also perceived as timely, and never annoying when arriving.

The participants TEMPUS:?² reflected about the aim and value of the messages/exercises, and of their own improvement in pain, *in terms of whether there was an association between the exercises that they had performed, and their improvement. They also stated that they forgot to perform their exercises when their pain decreased.* In order to maintain the improvement, they created own routines for continued compliance (e.g. routines when going to the gym or to the golf . . . , mobile alerts, or an exercise diary, etc). Some of the participants also requested extended exercises, in order to stay pain free.

Method: Evidence based research is requested for a profession like Naprapathy, in its striving for integration in the national health care system. Long term follow-ups are important in evidence based research, and the home exercises involved in the Naprapathic treatment concept may play an important role. Therefore it is important to explore the common experiences of an intention aimed to enhance its long term effects. A phenomenological approach and an inductive method were chosen, in order to try to capture the participants own experiences as much as possible, and what sehave in common, and to

avoid interpretation of any underlying, latent meanings from the researcher. Looking for similarities might have biased the study though, since the interviewees were all very positive to the phenomenon, but this wasn't known until the interviews were performed. Strengths with this study is that the research question of the study is new, that the sample was chosen from the "real world", and of equal number from both gender(s). Also, it comprised "older adults", which is a patient group not often included in trials. This may be both a strength and a weakness though, with regards to the transferability of our study, since it is difficult to compare the results with results from studies on younger patients. Still, what is important with this study is how the SMS's are perceived, and whether it seems possible to change peoples' attitudes towards health behaviour modification, with a simple technical tool. The fact that SMS's are perceived as something positive regardless of age, has been proved in earlier studies, yet those/earlier studies have mostly focused on the effects of the reminders, not on the patient's experiences of them. The standards with regards to the frequency and the duration of the SMS messages vary a lot in former studies (13), as compared with this, which is a weakness.

Utveckla? . *Results:* To the best of our knowledge no studies on the subject experiences of SMS reminders for adherence to continued physical exercises after manual treatment have been published before, which makes it difficult to evaluate the possibility to transfer this study to other contexts, such as hospital settings for example. In a private clinic most treatments are privately financed, why the participants might be more motivated to continued compliance, (in order not to spend too much money on (additional) treatment sessions), as compared with hospital care, which is (financed), and where the system supports many appointments, in that the cost for each treatment then decreases. The most salient - and valuable - finding in this study is probably the fact that the participants (internalised) their exercises, by reflecting and finding their own routines for continued compliance. The length of intervention and frequency of messages in earlier studies vary (11, 13), as compared with ours, and an important question is how often and for how long it is necessary for the SMS messages to come, in order to have long term effects on patients' pain and disorders?

Former studies on the effects/outcomes of SMS reminders have found that the outcomes of such interventions, in terms of medication adherence, and clinical management and health-related behaviour modification are significant improvement and differences suggesting positive trends (13, 22). A limited amount of studies with small sample sizes, have evaluated text messaging as a method to promote physical activity, with heterogeneous but positive effect sizes (22). Previous research on the long term effects of Naprapathic manual therapy have shown continuing positive effects over time (**reff; 23?**). (The Naprapathic treatment concept includes time to explain the mechanisms of pain and dysfunctions for the patient, and to tailor his or her treatment, as well as giving a limited amount of specific home exercises.) Clinical experience from Naprapathic treatments is that the patients are well motivated to improve their pain and dysfunction, and well aware of the importance of their own contribution to a successful outcome. This combined treatment concept is believed to play an important role for the positive long term effects of the treatment. A major factor that contributes to increase quality of care and adherence to expert advice is improving people's understanding of what is provided in the realm of medical services (25). If so, the results of this study, where SMS messages are experienced as positive, may sustain improved long term effects of a treatment, thus contribute to increased health literacy and independency for the patients, (which is a strength). This (reasoning) may be/is supported by the fact that all the participants found the SMS's simple and valuable, that their exercises were easy to perform, and that they created own routines for continued compliance. It was also appreciated for them to practice memorising things. This may be easier to achieve when turning to elderly, since they may be more motivated to practice something that stimulates them to memorize, their health is more vulnerable compared to younger people, and they have a less stressful everyday's life than the working population, hence time for reflection and time to perform new activities. Though, a previously published study on the effects of reminders via SMS concluded that text messaging was a

tool for behaviour change across age (11).

Strengths and weaknesses: A strength with this study is that the result was distinct; the SMS messages were perceived as positive, like in earlier studies (22), and they made the patients reflect on their exercises, and on how to stay pain free. Thus the study has clinical relevance. It also has technical implications in that the method is cheap, timely, easy to start up, which has also been found before (13), and it is possible to develop (elaborate?) the messages with extended and individually tailored exercises, for example. There is also the possibility of using SMS messages the other way around, as found in an earlier study (24), in order to enhance long term follow-ups in clinical trials, thus an important contribution in striving for evidence based research/knowledge, which is a strength.

The fact that the participants experienced satisfaction with their reminders of exercises, and that their pain improved, might imply that those patients require a decreased number of treatment sessions. The manual therapist and the researcher/interviewer was one and the same person in the current study, which is a weakness, but when reflecting about the study, the/a manual therapist would rather lose than gain, on positive outcomes of this study, in terms of the number of treatment sessions needed for each patient, and the need for follow up appointments. Hence, this would increase the study's credibility, which is also a strength. The sample of participants in the present study was selected, in that they had previously sought a privately financed care, outside the traditional health care system, and this may have motivated them more to continue with their home exercises, in order to keep the costs down. This may be considered both a weakness, in terms of the transferability of the results to other groups of patients, but also a strength, in that it might imply increased independency and decreased costs for the patients.

The interviewer of/in this study was the clinician who had treated the patients/participants, which may weaken/decrease the (study's) credibility, due to possible placebo effects, but the majority of previous studies have concluded that both the effects and experiences of SMS reminders are very positive (13). The (active) role of the therapist/researcher (interviewer) may also have an impact when it comes to reflexion and creation, but the method used in this study (STC) appreciates that the researcher in the final analysis reflects on whether the findings challenge the researcher's preconceptions. In this study they did (the participants were expected to find the SMS's a little annoying, and their reflection and creation were not expected), which contributes to the reflexivity of the study, thus a strength.

The finding about the INTERNALISING may be difficult to transfer to when only using the SMS, since it may be that the participants' reflection and creation emerged as a result of the interview; somebody was interested in the participants' opinions and thoughts, they had a lot of time to reflect during the interview, and were being listened to. Previous studies have concluded that SMS combined with other delivery approaches, i.e. "face-to-face", telephone interviews or implementation intentions planning in advance, were significantly more effective for changing health behaviour than one method only (23, 26). Therefore continued compliance may not have been as obvious without the interviews, which is important to consider when planning for future studies and interventions.

A previously published study on SMS messaging the other way around, where the patients sent SMS about the clinical course of their low back pain, found that compliance may "possibly somewhat be affected by outcome" (24). It might be that patients with better treatment outcomes are more susceptible to respond to SMS:s, compared to those with less improvement, yet this is in contrast to the findings in the present study, where the patients stated that they forgot - or simply didn't do - their exercises when not being in pain anymore. Nevertheless, the use of short message services of individualized/tailored and automatized exercises, and long-term follow-up feed-back, instead of "treatment when needed", and reappointment when needed, seem to be within reach in the future.

Conclusion

The main findings in this study were that SMS reminders of home exercises after Naprapathic manual therapy for recurrent LBP were appreciated. The participants reflected about the aim and the value of the exercises, and whether the exercises were the reason for their improvement in pain. The participants appreciated that the reminders made them practice memorising, and realized that they easily forgot to perform the exercises when the pain improved. In order to maintain the improvement in pain and physical function the participants created own routines for continued compliance. Further studies are needed to investigate how often and for how long it is necessary for the SMS's to arrive, in order to achieve continued compliance with the exercises, and to evaluate the long term effects in pain and physical function after a session of SMS reminders of exercises following manual treatment.

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