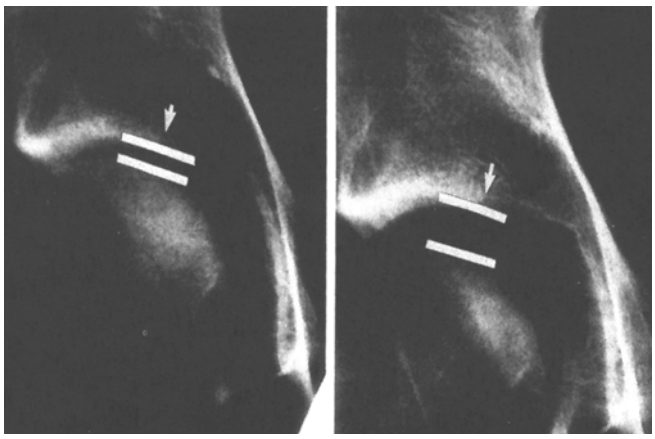
Physiotherapy for painful and hypomobile hip joints

Theoretical considerations and a trial comparing standard to forceful manual traction mobilization



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Picture on front cover:

Figure 1 from the paper:

Arvidsson I. The hip joint: forces needed for distraction and the appearance of the vacuum phenomenon. *Scand J Rhabil Med* 1990;22:157-61.

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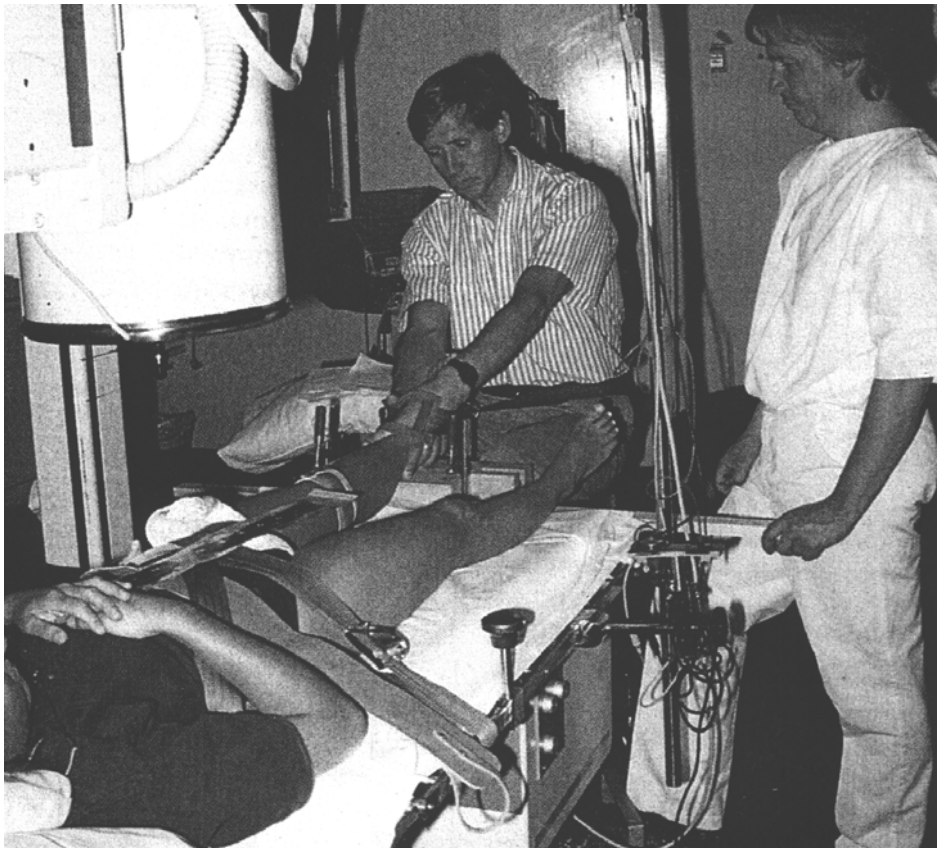

The validation of the forceful manual traction mobilization technique (with kind permission from the authors Samuelsen & Høiseth [1990] and the journal Fysioterapeuten).

Preface

The basic idea for the thesis was developed after working with colleagues in private practice at a clinic in Oslo, 1998. Much due to the inspiration, ideas and practical guidance given by the senior physiotherapist Gunnar Samuelsen, I felt comfortable treating patients with hip problems. His basic approach to these challenges is grounded in 4 major treatments modalities: forceful manual traction mobilization, deep gluteal massage, information and specific exercises.

The reasoning of Gunnar Samuelsen regarding mobilization through manual traction was especially impressive, though it had some support in empiric evidence and seemed to make sense to both therapists and patients. My next years in private practice, where I tended to see remarkable treatment effects applying the basic ideas, inspired me to scrutinize and share them through a randomized controlled trial. In this I had the pleasure of getting the experimental treatment performed by Gunnar Samuelsen and Anders Bakke. Thanks a lot, my friends!

I am thankful to my supervisor Professor Anne Elisabeth Ljunggren for her wise directions, invaluable effort and support in the writing process. Without the statistical help from Professor Rolf Moe-Nilssen and Associate Professor Liv Inger Strand, the quality of the trial had been less. This work was supported financially by the Norwegian Foundation for Research in Physiotherapy.

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Sammendrag

Fysioterapi for smertefulle og hypomobile hofteledd - teoretiske betraktninger og en studie av standard versus kraftfull manuell traksjonsmobilisering

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Hensikt Sammenligne effekten av kraftfull manuell traksjonsmobilisering med standard mobilisering med ukjent kraft i behandling av pasienter med hoftesmerter og hypomobilitet i privat praksis, og å dedusere effekt på rapporterte resultatmål fra tidligere studier. **Design** Prospektiv målerblindet blokkrandomisert kontrollert forsøk med 2 parallelle behandlingsgrupper. **Materiale** I den kraftfulle gruppen (n = 10) og kontrollgruppen (n = 9) var gjennomsnittlig (standardavvik) alder 59 (12). Klientene var rekruttert fra ventelister til private fysioterapiinstitutter. **Intervensjon** Begge grupper mottok 12 ukers behandling med øvelser, informasjon og manuell traksjonsmobilisering. Traksjonen ble progrediert til 800 N i eksperimentgruppen. **Hovedutkomme** HOOS-t, en variabel sammensatt av smerte, stivhet, funksjon og hofterelatert livskvalitet i det sykdoms- og leddspesifikke måleinstrumentet Hip disability and Osteoarthritis Outcome Score (HOOS). **Resultat** Deltakerne som mottok kraftfull mobilisering fremviste overlegne viktige kliniske effekter på HOOS-t, med forbedring ≥ 20 poeng på en 0-100 skala hvor respondenter/ikke-respondenter var 6/10 og 0/9 i henholdsvis kraftfull- og standard terapi-gruppen (P = 0.011). Effekten på smerte var svært stor (OR = 32), og det var ingen bivirkninger. **Konklusjon** Funnene indikerer at kraftfull traksjonsmobilisering er overlegent effektiv i forhold til standard mobilisering, og dessuten i forhold til annen konservativ behandling for denne pasientgruppen i primærhelsetjenesten. Leger anbefales å henvise pasienter til kraftfull traksjonsbehandling. Indirekte evidens antyder effekt på Deltakelse, Nytte (Helserelatert livskvalitet) og Kostnader. Det er et ønske at politikere fremmer incitamenter for behandlingsformen.

Nøkkelord Hofteartrose, manipulasjon, traksjon, randomisert kontrollert forsøk

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Abstract

Physiotherapy for painful and hypomobile hip joints - theoretical considerations and a trial comparing standard to forceful manual traction mobilization

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Objectives To compare the effectiveness of forceful manual traction mobilization treatment to standard mobilization of unknown forces in patients with hip pain and hypomobility in private physiotherapy practise, and to deduce these results into other important health measures reported in the literature. **Design** Prospective rater-blinded block randomised controlled trial (RCT) with 2 parallel treatment groups. **Participants** In the experiment group (n = 10) and control group (n = 9) the mean (standard deviation) age was 59 (12). The clients were recruited from waiting lists of outpatient clinics. **Interventions** Both groups received 12 weeks of exercise, information, and manual traction mobilization. In the innovative group the traction force was progressed up to 800 N. **Main outcome measure** HOOS-t, a variable comprised of pain, stiffness, function and hip-related quality of life on the disease specific Hip disability and Osteoarthritis Outcome Score (HOOS). **Results** The participants receiving forceful mobilization showed large superior clinical treatment effect on HOOS-t by improvement ≥ 20 point on a 0 – 100 scale where responders/non-responders were 6/10 and 0/9 in the forceful and standard therapy group, respectively ($P = 0.011$). The effect on pain was very large (OR = 32), and there were no adverse effects. **Conclusions** These findings indicate treatment by forceful traction mobilization to be clearly superior to standard mobilization, in addition to other conservative therapies for these patients in primary care. General practitioners are suggested to refer to this treatment. Indirect evidence suggests effect in Participation, Utility (Health Related Quality of Life) and Costs. Politicians are asked to afford financial incitements for this approach.

Keywords Osteoarthritis, Hip; Manipulation; Traction; Randomized Controlled Trial

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Abbreviations and definitions

CI	Confidence Interval
ACR	The American College of Rheumatology
ADL	Activity limitation in Daily Living: a subscale of the HOOS, and a part of Function
CV	Coefficient of Variance: an expression of relative reliability
ES	Effect size: an effect magnitude coefficient
ESR	Erythrocyte Sedimentation Rate
Function	An outcome domain comprised of ADL and R&S of the HOOS.
HOOS	Hip disability and Osteoarthritis Outcome Score: a disease- and joint-specific outcome measure
HOOS-t	An outcome domain in the HOOS comprised by the subscales Pain, Stiffness, ADL, R&S, and HR-QL
HRQL	Health Related Quality of Life: a broad health outcome domain
HR-QL	Hip-Related Quality of Life: a subscale of the HOOS
JSN	Joint Space Narrowing
JSW	Joint Space Width
ICF	The International Classification of Functioning, Disability and Health afforded by the WHO
IQR	InterQuartile Range: a statistical measure of disparity expressing the range between the 25^{th} and 75^{th} percentile
Manipulation	A small-amplitude rapid movement which the patient cannot prevent from taking place
Mobilization	A passive movement where rhythm and grade are such that the patient can prevent it from being performed
OA	OsteoArthritis
OARSI	The OsteoArthritis Research Society International: a formal organization
OMERACT	Outcome Measures in Rheumatoid Arthritis Clinical Trials: an informal organization of international researchers
OR	Odds Ratio
Pain	A subscale of the HOOS
RA	Rheumatoid Arthritis
ROM	Range Of Motion
RC	The Repeatability Coefficient: expresses the absolute reliability in the same unit as the measurement

RR	Risk Ratio
R&S	Activity limitation in Recreation and Sport: a subscale of the HOOS, and a part of Function
RCT	Randomized Controlled Trial
SD	Standard Deviation
SEM	Standard Error of Measurement: expresses the measurement error in the same units as the original measurement
SF-36	Medical Outcome Studies 36-item Short-Form Health Survey: a generic health measure
SRM	Standardized Response Mean: an effect magnitude coefficient
Stiffness	Symptoms other, including stiffness: a subscale of the HOOS.
THR	Total Hip Replacement: the surgical procedure
Traction	Right-angled translation of the joint surfaces: an accessory movement
WHO	The World Health Organization
WOMAC	The Western Ontario McMaster Universities Osteoarthritis Index: a disease- and lower-limb-specific outcome measure

1 Theoretical basis

Problem

1.01 *Hip area*

Osteoarthritis (OA), the most frequent joint disorder in the world today (Brandt, Doherty, & Lohmander, 2003), represents a complex disease process in which a combination of systemic and local mechanisms result in characteristic pathological and radiological changes. These abnormalities are often, but not always, associated with symptoms and disability. OA has been recognized in all human populations which has been examined to date, and can be found in skeletal remains from Neolithic times some 5000 years BC (Rogers, Watt, & Dieppe, 1981). However, our understanding of the aetiology, clinical features, and the natural history of OA remains incomplete.

Idiopathic OA of the hip joint is the problem area of this thesis, and as such a range of conditions known to predispose to hip OA is not mentioned here, as for instance trauma. To be able to understand the hip joint problem area, I present an overview of definitions

and diagnostics which hopefully make it easier to understand the divergence in evidence regarding osteoarthritis as a disease in general and hip osteoarthritis in particular.

1.02 *Defining hip osteoarthritis*

There is no unitary accepted definition on hip pain today (Birrell, Lunt, Macfarlane, & Silman, 2005) and concerning OA there is a range of definitions. OA has been defined as a destabilization of the normal coupling of degradation and synthesis of articular cartilage chondrocytes, extracellular matrix and subchondral bone (Tanaka, Hamanishi, Kikuchi, & Fukuda, 1998). This reflects a narrow physiological perspective as the whole joint usually is affected (Brandt et al., 2003).

OA of the hip joint has been classified by the American College of Rheumatology (ACR) (Altman et al., 1991). They presented 2 main classifications: one purely clinical and the other included also added x-ray signs. The clinical is based on history, physical examination and laboratory test. Within the same classification they also presented a non-invasive alternative by replacing the laboratory test with measuring range of motion (ROM) in flexion. The algorithm leading to this classification of hip OA required the combination of (1) hip pain on most days the last month, (2) reduced internal rotation ($\leq$ 15˚), (3) erythrocyte sedimentation rate (ESR) $\leq$ 45 mm/hr or flexion $\leq$ 115˚, (4) pain on hip internal rotation in flexion, (5) morning stiffness lasting $\leq$ 60 minutes, and (6) age > 50 years. This clinical classification was documented as reasonable sensitive (86%) but not very specific (75%) (Altman et al., 1991).

The ACR research group also presented a classification based on combined clinical and radiological criteria. This included hip pain as above, and at least 2 of the 3 following features: (1) ESR < 20 mm/hr, (2) radiographic osteophytes, (3) radiographic joint space narrowing (JSN). This classification yielded sensitivity of 91% and specificity of 89%. There is strong disagreement about the ACR classifications of hip OA (Vogels, Hendriks, van Baar, Dekker, & Hopman-Rock, 2003; Klassbo, Larsson, & Mannevik, 2003b). Even though evidence of poor validity has been established (Bierma-Zeinstra, Bohnen, Ginai, Prins, & Verhaar, 1999; Klassbo, Harms-Ringdahl, & Larsson, 2003a) they are still widely used (van Baar et al., 2001; Hoeksma et al., 2004; Arokoski, Haara, Helminen, & Arokoski, 2004), especially the one combining clinical and radiological information.

1.03 *Diagnostics*

Diagnosing through standard radiographic projection is the common method (Klassbo, 2003), even though most clinical signs and symptoms are unrelated to the degree of radiographic change (Birrell et al., 2000). There has lately been a sharpening in the minimum joint space width (JSW) for classifying hip OA. Broadly seen, the studies done 2 decades ago used a minimum JSW of 3 mm while those made 1 decade ago used a limit of 2.5 mm. Based on newly big-scale studies on non-diseased individuals the natural reference ranges have been further evidenced and thus pushed the cut-off to < 2 mm (Jacobsen, Sonne-Holm, Soballe, Gebuhr, & Lund, 2004). Classifying hip OA for epidemiological studies based on JSW < 2mm also has strong support in the fact that it is the value that has showed the highest positive correlation to hip pain (Jacobsen et al., 2004).

One study reported arthroscopic findings in the early stage of hip OA (Santori & Villar, 1999). Among 186 arthroscopic procedures in plane radiographic normal hips of at least 6 months of hip symptoms, they found OA in 32%. Also magnetic resonance imaging has been compared to arthroscopy (Keeney et al., 2004). The authors concluded that a negative image does not exclude important intra-articular pathology that can be identified and operated on using the arthroscope. Recent improvements in technique and instrumentation have supposedly made hip arthroscopy an efficacious way to diagnose and treat a variety of intra-articular problems and give small complication rates (McCarthy & Lee, 2004). These authors suggest candidates for arthroscopy amongst patients who have mechanical symptoms (catching, locking, or buckling) and have failed to respond to conservative therapy, but who do not show obvious degenerative signs on radiographs. Arthroscopy has also been described as complicated, with questionable indications, low availability and high costs (Parisien, 1998).

In a study from UK, new presenters experiencing hip pain with radiographic OA were compared on restricted hip ROM to presenters experiencing hip pain without radiographic OA (Birrell et al., 2001). Restriction in internal rotation was found most predictive and flexion least predictive of radiographic OA. Restriction in any single plane had a sensitivity of 86% for moderate and 100% for severe OA (specificity was 54 and 42% respectively), whereas restriction in all three planes had increased discrimination (sensitivity was 33% for mild to moderate OA and 54% for severe OA; specificity was 93 and 88% respectively). The authors therefore concluded that

restriction in range of motion was predictive of the presence of OA in new hip pain presenters in primary care, and that the results from range of motion tests could be used to inform decisions regarding radiography (Birrell et al., 2001).

A Swiss group of orthopaedic surgeons, who has performed over 600 dislocations connected with osteoplasty in patients with femoro-acetabular impingement, reported a great lack of sensitivity of arthroscopic examinations in detecting true cartilage lesions of the hip (Ganz et al., 2003). It can then been realized that the figures coming from epidemiological studies using purely radiographic criteria (Croft, Cooper, Wickham, & Coggon, 1990) do not reflect the true proportions of the population actually undergoing cartilage degeneration, and by a pathological definition OA. It has been proposed that the disease processes can go on for a long time before the individual reports any symptoms (Petersson, 1997). Such data and theories have paved the road for a scientific approach toward identifying biochemical markers in the body fluids, which in the future can make it possible to intervene against OA before the stage of the structural damage (Zhang et al., 2005).

1.04 *Prognosis*

In 3 reviews, miscellaneous prognoses of patients with hip OA have been reported among patient subgroups (Felson, 1993; Hochberg, 1996; Lievense, Bierma-Zeinstra, Verhagen, Verhaar, & Koes, 2002); pain relating to hip OA can lessen and disappear totally, and radiological changes have been noted to reverse in some patients. In the only long-term study the majority of 119 non-operated patients with hip OA had less pain on an index after 10 years (Danielsson, 1993). In another study only a minority of persons affected, about 1.5% in the age group 35-85 years old, demonstrated the need for total hip replacement (THR) over a period of several years (Frankel et al., 1999). Generally, many cases that come to surgery have relatively short histories of severe symptoms, suggesting that a progressive phase lasting between 3 months and 3 years often precede the advanced stages of hip OA (Brandt et al., 2003). For the majority of patients with hip osteoarthritis the pain therefore is controlled through activity modifications.

The latest review on prognostic factors of hip OA found strong evidence for faster disease progression in patients with supero-lateral migration of the femoral head and in those with an atrophic bone response (Lievense et al., 2002). Conflicting evidence of

association with disease progression was reported in patients who (a) had higher age at first consultation, (b) were female, or (c) showed reduction in mean JSN per year. The same group judged strong evidence for no relationship between body mass index and disease progression. They also found limited evidence for a negative relationship between JSW at first radiographic consultation and the need for THR. Limited evidence was also reported for no relationship between hip dysplasia and disease progression. This is in agreement with earlier reports of how adult hip dysplasia, when left untreated, leads to secondary OA in 40-50% of cases by the time the individual reaches 50 years of age (Li & Ganz, 2003). Lievense et al. (2002) pointed out that the samples in their study were all recruited from hospital records, and therefore the results do not necessarily reflect the situation in primary care.

To judge disease progression through the need for THR is not wise according to a Swedish scientific duo (Danielsson & Lindberg, 1997) who documented the prevalence and disease progression by radiographs to have been stable over the last 4 decades, while the THR rate was shown only to increase markedly over the last decade. They proposed the latter event to be due to better results from surgery as well as to more liberal indications for such.

1.05 *Epidemiology*

Epidemiological surveys of hip OA yield varying age related prevalence rates (Ingvarsson, Hagglund, & Lohmander, 1999). Comprehensive reviews of hip OA prevalence in different populations have been undertaken (Felson & Zhang, 1998; Hoaglund & Steinbach, 2001), but comparing figures amongst them are difficult due to variability in hip OA classifications.

The only long-time review, based on 12,000 colon radiographs, reported the prevalence of hip OA in Malmö, Sweden, for the period 1956-1995 to follow an exponential curve of 1% in subjects aged 50 years increasing to 10% in those aged 85 years and older (Danielsson et al., 1997) using JSWs between 3-4 mm depending on age. They documented the prevalence to have been unchanged over the last 4 decades. Lately, a high quality cohort study from Denmark based on 4,151 subjects, presented hip OA prevalence ranging from 4-5% in subjects $\geq$ 60 years old using a JSW limit of 2 mm (Jacobsen et al., 2004). Studies in the US population provided estimates of 4-7% for males in the age group between 45 to 74 years and between 3-4.5% in females by the

2.5 mm JSW limit (Hirsch et al., 1998). As such the prevalence on the mainland Caucasian population in seems to be well defined to between 3-7% for those ≥ 60 years old and increasing exponentially with age. The sex differences reported from US has not been confirmed in Europe.

In England the proportion of hip OA in subjects aged 60-75 was 14.4%, while higher prevalence is reported from Iceland (Ingvarsson et al., 1999): Among subjects 35 years and older the prevalence was 10.8%, rising from 2% at 35-39 years old to 36% for those over 85 years or older. Prevalence reported from smaller Islands, e.g. Gotland island (Forsberg & Nilsson, 1992), is clearly higher than on the mainland, giving supporting evidence of heritage as an important factor in this disease.

Figure 1 displays the results from a prospective cohort study where 12 layman descriptions of common musculoskeletal diseases were part of the questionnaires given to a random sample of the general Dutch population aged 25 years or more [baseline: n = 3,664, follow-up after six months: n = 2,338] (Picavet & Hazes, 2003). In this study, hip OA prevalence based on self-reports was about twice that of the x-ray based values from the European mainland population, but both rates increased exponentially with age.

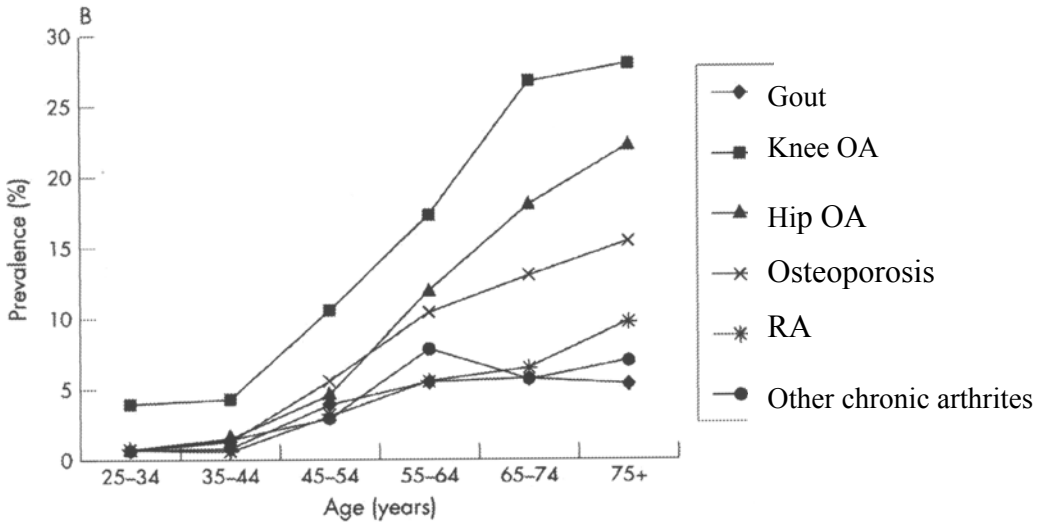

Fig. 1. Self-reported prevalence (%) in the Netherlands. Kindly permitted by Picavet & Hazes (2003).

Reports on incidence of hip OA are scarce compared to those of prevalence. A WHO-report from their scientist group stated that because of problem of definition the incidence of osteoarthritis cannot be estimated (WHO, 2003). Yet some data exists. Australian researchers have made calculations (Mathers, Vos, & Stevenson, 1999) based on prevalence-figures indicating the incidence of osteoarthritis to be higher among females than males in all age groups (2.95 per 1000 population vs 1.71 per 1000). For females, the highest incidence estimate was among those aged 65–74 years, reaching approximately 13.5 per 1000 population per year; for men, the highest incidence was among those aged $\geq$75 years (approximately 9 per 1000 population per year). Hip OA incidence has been given for people in a health maintenance organization in central Massachusetts, US (Oliveria, Felson, Reed, Cirillo, & Walker, 1995). A hip OA incidence was defined as the first evidence of OA by radiography (grade > or = 2 on the Kellgren-Lawrence scale of 0-4) plus joint pain and stiffness at the time the radiograph was obtained or up to 1 year before the radiograph was taken. In this study, hip OA incidence of 0.88 per 1000 population per year was reported as well as higher incidence for female than for males aged 50 years or more.

1.06 *Aetiology and pathophysiology*

A current definition of OA in general, emphasizes that it is a process involving a disturbance of the normal balance of degradation and repair in the articular cartilage and subchondral bone tissues (Creamer, 1999). This process may or may not be accompanied by symptoms of joint pain and loss of normal function. According to this definition OA can be considered as a number of processes rather than a distinct disease entity. The OA processes may be seen as resulting from discrepancy between the demands of the environment on the joint and the capacity of its cells and matrix to respond to those demands. Consequently OA could be the result of excessive demands on normal tissue, or normal stress on tissue with lowered capacity to respond to stress.

Joint injury can alter biomechanics, which might lead to further damage, and stimulate an attempted tissue repair. In some people the disease processes seems to stop and actually reverse (Danielsson, 1993). However, in some instances, the repair process is insufficient and the condition gets increasingly worse. There appears to be a relatively small subset of patients with hip OA who experience rapid progression of the disease (Altman et al., 2004).

The aetiology of idiopathic OA of the hip joint is – by definition – not known, but it is suspected that the risk factor for different subsets of the population are dissimilar (Tepper & Hochberg, 1993). Known hip risk factors are obesity, adverse mechanical factors, dysplasia, and hard physical activity (Lievense et al., 2002). General risk factors are age, female sex, co-morbidity & co-medication, and genetics (Zhang et al., 2005).

Regarding biomechanical factors, interesting evidence are put forward attempting to explain most cases of idiopathic hip OA as having their sources in femoro-acetabular impingement (Ganz et al., 2003). These authors provide insight into early labral and cartilage changes due to abnormal contact between the proximal femur and the acetabular rim occurring during end-range motion. For this phenomenon they present data of treatment effects by osteoplasty to increase the clearance between the femur and acetabulum for hip motion. The abnormal mechanics are named Cam and Pincher impingement, pertaining to the causative abnormal anatomy in the femoral head/neck and acetabulum, respectively (Ganz et al., 2003). The radiological abnormalities highlighted by these authors are not normally screened for in a routine radiological examination, and the patients therefore are classified as having idiopathic hip OA (Wagner et al., 2003).

The ACR recommends range of motion as a variable for classifying hip OA (Altman et al., 1991), and ROM deficits have a long history of being associated with OA (Cyriax, 1970). No cohort study following subjects on the ROM variable along a continuum, progressing from a more or less normal state to a state of hip OA, was found searching PubMed and EMBASE. Only such studies can give highly valid information of whether decreased ROM can be seen as a possible causative factor for hip OA, even though the face validity of this seems good. This is due to the association found between restricted ROM and radiological hip OA (Birrell, Johnell, & Silman, 1999) and the association documented between disability and ROM deficits in individuals with hip OA (Steultjens, Dekker, van Baar, Oostendorp, & Bijlsma, 2000).

A cross-sectional study comparing male participants with hip OA to age matched healthy controls found significant lower abduction, adduction, and flexion muscle strength in those with hip OA (Arokoski et al., 2002). No prospective cohort study was found, examining the strength variable. The muscles provide strength and protection to the skeleton and joint surfaces by distributing loads and absorbing shock (Nordin &

Frankel, 2001), and by that reason it should be worth investigating as a risk factor for hip OA.

1.07 *Health and social impacts*

The socio–economical impacts of hip OA exclusively seem to be scantily documented. My searches in Medline and EMBASE mainly gave hits on articles covering the economical side of THR surgery. A German research group reviewed the administrative and literature data sources in OECD countries and reported the crude primary THR rate to vary between 50 and 130 procedures per 100 000 inhabitants in the 1990s (Merx et al., 2003). The crude overall hip implantation rate, summarising THR, partial hip replacement, and hip revision procedures, was reported to range from 60 to 200 procedures per 100 000 inhabitants in the late 1990s. They concluded the differences in hip replacement rates to be substantial and thought it was due to various causes, including different coding systems, country-specific differences in the health care system, in total expenditure on health per capita, in the population age structure, and in different indication criteria for THR.

Comparison of the economic impact of OA in general to other diseases has been made, but no information was found for hip OA in particular. The economical burden to society incurred by patients with rheumatoid arthritis (RA), OA, or high blood pressure was compared in a prospective study in Ontario, Canada (Maetzel, Li, Pencharz, Tomlinson, & Bombardier, 2004). They found the indirect costs related to RA to be up to 5 times higher than indirect costs incurred by patients with OA or high blood pressure, or both. The direct disease costs for RA patients (n = 253) were about twice the size of that of OA patients (n = 140), i.e. US$ 9,300 and $ 4,900. For realizing the cost for society caused by hip OA, these figures must bee seen together with the hip OA prevalence, which is shown in Figure 1 to be over 2 times that of RA.

Pain and function is seen as the 2 most important health outcome variables in OA by the informal international science network OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) and the formal organization OARSI (OsteoArthritis Research Society International) (Pham et al., 2004). I reviewed the few RCTs on hip OA which used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) as the disease specific outcome measure: Baseline mean values when given on a 0-100 scale, best to worst, were 50, 50 and 60 for pain, function and stiffness, respectively

(Harlow et al., 2004; Makarowski, Zhao, Bevirt, & Recker, 2002). These figures do not necessarily represent the population, due to the 2 used eligibility criteria: (1) experiencing pain within an upper & lower limit and (2) experiencing pain flare-ups while discontinuing medication.

A recent Italian cross-sectional survey has shed some light on the burden in pain, function and health related quality of life (HRQL) of the population of hip OA patient, using the disease specific measure WOMAC and the generic HRQL-instrument Short Form 36 (SF-36) (Salaffi, Carotti, & Grassi, 2005). The participants (n = 107, mean age 68) had hip OA according to the ACR criteria tree including the x-ray variable, and they were all recruited from hospitals department of rheumatology treating facilities. Mean WOMAC scores in pain and function were 43 and 49 on a 0-100 scale - best to worst, respectively. In HRQL, as measured by the SF-36, the participants had the lowest (worst) mean scores in Role Limitations (physical) and Bodily Pain, being 25 and 26 on a 0-100 scale - worst to best, respectively. This is 60% worse than the general population by the same average age when both genders are combined (Loge & Kaasa, 1998). In the rest of the 6 subscales of the SF-36, including Social Functioning, the hip OA patients showed values not statistical significant different from the normal population.

One survey gives reference values for the healthy population in WOMAC scores (Lieberman, Hawker, & Wright, 2001). A random sample of 184 individuals who had no prior history of hip or knee pain or pathology was evaluated. The average WOMAC scores were 0.01, 1.8 and 0.4 in pain, function, and stiffness, respectively. The same researchers also concluded that adults who are healthy and do not have prior history of the hip or knee joint, do not show statistically significant decline in hip function as they grow older., They assessed participants of 3 different age groups (58-64 65-74, and ≥ 75) in Harris hip score, a disease-specific impairment and function measure.

Treatment by physiotherapy

1.08 *Patient information*

The effect of physiotherapy treatment is well documented in OA-related disability. A review of treatment studies with patient information as the only management has revealed effects of 15-30% reduction of symptoms (Hirano, Laurent, & Lorig, 1994). A

meta-analysis has made known that information reduced pain intensity 20% more than use of NSAIDs (Superio-Cabuslay, Ward, & Lorig, 1996) in OA patients. One study have indicated moderate and small effect sizes (ES) in pain and activity restrictions respectively, when information was given to patients with hip disability (Klassbo, Larsson, & Harms-Ringdahl, 2003c) .

1.09 *Exercises*

RCTs examining exercises as the only treatment modality have shown small to medium ES in patients with hip OA (van Baar, Assendelft, Dekker, Oostendorp, & Bijlsma, 1999). The latest Cochran review failed to find substantial evidence for the effect of exercises on hip OA-related disability due to few high quality studies with adequate power (Fransen, McConnell, & Bell, 2003). Regarding knee OA-related disability they found substantial evidence for important treatment effects. The Cochran review used the strictest criteria for retrieving original data, and for separating the effect of treatment of hip OA from that of knee OA. The most recent reviews have concluded that there exists insufficient data to provide useful guidelines on the optimal exercise type or dosage in patients with knee or hip OA (Ebell, 2004; Kettunen & Kujala, 2004). Both exercises of high and low intensity show treatment effects.

1.10 *Continuous passive motion*

Continuous passive motion of 1.7 - 7.6 (median 3.5) hours per day over 12 weeks has shown statistical significant improvement on pain (VAS), free walking speed and Sickness Impact Profile in patients with hip OA-related disability (Simkin et al., 1999). Concerning pain while walking, 7 patients reported total relief, 8 improvement, 5 worsening, and 1 no change after the treatment period. In this uncontrolled study (N = 21) patients gained the same effects regardless of the time exposed to the modality. These data coincide with the fact that for continuous passive motion in general the lowest effective treatment dose has not been found (Salter, 1996). Clearly this treatment modality deserves further scrutinizing.

1.11 *Manual therapy*

Mobilization has been defined as passive movement which the patient can prevent from happening (Maitland & Banks, 2001), and this type of manual treatment is part of both

bachelor and master educational programs in physiotherapy in several countries (Kaltenborn, 2002; Maitland, 1991). This therapy are primarily used to reverse hypomobility, maintain mobility, delay progressive stiffness and reduce pain (Kaltenborn, 2002). Today there is little evidence supporting such treatment effects caused by manual mobilizations in patients with painful hip hypomobility and concomitant disability (Marques et al., 1983; Nyfos, 1983). Hip traction as passive mobilization with forces from 100-250 N has shown negligible treatment effects in patients with hip OA (Marques et al., 1983; Nyfos, 1983). These studies showed short-time effects on pain, ROM and free walking speed compared to the control treatment groups which received placebo traction (Nyfos, 1983) and naproxen (Marques et al., 1983). Based on the not so impressive results, the authors concluded that there was no need for further studies regarding this modality in patients with disability related to hip OA (Marques et al., 1983; Nyfos, 1983).

Manipulations have been stringently defined as a small-amplitude rapid movement which the patient cannot prevent from taking place (Maitland et al., 2001). Recently a RCT compared manual therapy with exercise therapy (Hoeksma et al., 2004). The manual treatment given was forceful high velocity low amplitude manipulations (Cyriax & Cyriax, 1996) 5 times per treatment session over 9 consultations as well as self-stretching (Evjenth & Hamberg, 1984). The primary outcome variable was general improvement experienced by the patient, and the success rates after 5 weeks of treatment were reported as 81% in the manual therapy group and 50% in the exercise group. Odds ratio (OR) was 1.92 with a 95% confidence interval of 1.30 to 2.60. This OR-effect-magnitude is regarded as small (Hopkins, 1997). Furthermore, patients in the manual therapy group had statistically significant better outcomes on pain, stiffness, hip function, and active assisted ROM compared to the exercise group. The effect on all the secondary outcome variables except stiffness endured after 29 weeks. The authors therefore concluded manual therapy to be superior to exercise therapy in patients with hip disabilities related to OA.

There has so far been no study comparing different types of manual mobilization techniques in patients with hip-related disability. This thesis therefore presents a RCT comparing 2 different treatment techniques of manual traction mobilizations.

2 Aims and hypothesis

The aim of the thesis was first to compare the effects of 2 traction mobilization techniques in disability and passive ROM in patients with hip pain, hypomobility, and disability through a RCT. Second, to compare the effect magnitudes in Pain and Function in the present study to those reported in other trials which applied conservative treatment methods. And third, to deduce the present results to other health domains based on results shown in other clinical trials.

The hypothesis stated that the participant receiving forceful mobilization would show superior clinical important improvement in the main outcome HOOS-t (Hip disability and Osteoarthritis Outcome Score [HOOS] total) compared to those receiving standard mobilization after the 12 week trial period. The HOOS-t is a construct comprised of Pain, Stiffness, ADL (Activity limitation in daily Life), R&S (Activity limitation in recreation & sport), and HR-QL (Hip-related quality of life) in the HOOS (Klassbo et al., 2003b).

3 Paper

TITLE: Superior effect of forceful manual traction mobilizations compared to standard mobilizations in treatment of painful hip hypomobility – a randomized controlled trial

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Abstract

Objectives Compare the effectiveness of forceful manual traction mobilization treatment to standard mobilization of unknown forces in patients with hip pain, hypomobility, and disability. **Design** Prospective rater-blinded block randomised controlled trial (RCT) with 2 parallel treatment groups. **Setting** Regular private physiotherapy practice. Two physiotherapists in 1 clinic performed the innovative and 8 physiotherapists in 6 clinics the standard treatment. **Participants** In the experiment group (n = 10) and control group (n = 9) the mean (standard deviation) age was 59 (12). The clients were recruited from waiting lists of outpatient physiotherapy clinics, and 15 had radiographic OA. **Interventions** Both groups received 12 weeks of exercise, information, and manual traction mobilization. In the innovative group the traction force was progressed up to 800 N. **Main outcome measure** HOOS-t, a variable comprised of Pain, Stiffness, Function and Hip-related quality of life in the disease-, and joint-specific Hip disability and Osteoarthritis Outcome Score (HOOS). **Results** The participants receiving forceful mobilization showed large superior clinical treatment effect on HOOS-t by improvement ≥ 20 point on a 0 – 100 scale, where responders/non-responders were 6/10 and 0/9 in experiment and control group, respectively (P = 0.011). The effect size (1.1) was large. On pain the effect was very large (OR 32). There were no adverse effects. **Conclusions** These findings indicate treatment by forceful traction mobilization to be highly effective in patients in primary health care having hip pain, hypomobility, and disability. The long term effect is still to be documented.

Keywords: Osteoarthritis, Hip; Manipulation; Traction; Randomized Controlled Trial

Introduction

Hip osteoarthritis (OA) is a common cause of disability. The incidence of hip joint OA for men and women is reported to 88 per 100 000 in the age group 60-69 year and to peak with 600 persons aged 70-79 [1]. A prevalence of 4-5% has recently been described in persons aged 60 years and older in Copenhagen, Denmark [2]. Most clinical signs and symptoms have been found unrelated to the degree of radiographic change [3], and thus characterize a larger patient group than those fulfilling the widely used evidence-based classification criteria of hip OA [4,5].

Clinically, the hypomobility in individuals with painful osteoarthritic hips has sparsely been shown reversible by exercise therapy [6-9]. Recently, manipulations in form of high velocity, small amplitude thrust in traction and stretching were reported to improve Range of Motion (ROM) and disability more than exercise therapy [10]. Joint mobilizations, also feasible to non-manipulative physiotherapists, have as today not shown therapeutic effectiveness in trials concerning patients with concomitant hip hypomobility and disability [11-14]. Traction as passive mobilization with forces from 100-250 N has documented negligible treatment effects on impairment, symptoms and function in individuals with hip OA in RCTs [11,12]. This might be due to lack of adequate force-progression treating this massive joint.

A traction force of 400-600 N has proven adequate to reach the linear region of the load-deformation curve in non-diseased [15] and former patients with hip disability [16]. Cyclic deformation causes hysteresis, or permanently increased length of the joint capsule, if the deformation reaches over the toe region on the load-deformation curve through a unknown number of repetitions [17]. The manual traction mobilization technique of Samuelsen has documented the ability to deform the hip joint into the linear region of the load-displacement curve [16]. Samuelsen has long argued that a physiotherapist is capable of judging by traction assessment whether a hip possesses hyper-stiffness and thus has indication for traction mobilization treatment, and that this seems be performed reliably by utilizing the necessary force through a stable technique [16].

The objective of the present RCT was to compare the effect of manual traction mobilization forces graded up to 800 N [16] to traction mobilizations of a unknown forces [18] in patients with painful hip hypomobility and concomitant disability. The treatment hypothesis stated that patients receiving forces ranging up to 800 N over 12 weeks would experience superior important clinical effects as compared to those receiving unknown traction forces. The main outcome variable was `Hip disability and

Osteoarthritis Outcome Score total` (HOOS-t) [19]. The secondary outcome variables were the 5 subscales compiling the HOOS-t as well as passive ROM. The results were meant to guide therapists in treatment of this group of patients.

Methods

Study design

A prospective single blinded block RCT with two parallel treatment groups was carried out. The treatment sequence was generated using a block partition method via a random numbered table [20]. The allocation concealment was effectuated by putting small numbered tickets into opaque grey envelopes which were glue sealed and shuffled together into a large white envelope containing one block sequence. The block sizes were coined flipped between 4 and 6 participants. The total sequence was generated in advance of starting patient enrolment for a target total sample size of 50 participants based on a power estimate of 0.80, using the nomogram offered by Altman [21], where the standardized treatment difference was set to 0.80 for the primary outcome and the α level to 0.05.

Before enrolment, the patients signed an informed consent and underwent a clinical test procedure performed by the author. The patients then chose their own grey envelope from the large white one and signed their names on the envelope before opening it. They then signed the allocation list showing their treatment groups.

The assessors responsible for the ROM measurements were blinded in the sense that the patients were told by the consent paper and orally in front of the tests that this information was not to be disclosed to the raters. Actual disclosure levels were not measured. The patients filled in the self-rating questionnaires at home before returning for testing both at baseline and follow-up. The ROM tests were carried out within 14 days after the last treatment session by the same raters as at baseline. No efforts were done blinding neither therapists nor patients.

Subjects

Candidates were men and women between 30 and 90 years referred to outpatient physiotherapy for hip-related disability in Oslo County, Norway from December 2003 to October 2004, who had: (a) persistent pain in or from the hip [22] daily the last 8 weeks, (b) reduced hip mobility, defined as passive ROM < 2 standard deviations (SD) of the reported mean active ROM for their age group [23] in at least 1 direction on the

painful side, and (c) pain located toward the hip joint when tested by passive firm end-pressure in physiological rotation(s).

Patients were excluded if they had: (a) history or signs in accordance with labral injury and, or a free intra-articular body, (b) trauma, deformity or osteoarthritis due to early hip disease, (c) medically diagnosed inflammatory disease, (d) showed obvious neurological signs such as sensory or motor paralysis, (e) other diseases which entailed a powerful constraint on the physical, psychological, or social functioning, (f) additional pain from the lower back, pelvis, knee and/or ankle which overshadowed the pain from the hip, (g) problems receiving information due to inadequate hearing, sight, intellect or knowledge in the Norwegian language, (h) fulfilled the Swedish criteria for total hip replacement defined as: had serious and persistent pain at rest despite medications, had tried all other pain treatment modalities, and had disturbed sleep, and a walking function of less than 300-400 m even with walking aids [24].

Interventions

All physiotherapists and primary physicians in the area received a written invitation to refer patients to the project. This gave very few voluntaries, and nearly all participants were therefore recruited by me from the waiting lists of 4 physiotherapy clinics in different areas of the city. Two patients were referred from general practitioners.

In the experiment group all treatment were performed by 2 physiotherapists in 1 clinic who had over 10 years of experience with forceful manual traction mobilization of painful hip hypomobility. One of the therapists had earlier described the technique used in this group [16]. The last month before the trial the therapists once daily calibrated their force effort during traction, while this was done once weekly during the trial by applying forces to a model of a foot connected to a fish-scale which again was connected to the bench. The blinded therapists applied forces within accuracy of about 50 N.

The mobilization technique of Samuelsen [16] is carried out with the patient lying supine on the left hand side of the plinth (while treating the right side) first with the hip in the maximal loosed-packed position [18] as has been shown to facilitate joint separation [15]. As the stiffness in this position decreases, as judged by the therapists, traction is performed with the joint pre-positioned in the hypomobile direction (Figure 1).

[FIGURE 1 INSERT HERE]

Each patient received about 15 minutes of manual traction mobilization each session, graded according to Maitland [25]. The average holding time in the first sessions varied from 20-40 seconds, and decreased to 10-15 seconds as the therapists judged the elasticity to have improved.

In the control group the participants were treated in 6 clinics by 8 different physiotherapists, of whom 3 were licensed specialists in manipulative therapy, treating 4 of 9 patients. The therapists had used the standard manual traction mobilization technique [18] on a regular basis, had at least 5 years of clinical experience, and worked nearby the patient's home or workplace. The author contacted the therapists per phone to make sure these criteria were fulfilled. The control mobilizations [18] were performed without standardization of the applied forces. The therapists were urged to do their traction mobilizations as were normal for them.

Both treatment groups received soft tissue techniques, exercises, and information for which no restrictions were imposed by the trial administrator. Other treatment modalities were disencouraged during the treatment period. No effort was made controlling compliance regarding home exercises. The therapists agreed to aim at 2 treatment sessions per week over 12 weeks. Every treatment session lasted 30 minutes totally.

Procedures

Before the enrolment all participants completed a questionnaire regarding demographic variables, previous complaint(s), duration of symptoms, co-interventions, and previous treatment with manual traction mobilization. The use of non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics were permitted as needed in both groups and were recorded at baseline and at discharge (follow-up) as were the other measurements.

Two physiotherapy students were measuring passive joint mobility. They were neither located near to nor had connections to the treatment institutes; consequently the measurements were performed in an environment separate from the physiotherapy treatment locations.

Outcome assessment

The primary outcome variable was HOOS-t as measured by the patient self-reporting questionnaire Hip disability and Osteoarthritis Outcome Score (HOOS) [19]. This scale comprises 39 items, each with standardised answer options given in a 5-boxed grading scale scored from 0 to 4. The HOOS contain and is an extension of the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) which is recommended [26,27]

due to the evidence of adequate reliability, validity and responsiveness for lower limb OA [28-30]. The Swedish version of HOOS has been validated for patients with hip disability and hip OA [19,31] and showed better sensitivity than the WOMAC. The Swedish scale was translated to Norwegian through an ethnocentric approach.

Secondary outcome measures were the 5 subscales of HOOS [19], and passive ROM in the most affected hip regarding pain and ROM deficits. The subscales of HOOS are: Pain; Symptoms others, including stiffness (Stiffness); Activity limitation in daily living (ADL); Activity limitation in recreation & sport (R&S); and Hip-related quality of life (HR-QL). Measurements of passive ROM were taken using a goniometer with a scale marked in 5˚ increments. The reliability of this protocol has been reported [32]. The raters were coached by the author in the protocol adapted from that of Norkin & White [33]. The measures were taken by all orthogonal axes with the patients lying, except for rotation which was measured only with the participants sitting. A pressure scale was used as a mean of controlling the degree of pressure to 50 N measuring flexion [34]. The intra-rater reliability was assessed prior to baseline (see Results).

Data analysis

Analysis was performed according to the intention to treat principle [35]. The only patient who dropped out before the follow-up tests was given the median change scores for the rest of the control group to which he belonged.

A null hypothesis of no clinically important difference between the treatment groups in HOOS-t was expressed. The alternative hypothesis for the outcome in HOOS-t was that the experimental group would gain superior clinically important improvement. First the change scores within and between groups were calculated in medians, interqartile ranges (IQR) and percentages. The between differences were tested for significance by the Mann Whitney U Test. Non-parametric confidence intervals (CI) were calculated for both type of differences [36].

Two different cut-offs for clinically important improvement set to ≥ 50% and ≥ 20 points, were used to dichotomize participants into responders and non-responders [37]. The differences in proportions calculated from the cross-tables were tested for significance using Fisher's Exact Test.

Odds ratios (OR) were calculated for the cross-tables by $(\text{responders/non-responders})_E/(\text{responders/non-responders})_C$, and Relative risk (RR), taking $(\text{responders}/n_E)_E/(\text{responders}/n_C)_C$, where $_E$experiment group, $_C$control group and n is the number of participants in each group. The OR and RR effect magnitudes were interpreted according to the scales afforded by Hopkins [38]: OR; trivial (< 1.5), small

(≥ 1.5 < 3.5), moderate (≥ 3.5 < 9.0), large (≥ 9.0 < 32), very large (≥ 32); and the equivalent values for RR; 1.2, 1.9, 3.0, 5.7, and 19.

Effect sizes (ES) were calculated for the ROM-data by Standardized Response Mean (SRM), dividing the change scores between the intervention groups on the standard deviation of the change scores in the total sample [39]. ES for the HOOS-data were made by dividing the differences in median change scores between the intervention groups on the IQR for the change scores of the total sample [40]. These ES were interpreted according to the rule of thumb afforded by Cohen [41]: ES; trivial (< 0.2), small (≥ 0.2 < 0.5), moderate (≥ 0.5 < 0.8), or large (≥ 0.8).

Values for passive ROM change scores were given in mean and standard deviation (SD) and the between group differences were tested for statistical significance by the Independent T-test. The ROM measurements were tested for intra-rater reliability by the relative statistic Coefficient of Variance (CV) [42] and the absolute statistic Repeatability Coefficient (RC) as afforded by Bland & Altman [43]. The minimal clinically important difference (MCID) for the ROM measures was defined as 5˚ in each direction, and 30˚ for total ROM (5˚x 6). For all analyses, statistical significance was considered at a 2-tailed level of ≤ 0.05. The calculations were made using SPSS/Exel/PC.

Ethics

The study protocol was recommended by the Ethics Committee for Medical Research in West, Norway. The study was approved by the Norwegian Social Science Data Service, and it was conducted in accordance with the Declaration of Helsinki of 1975, as amended in 2000. Written and oral informed consent was obtained from all patients before inclusion.

Results

Subject characteristics

[FIGURE 2 INSERT HERE]

A flow diagram of the progress of the trial is shown in Figure 2. Twenty voluntaries were excluded due to lumbar pain (n = 6), pelvic pain (n = 4), enthesopathies without joint pain (n = 7), and to small ROM-deficits (n = 3). The number of analysed

participants equals that of the number randomised to the trial. One participant dropped out after the first treatment session, and was considered as non-compliant.

The 2 groups were basically similar at baseline (Table 1), except there were more females, distal pain irradiating, and longer duration of pain in the experimental group as compared to the control group.

[TABLE 1 INSERT HERE]

The median (IQR) treatment sessions accomplished were 13.5 (5) and 20 (6) for the experiment and control group, respectively. This difference was statistically significant ($P = 0.007$). One patient in the control group received a co-intervention of therapeutic low-intensity ultrasound. No participants in either group withdraw due to increased complaints, or received therapy from other health professionals. Neither was there reported any adverse effects. There was negligible difference in number of participants using analgesics and NSAIDs between the treatment groups, both at baseline and follow-up (results not shown).

Reliability of ROM measures

The lowest CV was found for total hip motion (1.3%) and flexion (6.3%) [Appendix 1]. The RC proved to be 7˚, 8˚ and 50˚ for flexion, medial rotation and total ROM, respectively, which were the most accurate directions. The RCs in those directions showing the highest relative reliability by CV (lowest CV values) did not meet the pre-determined MCID levels (Appendix 2). I still decided to report the ROM in flexion, rotations (pooled by individual medial or lateral rotation according to the direction showing the clearest ROM-deficits) and total ROM from the most affected hip by pain and ROM-deficits.

Outcomes

All volunteers in the experiment group expressed reduced level of disability in the main outcome HOOS-t at follow-up compared to baseline (Figure 3). In the control group 4 participants expressed deterioration, 2 negligible changes, and 3 improvements in their level of disability (Figure 4).

[FIGURES 3 AND 4 INSERT HERE]

The median differences between the groups in the main outcome HOOS-t, as well as in Stiffness, ADL, and R&S were statistically significant (Table 2). Pain was nearly significant, while HR-QL definitely was not. The CIs for median between group differences were highest for R&S, followed by Pain, HOOS-t, Stiffness and ADL, respectively. None of these CIs passed 0. The 95% CI for HR-QL passed 0, showing no real effect on this quality. The within experimental group 95 % CI showed the same ranking and about same effect magnitudes as mentioned above, although the Pain score was markedly higher than between groups. In the control group the CIs in all but Pain passed 0. The latter contained 0, indicating weak evidence for treatment effect on Pain in 95% of the population.

[TABLE 2 INSERT HERE]

On the main outcome HOOS-t, when judged by the absolute limit, patients respondent rate in the experiment group (6/10) was clearly higher than in the control group (0/9), a difference which was statistically significant (Table 3). By the relative 50% limit still more patients responded on HOOS-t in the experiment group than in the control group, but the difference was no longer statistically significant (Table 3).

[TABLE 3 INSERT HERE]

More participants responded in the experiment group by all secondary HOOS outcome measures by both limits, except for HR-QL (Table 3). The between group difference in Pain was statistically significant by the 50% limit, but not by the absolute limit. Evaluation by Stiffness and R&S gave *P* values slightly over the limit for statistically significance. The responder rates in ADL and HR-QL displayed the smallest differences between the groups, and in the latter there was no difference when judging by the relative limit.

The highest effect magnitude by OR was found in Pain, being judged as a very large by the relative limit (Table 3). The other OR values which were possible to calculate (did not contain zero in the denominator) showed large effect on R&S and moderate on ADL by the 50% improvement limit.

The experimental group displayed very large effect in Pain and large effects in function (R&S and ADL) in RR by the 50% limit (Table 3). Pain and R&S showed large effects by the absolute 20 point limit. The other variables were not calculable.

[TABLE 4 INSERT HERE]

In joint mobility (Table 4) there were small non-clinically important improvements in passive ROMs (1-3˚) for the experiment group, and non-clinically important reductions in mobility (-1 to -1.5˚) for the control group. The differences between groups were far from being statistically significant, and the CIs were equally distributed on both sides of 0, displaying no real effects.

[INSERT TABLE 5 HERE]

All ES were positive, i.e. in favour of the experiment group (Table 5). The ES for the major outcome HOOS-t was large. ES were also large for Stiffness, and for function in both ADL and R&S. In Pain and HR-QL the ES were moderate, whereas those for ROM were trivial (Table 5).

Discussion

Results synopsis

The participants with hip hypomobility and disability receiving graded traction mobilization forces up to 800 N experienced superior important clinical effects as compared to the control group receiving traction by unknown forces in the main outcome variable HOOS-t evaluated by individual absolute improvement. The ES was large. In Pain, the experiment group displayed superior important clinical effects by the 50% improvement limit, and the effect magnitude was very large. Statistically significant differences were found in Function (ADL & R&S) and Stiffness, with large ES in favour of the forceful mobilization group. The number of treatments used in the forceful group was 33% less then that for the standard treatment group. No clinically important differences were found in passive ROM nor HR-QL, but the latter showed moderate ES in favour of forceful mobilization group. In sum, this represents firm evidence in support of superior treatment effect by forceful traction mobilization as compared to mobilizations by unknown traction forces.

Manual therapy comparisons

This is the first RCT to show clinically important and statistically significant treatment outcomes due to manual traction mobilization, defined as passive joint movement with rhythm and grade such that the patient can prevent it [44]. It is also the first study to

document major differences in treatment effect due to choice of mobilization technique. The HOOS-t was chosen as the main outcome measure because it might be the one variable that best grasps the total picture of the clinical status of the participants. Anyway, pain is considered, together with function, as the main outcome variable in clinical trial for OA by the majority of the research society [39]. Seen in retrospect, it would have made the comparisons to other studies easier to have chosen Pain as the main outcome variable. Most comparisons are therefore made on Pain.

The effect on Pain here is regarded as very high [38]. In the only other RCT reporting effects of manual therapy in stiff hip patients, manipulation (defined as small-amplitude rapid movements which the patient cannot prevent from taking place [44]) and stretching was found superior to exercise therapy [10]. Because Hoeksma et al. [10] didn't report individually clinical important outcomes for pain, their results were translated into that variable. This was done based on data on 2,724 subjects from 10 placebo-controlled clinical trials, from which Farrar et al. [45] found a high correlation between 30% pain reduction and the answer `*much improved*` on the Patient Global Impression of Change (PGIC) scale. Hoeksma et al. [10] used the cut-off `*improved*` on PGIC for categorizing participants as responders or not. The changing of their cut-off level to much improved, increased the OR from 1.9 to 3.8 in favour of the manipulation group. The forceful mobilization treatment showed a 88% higher effect on pain than the manipulation and stretching treatment [10].

The effect on Pain through forceful mobilization in this study might be due to a sub-provocative stimulus enhancing the hip joint nutrition by improving capsular vascularity via tightening and relaxation of the connective tissue (the stretch squeeze effect), and by adding durable and intense piezo-electrical impulses through stressing the electrical molecular bindings within the connective tissue. Together, this might have facilitated intra-capsular lymphatic drainage, protein synthesis, and reduction of intra-arthicular & intra-capsular oedema, and thus speeded the healing of the connective-tissue enclosing the articulating surfaces, without increasing an often already raised intra-arthicular pressure caused by swelling [46,47]. Low-graded synovial inflammation is common in hip OA patients [48], as is oedema [47] and increased synthesis of proteoglycans and collagen fibres within the joint space, the capsule and synovial membrane [49].

The fact that the control group did not receive the same size of effect on pain, suggests that the force progression principle, as highlighted by Maitland and McKenzie [25,50], was not followed through in that group. To take out the 1-1.5 cm of accessory motion by traction, forces of at least 400-600 N are required [15,16], and this probably

was not achieved in the control participants: Prior to the trial we made an experiment using the Kaltenborn technique which showed the bench to move forward on the floor before reaching 350 N. This force had been applied to a model of a foot tied to a fish-scale, again fixed to a regular heavy therapy bench with 1 individual weighting 77 kilos on top. The bench was placed first on wood with floor sealer and then on floor covering, but the results were about equal.

It is also possible that the repetitive and forceful, but still delicately graded [25] mobilizations had a modulating effect on central and peripheral sensitivity [51]. Inducing signals from Aδ mechanoreceptor into the central nervous tissues have been linked to long-term depression of synaptic activity [52]. In addition, both within the synovial membrane and capsule, perineurial and endoneurial fibrosis are common and may be morphologic transducers of the chronic joint pain in hip OA [49]. Enhanced healing of nervous tissue has been reported due to nervous mobilization [51], and the effect seen here might as well be due to direct mobilization of the intra-capsular nervous tissue, thus promoting healing of peripheral nerve pathology. Anyway, inaccurate grading would probably give inadequate effects: by using too little force one would gain suboptimal stretch-squeeze-lymph-drainage-, piezo-eletrical- and nerve-mobilization-effects, and by being to ponderous one would risk adding pain stimuli to an already sensitized nervous system.

The manipulation study by Hoeksma et al. [10] documented clear and distinct large effect sizes in a combined function and impairment scale (Harris Hip score) and in active assisted ROM. In the present trial moderate (in OR) to large effect (in SRM) on function (ADL), and negligible effects on passive ROM were found. Possible mechanisms for the superior effect in function (small) and in ROM (large) of manipulation and stretching in the study of Hoeksma et al. [10] as compared to that of forceful mobilization, might be because the hip stiffness being more effectively decreased by manipulations. Since the number of deformation cycles needed to reduce stiffness by the hysteresis-effect is unknown [17], the cycles in the present study were estimated, ranging from 20 to 50. In comparison, Torstensen reported to normalize a very large capsular shoulder hypomobility solely by medical exercise therapy [53] using 1000 cyclic loadings. In the spine, the numbers of cyclic deformations for inducing collagen tissue fatigue injury is reported to be over 3000 [54,55]. Interesting, it seemed to Callaghan and McGill that the number of cycles were more important than the force applied [54]. Clearly both the frequency and force needed to achieve hip joint hysteresis by traction mobilization warrants further investigations.

In the study by Hoeksma et al [10], due to the speed and force of the manipulation, molecular bindings probably were ripped off within the capsule, thus causing the major improvements in ROM reported in the very stiff joints. High speed deformation leads to raised material stiffness and increased brittleness of viscoelastic materials [56], and bones and ligaments break their molecular bindings this way [57]. They used 2 treatments per week probably inducing graded trauma over the 5 weeks total treatment period. The possible subtle inflammation response after each session seemed to settle within the next. These subtle reactions together with possible provoking stretching by physiological rotations might have depressed the pain effect measured directly after the 5 week intervention period [10]. The further pain reduction reported after the first follow-up supports this notion. The 2 participants in the present forceful mobilization group who were deemed as non-pain-responders, showed the absolute lowest total ROM values of all trial participants, and might have needed further force progression. Maybe in form of a high speed trust technique, or grade 5 (of 5) manipulation as wisely nominated by Maitland [25].

Non-manual therapy comparisons

A recent review on exercise treatment for OA included only 2 high quality studies giving explicit results for the hip joint [58]. Both studies reported small to moderate effects regarding pain and function. According to the much larger effects seen in the present study, exercise therapy should be seen only as a supplement to forceful traction mobilization treatment for patients with hip pain and disability. On the other hand, for improving function and ROM in *very* hypomobile individuals, like those in the study of Hoeksma et al. [10], manipulation should probably be the first line treatment. Self–stretching was part of the exercise treatment of the experimental group in the RCT of van Baar et al. [9] and in the control group of Hoeksma et al. [10], but only in the manipulation group did the participants show large clinical important effect on ROM. Therefore, the most effective modality for hip joint hypomobility, as far, seems to be the manipulation technique, first described by Cyriax [59]. In a sequence, treating a very hypomobile client, the therapist might wisely apply manipulations in the first sessions, and as the excessive stiffness is amended, start traction mobilization to address pain.

Information as treatment for patients with hip disability with or without OA is also sparsely documented, even though a meta-analysis exists for OA in general [60]. NSAIDs are highly recommended by general practitioners as treatment for lower limb OA [61], and most patients in my study received these drugs either alone or in combination with analgesics. Effects from NSAIDs have lately been systematically

reviewed [61-64], but few studies with adequate quality giving explicit data regarding treatment in hip OA were found. The extracted ES regarding pain and function were small (0.2 to 0.3) compared to placebo treatment [61]. This is about 70-80% less than what is shown in the present study. Taking into account the seriously adverse effects of gastrointestinal ulcers and perforations seen in 5-13% of patients in these short-term studies of mean 5-7 weeks [63], Bjordal et al. might be right suggesting that long-term use of NSAIDs probably does more harm that good for patients with hip OA [65].

Study design

The author self-rated this study using the quality evaluation scale afforded by Jadad et al. [66] which resulted in 3 out of 5 points. According to the scale this sum indicates the characteristic of high-quality. The study has its most important weakness in the blinding. First, the efficacy of the rater-blinding should have been measured, although meticulously effort was taken instructing the clients not to reveal their group participation. Secondly, the participants might have been blinded. The problem faced was that in the same period 2 other hip OA trials took place in Oslo making it difficult to recruit clients. As many of the clients thus insisted on having the treatment location revealed, it was decided not to try blinding them. The alternative solution, training therapists in more clinics to do the experimental approach, was not a real option. It was not possible to blind the therapists in this study. The double-blinding criteria might not seem feasible for physiotherapy trials.

Subjects

The included subjects displayed equality of most baseline factors. Age, which is the most important known risk factor for OA, did not show differences. Another strength is that the outcome measures were equal at baseline, and the key to a successful clinical trial is to avoid any biases in comparison between groups [21]. A weakness regarding the baseline comparison is that the second best evidence supported negative prognostic factor, superolateral migration of the femoral head [67], was not examined. An absolute cut-off value for Pain does presuppose a minimum Pain-level criteria securing eligibility to avoid the floor effect. This was not used.

Interventions

We made serious efforts to standardize the force applied during traction. The reliability of the force application might also have been examined. On the other hand, the therapists used clinic-like procedures regarding accuracy and time efforts in both

treatment groups. The intervention should therefore be easily applicable in a busy outpatient private practice setting, which might also enhance the replication of the trial.

The manual traction mobilizations method of Samuelsen [16] might be regarded as an highly effort-demanding approach. However, in support of the feasibility of the forceful method, normally strong female 50 year old therapists are fully capable of handling this force, as documented by measurements taken with our fish-scale arrangement. The technique is mostly a matter of handling skills, as the muscles affording the force are the strongest in the human body and the sitting position is very stable. The latter also facilitates grading accuracy.

The low standardization of the patient information and exercises is a weakness in this trial. Having better controlled these factors would have raised the validity of deducing the difference in effect as coming mostly from the mode of mobilization. A problem faced was that imposing extra effort on the control therapist, made them harder to recruit. On the other hand, the ES seen in this trial is of such magnitude that not even by adding the highest ES seen in hip OA information [24] and exercise trials [68] would have resulted in the equivalent. Adding like that might not even be reasonable because most therapists would combine information with exercises. The effect magnitude therefore is seen as supporting the forceful mobilization approach to be the main factor responsible for the effects.

Procedures

ROM measurements were taken by 2 raters, which is highly recommended [32]. Each test at baseline and follow-up were rated only once. Repeated measurements would have given higher reliability due to the fact that replicated measurements in each combination of experimental conditions give better precision for estimating the effect of difference [21].

The treatment period of 12 weeks is regarded as adequate compared to the time needed for inducing tissue changes in the synovial membrane, synovial fluid, and cartilage matrix [69,70]. For subchondral bone and fibro-cartilage tissue the time seems too short [69,70]. Treatment towards mobilization of the nerve tissue has shown effect in RCTs lasting 4-10 weeks [51], whereas injured synovial cartilage does not normally recover in adults [70].

Outcome measures

The HOOS was chosen over the WOMAC because it is not only disease–specific, but also a joint-specific outcome measure. In addition, the patients were from primary care

whereas the WOMAC has been most widely tested on the secondary health care population [29]. The HOOS has also proven to be more responsive than the WOMAC, at least in THR operated clients [31].

This is the only RCT which has used the HOOS so far, and the young scale needs further testing [19]. The HOOS has its own subscale for HR-QL for which the present data has raised suspicion against the responsiveness of the item: "How often do you think about your hip?" This as only 1 out of 19 participants reported to have changed their frequency of thinking. Maybe the question rather should be: How often do you have negative thoughts about your hip? In addition, HOOS should probably make explicit that it is the *average* quality during the last week which is at question. By not doing so, as is the case in the existing version, one might receive answers about the worst episode during this period.

The ROM-measurements were not reliable enough to dichotomize the participants into responders and non-responders: The absolute RCs were higher than the defined desirable MCIDs. This might be due to inexperienced raters. The study by Holm et al [32] found more reliable results for 2 inexperienced raters than for one experienced rater, but unfortunately they did not compare their reported RCs to assumable MCIDs. It is not recommended using a standard goniometer alone in future trials, but maybe combined with a force gauge. Other scientists have not reported absolute reliability values ([9,10]. The manipulation study by Hoeksma et al. [10] didn't report relative reliability values.

Data analyses

The cut-off used in this trial are anchored to the highest obtainable improvements in studies using NSAIDs as treatment modality [37]. Lately, 3 different cut-off values for minimal clinical important improvement, anchored to the patients expressing much improved treatment effects on a 5-point box-grading scale [71], have been documented in OA patients with different level of baseline symptoms: Those who had severe symptoms needed a higher level of change to consider themselves as clinically important improved than those with less severe symptoms [71]. These adjusted thresholds might be preferable to the single crude cut-off value applied in this trial.

Generalization of results

It is plausible that the forceful treatment is of clinical value not only to patients with idiopathic or primary OA, but also to those having the same symptoms and signs being

classified as having secondary OA. The ES might well be smaller due to their less advantageous prognosis.

It might show effect also in patients with painful hip joints without ROM-deficits, acting on other mechanisms than stiffness reduction. Individuals showing signs and symptoms towards sensitization of the central nervous system caused by nociception from other joints, e.g. the pelvis and lower lumbar spine, might also profit. Passive treatment also has the important advantage of requiring very little effort from the patient other than showing up for therapy, which for some is the absolute condition.

Conclusions

This RTC in primary health care showed clinical important post-treatment effects of forceful traction mobilization in HOOS-t, Pain, and Function in patients with idiopathic hip pain, hypomobility and disability. The result supports referral to this type of therapy in primary health care. Finding the number of elongation and relaxation cycles to achieve the hysteresis-effect is suggested. Trials are recommended using such data, larger sample size, further blinding, adequate reliable ROM measurements, known forces in both groups, and longer follow-up periods. Then, it is hypothesised that the treatment effect is still larger.

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Appendices

Appendix 1. Mean ($\overline{X}$) ROM and standard deviation (SD) of the right hip in students (n = 10) and in individuals under treatment for hip pain (n = 10). Intra-tester reliability between test 1 and 2 calculated by coefficient of variance (CV), repeatability coefficient (RC) and 2 times Standard Error of Measurement (SEM).

Movement	$\overline{X}$ (SD)	CV (%)	RC (˚)	2*SEM (˚)
Flexion[1]	120 (7.0)			
Flexion[2]	118 (8.0)	6.3	10.3	5.2
Extension[1]	19 (4.9)			
Extension[2]	18 (4.7)	26.1	7.9	4.6
Abduction[1]	18 (6.8)			
Abduction[2]	17 (5.1)	35.1	14.2	6.5
Adduction[1]	10 (4.3)			
Adduction[2]	8 (2.9)	40.9	8.7	4.5
Medial rotation[1]	27 (8.2)			
Medial rotation[2]	24 (7.9)	36.7	11.0	6.6
Lateral rotation[1]	27 (5.6)			
Lateral rotation[2]	27 (5.6)	21.0	11.0	7.3
Hip total motion[1]	216 (24.7)			
Hip total motion[2]	208 (27.8)	1.3	33.6	17.3

Appendix 2. The mean differences between measurement 1 and 2 in the different directions and the repeatability coefficients related to the desired measurement precision levels.

ROM direction	Mean	SD	RC (˚)	MCID	Conclusion
Medial rotation right	3	4	8	5	Unreliable
Flexion right	2	3	7	5	Unreliable
Total ROM right	16	25	50	30	Unreliable
Abduction right	1	6	12	5	Unreliable
Adduction right	2	3	7	5	Unreliable
Lateral rotation right	0	5	11	5	Unreliable
Extension right	2	3	7	5	Unreliable

SD: Standard deviation, RC: repeatability coefficient, MCID: minimal clinical important difference.

Vitae

Physiotherapist, MSc-student

Figures and legends

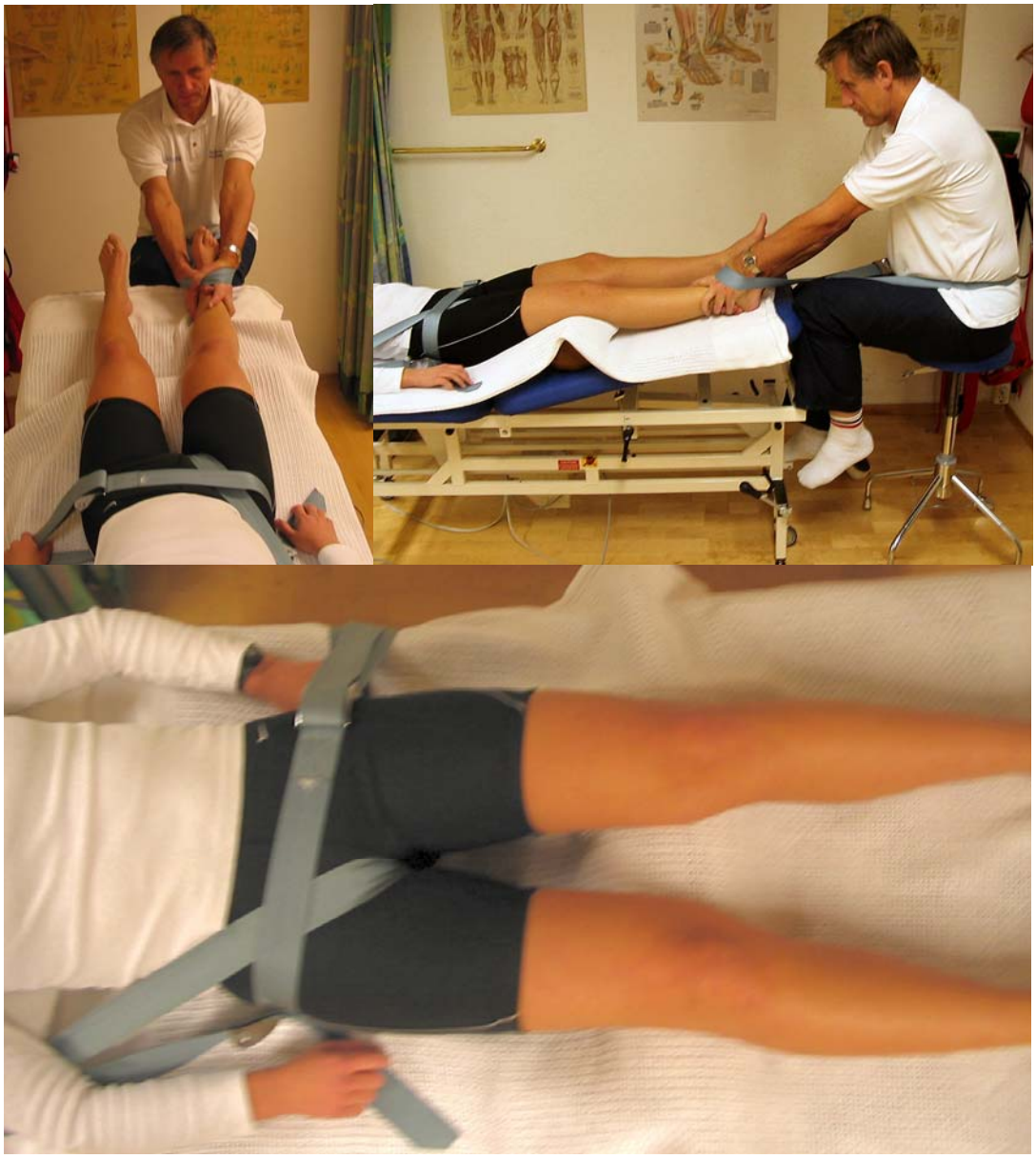

Fig. 1. Therapist (Samuelsen) performing traction mobilizations on the patient's right hip. The pillow under the pubic belt is not shown due to didactics. The belt resisting lateral glide looped the metal under the side of the plinth and turned around the pelvis in level directly inferior to the 2 anterior superior iliac spines and back in level with the posterior superior iliac spines to reconnect. Caudal glide was resisted by a belt looped from under the right hand side of the plinth around the ipsilateral pubic bone to recouple.

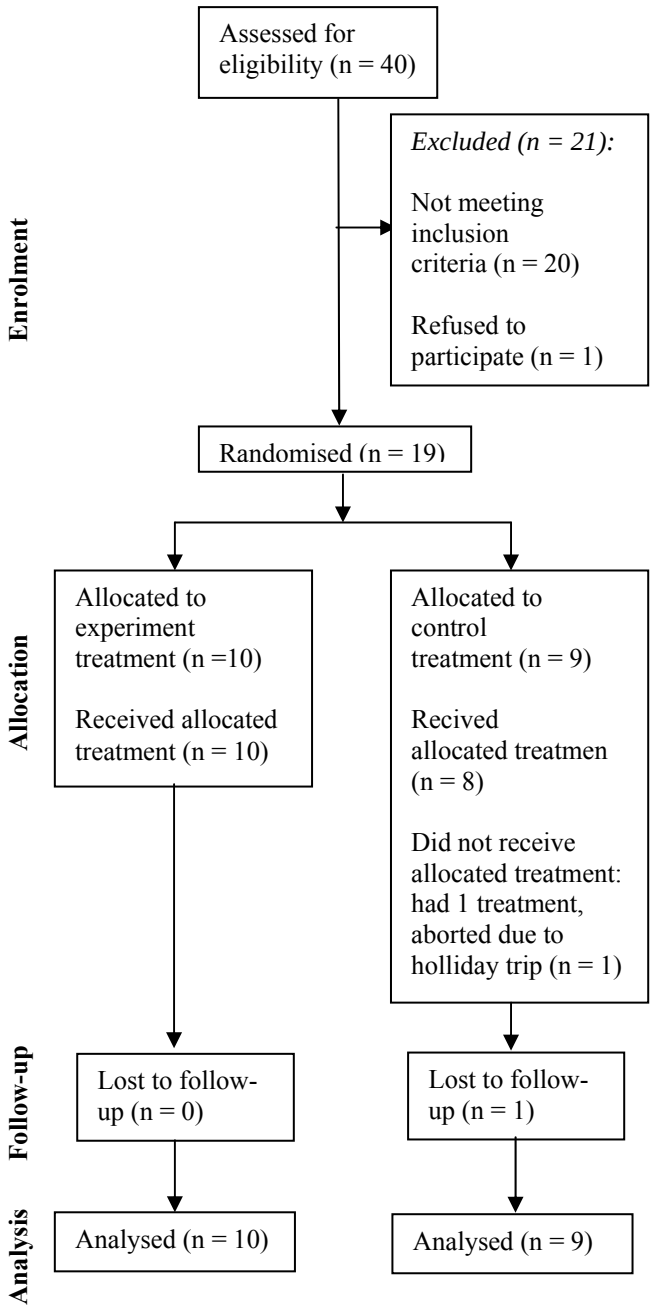

Fig. 2. The progress of the participants through the trial phases.

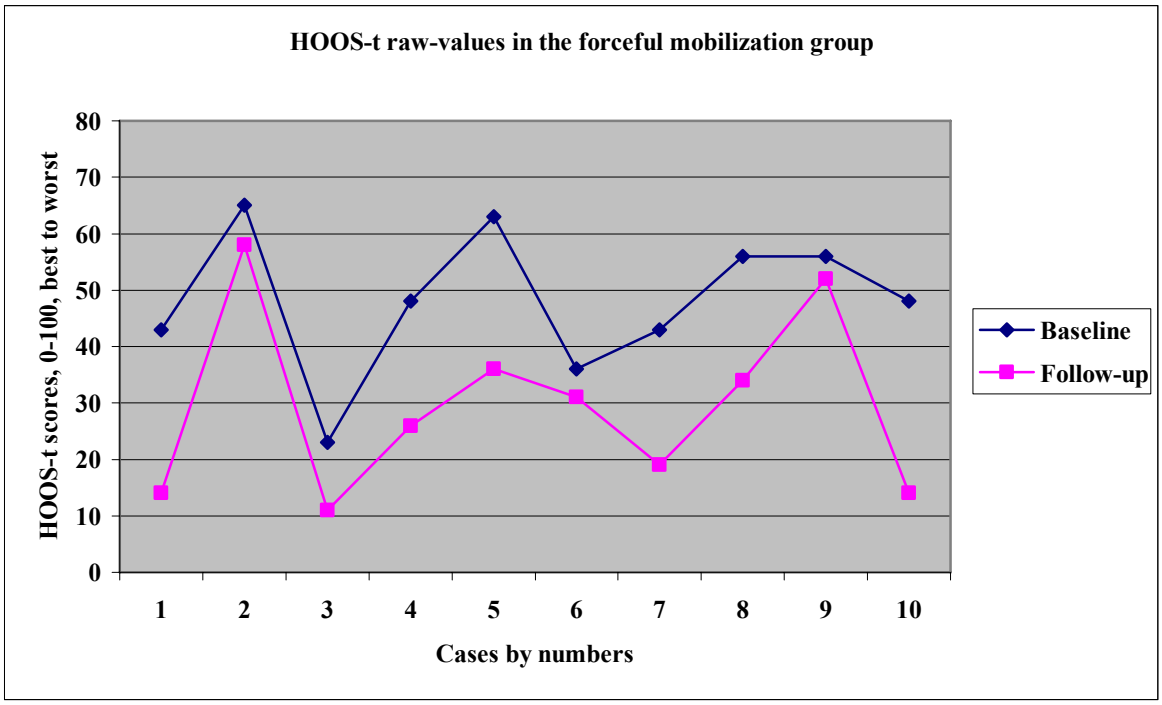

Fig. 3. Individual scores on HOOS-total for the experiment group before treatment (at baseline), and after treatment (at follow-up).

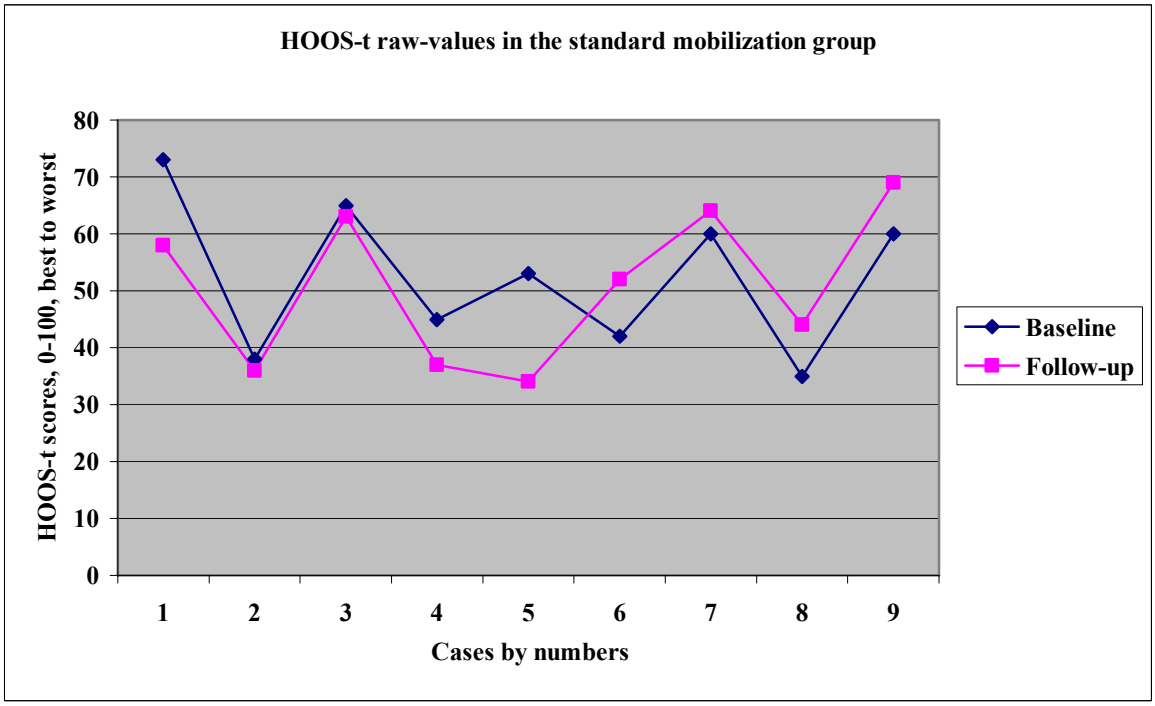

Fig. 4. The Individual HOOS-total scores for the control group.

Tables

Table 1**.** Baseline variables of demographics, pain, and Hip disability and Osteoarthritis Outcome Score (HOOS) in medians and interquartil range (IQR), if not otherwise specified.

Variables	Experimental group N = 10	Control group N = 9
Demographics:		
Age, yrs	62 (14)	57 (21)
Body mass index, kg/m^2	24 (4)	25 (7)
Gender female, n	6F	2F
Prognostic characteristics:		
Duration of complaint, yrs	10 (6)	5 (9)
Distal spread of pain:		
nates, tigh, calf, foot, n	1, 2, 2, 5	1, 5, 1, 2
Hip pain:		
Unilateral, n	4	6
In hard physical work which aggravates condition, n	4	4
OA x-ray verified, n	8	7
HOOS:		
Stiffness$_a$	43 (21)	55 (25)
Pain	46 (28)	44 (19)
ADL$_b$	38 (28)	41 (18)
R&S$_c$	63 (31)	56 (22)
HR-QL$_d$	59 (16)	63 (34)
HOOS-t$_e$	48 (17)	53 (23)

$_a$Symptoms other, included stiffness, $_b$Activity limitation in daily living, $_c$Activity limitation in recreation and sports, $_d$Hip-related quality of life, $_e$Hip osteoarthritis and Outcome Score-total. HOOS Scores: 0 = no disability, 100 = worst possible disability, HOOS-t = (∑ 5HOOS-subscores)/5.

Table 2. Within- and between-group comparisons. Absolute values are given in medians and interquartile range.

Variables		**Experimental group**			**Control group**			**Between group comparisons**		
	T$_a$	Scores	WGD$_b$	WG-CI$_c$	Scores	WGD	WG-CI	BGD$_d$	BG-CI$_e$	*P* values$_f$
HOOS-t$_g$	1	48 (17)	-22 (21)	-12,-27	53 (23)	-2 (23)	9,-11	-20	-6,-31	
	2	29 (26)	-46%		48 (26)	-3%		-40%		0.001
Stiffness	1	43 (21)	-15 (16)	-6,-25	55 (25)	0 (5)	13,-5	-15	-6,-25	
	2	25 (24)	-35%		55 (30)	0%		-31%		0.005
Pain	1	46 (28)	-29 (28)	-15,-36	44 (19)	-11 (25)	0,-25	-18	-6,-32	
	2	17 (14)	-63%		33 (13)	-25%		-40%		0.067
ADL$_h$	1	38 (28)	-22 (17)	-5,-27	41 (18)	-1 (18)	8,-10	-21	-2,-21	
	2	19 (33)	-57%		37 (22)	-2%		-53%		0.045
R&S$_i$	1	63 (31)	-28 (20)	-16,-38	56 (22)	3(38)	19,-11	-31	-13,-50	
	2	25 (39)	-44%		59 (25)	5%		-51%		0.045
HR-QL$_j$	1	59 (16)	-13(20)	0,-19	63 (54)	0 (31)	13,-13	-13	6,-25	
	2	47 (31)	-21%		63 (30)	0%		-21%		0.24

$_a$test nr., $_b$within-group difference, $_c$within-group confidence interval, $_d$between-group difference, $_e$between-group confidence interval, $_f$Mann-Whitney U test, $_g$Hip disability and Osteoarthritis Outcome Score-total, $_h$Activity limitation in daily living, $_i$Activity limitation in recreation & sport, $_j$Hip-related quality of life.

Table 3. Dichotomized differences in responders and non-responders between experiment (E) group (n =10) and control (C) group (n = 9) after 12 weeks of treatment assessed for significance by Fisher's exact test.

	HOOS-t	Stiffness	Pain	ADL	R&S	HR-QL
Improvement ≥ 20p.						
Nr. responders	E6, C0	E4, C0	E7, C2	E3, C0	E7, C2	E1, C2
P values	0.011	0.087	0.07	0.211	0.07	0.058
Odds ratio	--	--	8.2	--	8.2	0.45
Risk ratio	--	--	3.2	--	3.2	0.39
Improvement ≥ 50%						
Nr. responders	E4, C0	E5, C0	E8, C1	E5, C1	E6, C1	E0, C0
P values	0.087	0.057	0.005	0.141	0.057	--
Odds ratio	--	--	32.0	8.0	12.0	--
Risk ratio	--	--	7.2	4.5	5.4	--

p.: HOOS-points. For more abbreviations, see Table 1.

Table 4. Passive ROM comparisons. All results are given in mean (standard deviation) in the most affected hip regarding to pain and passive ROM-deficits. Rotation includes internal or external rotation values in the single patient according to the direction that showed most restriction. Positive values show increased ROM.

Variables	**Experimental group**			**Control group**		**Between group comparisons**	
	T_a	Scores	WGD_b	Scores	WGD	$BG\text{-}CI_c$	*P* $values_d$
Flexion	1	111(12)		113(9)			
	2	112(13)	1(6)	112(8)	-1(10)	-5 to 10	0.45
Rotation	1	14(8)		14(5)			
	2	15(10)	1(11)	13(8)	-1(7)	-5 to 5	0.967
ROM-total	1	178(38)		183(21)			
	2	181(34)	3(21)	182(34)	-1(27)	-25 to 30	0.75

$_a$test nr., $_b$within-group difference, $_c$between-group confidence interval, $_d$by the Independent t-test.

Table 5. Effect sizes (ES) for HOOS-scores and passive ROM-values

	HOOS-t	Stiffness	Pain	ADL	R&S	HR-QL	Flexion	Rotation	ROM-t_a
P.var$_b$	21	15	31	15	34	25	7	8	23
ES	1.1	1.0	0.7	0.8	1.0	0.6	0.15	0.1	0.07

$_a$ROM-total, $_b$pooled variability of experiment and control group.

For more abbreviations, see Table 1.

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4 Extended discussion

Methods

4.01 *Design*

The recruitment problem, and thus the decision not to blind the clients, could have had economical causes. In Norway, all patients with clear hip OA signs on radiographs have the costs connected with physiotherapy treatment refunded by the public health service system. This makes treatment of these patients a stable income source for the physiotherapists. Three clinic leaders stated frankly that this was the reason for not referring patients. The presumable competition of physiotherapy to NSAID treatment might have affected the general practitioners referral rate.

4.02 *Subjects*

Patient eligibility was secured by clinical findings and anamnesis alone, even though the majority of patients had OA according to the radiographic- and primary physicians-reports. The latter might facilitate comparison with other studies including patients with hip OA. The widely used hip OA classification criteria of the American College of Rheumatology were not chosen of 2 reasons. Firstly because evidence has emerged discrediting their validity (March, Schwarz, Carfrae, & Bagge, 1998; Bierma-Zeinstra et al., 1999; Klassbo et al., 2003a). Secondly, because I wanted to include patients with the

same symptoms and signs, but who lacked the most progressed signs of hip OA, believing this increased the external generalization of the results, as well as making it easier to increase the sample size.

4.03 *Methodological quality*

Researchers have defined trial quality as the degree of likelihood of the design to generate unbiased results and to approach the "therapeutic truth" (Jadad et al., 1996). Empirical evidence supports that RCTs which do not use a double-blinded design are more likely to show advantage of an innovation over a standard treatment (Colditz, Miller, & Mosteller, 1989), and yield statistically significant larger estimates of treatment effects ($P < 0.01$) (Schulz, Chalmers, Hayes, & Altman, 1995). Seen in this perspective, the results of this trial should be looked upon with some scepticism, even though the self-rated quality of the trial is considered to be high. On the other hand, the scale from Jadad et al. (1996) might not be particular suitable for physiotherapy trials due to the impracticality of blinding the therapists. Anyway, it can be reasoned that blinding the participants would have been a major improvement, as they were the true raters for all outcome measures in the HOOS.

When replicating a trial which has revealed large treatment effects, and therefore has been widely known, all those taking part in the subsequent research will know the effect and possibly be influenced by it (Wormnes & Manger, 2005). There is also ethical consideration towards withholding a documented efficient modality from half of the clients. This problem is exemplified by the lack of RCTs comparing THR surgery to other therapies (Brandt et al., 2003). This underlines the importance of the methodological quality of an innovative trial.

High internal validity is assumable when few alternative explanations for change in the dependent variable other than the effect of the independent variable are present (Domholdt, 2000). It is obvious that the degree of standardization of the therapy in the control group was low, as the aim was regular treatment which reasonably will differ due to therapist preference. Thus, there might have been differences in given information, exercises, as well as force of mobilization. On the other hand, the ES in the present trial were larger than those reported from exercise-, information- and mobilization-trials (Bjordal, Ljunggren, Klovning, & Slordal, 2004; Nyfos, 1983;

Superio-Cabuslay, Ward, & Lorig, 1996). This therefore is regarded as evidence supporting the important effect-mechanism to be the forceful mobilizations.

4.04 *Intervention*

The 2 interventions were performed by different therapists. The 2 experiment therapist might be regarded as hip joint specialists as they normally receive high rates of hip pain patients. Therapists experienced in successful hip joint treatment will probably show a superior self-confidence to those without such experience, which might have added to the effect. Motivation and coping is important for treatment results, as is the belief in the effect of treatment. The physiotherapists might have established new hope in their patients, and hope is shown to have direct effect on health outcome (Curry, Wells, Lochman, Craighead, & Nagy, 2003). On the other hand, negative narratives have been shown to be common among general practitioners regarding the prognosis of hip OA (Klassbo, 1993). Such narratives and expectations might also abundance in standard physiotherapy practice judged by the trivial to small treatment effects seen in the control group in the present trial.

4.05 *Outcome measures*

Choosing an appropriate functional outcome measure for a clinical trial involves a number of decisions. Not only does the clinician have to choose measures with sound measurement properties, but also there is the associate dilemma of deciding which type of measures to use. These measures generally fall into 2 broad categories, self-report measures and performance measures. I chose to use only the self-report measure HOOS, which reason will be explained.

Data suggest that the self-report measurements offer an efficient and cost effective method of comprehensively sampling from the domain of interest, compared to the timed tests (Stratford, Kennedy, Pagura, & Gollish, 2003). The relationship between self-report and performance measures have been examined (Stratford et al., 2003). In 3 previous studies these researchers found evidence suggesting modest relationship between performance measures and self-report measures. In their own study they found that the Self Paced Walking-, the Timed Up and Go- and the Stair Climbing-test were only moderately correlated with the Lower Extremity Functional Scale (Pearsons r = 0.44) using time as the only judgement criteria. Putting these 3 tests together did not

increase the association. By adding pain and exertion to the time criteria (Stratford et al., 2003), the correlation increased markedly (Pearsons r = 0.59). The explanation seemed to be that by increasing the breadth of health concept (i.e. time, pain and exertion) associated with the performance score, a greater correlation was achieved with the self-report measure. These efficiency and cost-effective advantages were important while deciding to use only self-rating measurement in the present trial: tests were to be administrated mainly by 1 person on a low budget. In the OA population, several studies support using self-report measures alone or in combination with physical performance measures (Kennedy, Stratford, Pagura, Walsh, & Woodhouse, 2002; Nilsdotter, Roos, Westerlund, Roos, & Lohmander, 2001; Steultjens, Dekker, van Baar, Oostendorp, & Bijlsma, 1999; Steultjens, Roorda, Dekker, & Bijlsma, 2001).

Another disadvantage with using time as the only judgement criteria may be that it would increase the performance to unnatural levels due to the short test interval involved. Such results therefore might not give insight into the individual's capacity in normal life situations where the tasks are to be regularly repeated over days and weeks.

The HOOS contains and is based on the WOMAC. The factorial or structural validity of the latter have received critics lately (Faucher et al., 2002; Kennedy et al., 2003; Thumboo, Chew, & Soh, 2001). Factorial validity is the extent to which domains hypothesized to make up measures – pain, stiffness and function in the case of the WOMAC – actually underlies patients` function (Stratford & Kennedy, 2004). Investigations suggest that the WOMAC items do not group by pain and function as originally conceived, but rather by activities with overlap the pain and function items (Kennedy et al., 2003). An important consequence of this poor factorial validity is that the WOMAC may not be capable of distinguishing between changes in pain and functional status when these attributes have discordant changes (Stratford et al., 2004). On the other hand, the HOOS is not identical to the WOMAC, and the factorial validity therefore might not be the same: The HOOS contains more items on both pain and the functional subscales. This side of HOOS' validity remains to be scrutinized.

The responsiveness of the HOOS is reported to be good in all subscales in patients undergoing THR surgery (Nilsdotter, Lohmander, Klassbo, & Roos, 2003). In patients without indications for surgery, i.e. with lower level of hip disability, this characteristic has been inadequately assessed (Klassbo et al., 2003b). The latter authors found only 1 *prerequisite* for responsiveness: all but 1 HOOS-subscale showed higher median scores

than those from the WOMAC. The relation between high scores and high responsiveness is uncertain, and might not exist at all. This can be exemplified by the HOOS-item 36 (appendix IV) which showed to be responsive in participants undergoing THR surgery (Nilsdotter et al., 2003), while unresponsive in the present trial. In the present trial all individuals experienced some pain after being discharged, while in the THR trial many patients became totally pain free, thus making it possible to forget about the hip.

The test-retest relative reliability (ICC 2.1) of the HOOS in the hip disability population is reported to be good, ranging from 0.78 in HR-QL to 0.93 in Pain (Klassbo et al., 2003b). The absolute reliability in form of either the SEM or the RC was not reported, and thus I could not calculate uncertainty margins neither for the baseline nor follow-up scores, as it is recommended in individual measurements (Finch, Brooks, Stratford, & Mayo, 2002). On the other hand, such calculations are not reported in comparable studies either (Hoeksma et al., 2004; van Baar et al., 1998).

In support of using a more sensitive scale the participants baseline WOMAC scores in this trial were compared to those reported in the RCT located in EMBASE and PubMed (Hawel, Klein, Singer, Mayrhofer, & Kahler, 2003; Singer, Mayrhofer, Klein, Hawel, & Kollenz, 2000; Haslam, 2001; Harlow et al., 2004; Makarowski et al., 2002). My values were on average 5, 10 and 1% lower, respectively.

Anyway, disability can not be captured by a single standard measure because at any given time disability is the result of three factors: capacity, will, and need (Brandt et al., 2003). This fact facilitates the measurement tool which also takes into account psychosocial factors. Data on participation restriction or mental function would have been interesting, and using e.g. the SF-36 would also have facilitated comparisons with other studies thus given a broader data base for comparison. On the other hand, major impact of the intervention was to be expected in the tissue-function, pain, and activity domains as they were directly targeted by the present intervention.

4.06 *Data analyses*

The statistical analyses might be considered inappropriate regarding multiplicity of probability tests due the lack of corrections preventing inflation of the *P* values. In addition, a Continuity Correction is recommended for small samples, as analysis of such

data tend to afford too optimistic *P* values (Altman, 1991). Furthermore, the Yates correction is recommended for 2x2 table analyses (Altman, 1991) in small samples. On the other hand, in such samples, the non-parametric methods are rather lacking in power, and therefore will tend to give less significant (larger) *P* values than an equivalent parametric test (Altman, 1991). I therefore chose not to make these corrections.

Regarding the criteria for dichotomizing participants into responders and non-responders, I didn't use the total OMERACT-OARSI algorithmic tree (Pham et al., 2004). That tree has 2 judgements, the first is the 20 points or 50% limit for high effect, and the second is the 10 point or 20% cut-off values for moderate effect. These are meant to be combined. I sat the high cut-off values in advance to facilitate comparisons with other studies using 1 cut-off value (Hoeksma et al., 2004; van Baar et al., 1998).

4.07 *Ethics*

The clients signed an informed consent (appendix I), and the trial was recommended by the Regional Ethics Committee (appendix II) and the Norwegian Social Science Data Service (appendix III). This study might therefore be regarded as keeping to the required ethical standards. Using best possible methodology and therefore being able to maximise the credibility of the trial's results might be regarded as an extension of the ethical requirements of a trial. This trial has possibilities for quality improvement.

Results

4.08 *Manual therapy mechanism*

Knowledge about the creep-effect held together with the seemingly ineffectiveness on ROM displayed here, neither supports mobilizations by Samuelsen`s (Samuelsen & Høgseth, 1990) nor Kaltenborn`s (Kaltenborn, 2002) methods to reduce stiffness in the hip joint. The creep-effect takes place when loading of a specimen is kept safely below the linear region of the load-deformation curve and the amount of load remains constant over an extended period. Deformation then increases relatively quickly at first, i.e. within the first 6 to 8 hours of loading (Nordin et al., 2001). Neither the standard nor innovative mobilization treatment took fully advantage of the creep- or the hysteresis-effect mechanisms. Clearly more research is needed to shed light also on a creep-

inducing approach towards the stiff hip. Recently a stretching approach has been recommended in hip OA clients (Cibulka & Threlkeld, 2004) where 1 client displaying hip hypomobility, stretching by physiological rotation was reported to markedly improve ROM, pain and disability. This patient received diagnosis and intervention shortly after onset of pain, and therefore does not seem comparable to the participants in this trial.

4.09 *Exercise comparisons*

Some differences between the hip joint and the shoulder needs highlighting considering using end range motions to reduce stiffness through the hysteresis-effect. The main difference between the 2 joint is the depth of the socket, which in the hip is covering the equator of the femoral head with labrum included (Gray, 2004; Dahl, 1999), whereas in the shoulder it quite shallow (Gray, 2004). Secondly, the hip capsule is far stiffer than the shoulder capsule (Gray, 2004). Therefore, by repeatedly moving a stiff and painful hip joint into outer range one might: a) cause the socket rim and labrum to impinge with the neck of the femur (Ganz et al., 2003), b) force the femoral head further into a fragile socket cartilage as the capsule tightens, c) cause the femoral head to impinge on the labrum as the head detours from the socket centre due to capsular restrictions (Harryman et al., 1990), and d) reduce the intra-capsular space, further increasing intra-articular pressure (Robertsson, Wingstrand, & Onnerfalt, 1995). The inflammation process necessary for removing cartilage debris possible abraded by physiologic end-range rotations, would cause release of inflammatory mediators, subsequent swelling and pain, even if the cartilage itself have no pain sensors. Further, the outer 3rd of the fibrocartilageous labrum have pain sensors (Suenaga et al., 2002). In sum, physiological end-range rotations have potential for further injuring the cartilage and labrum (Ganz et al., 2003), as well as irritating the synovial membrane (Robertsson et al., 1995) and a already sensitized nervous system (Butler, 2000). By treatment in traction, whether by mobilizations or manipulations, these risks probably are markedly reduced.

4.10 *Information comparisons*

Only 1 non-randomized study (Klassbo et al., 2003c) has indicated treatment effect by information in patients with hip disability. I calculated their study`s between group ES to be small and moderate in function and pain, respectively, based on reported median change scores and IQRs. Unfortunately, the control group showed as much deterioration

as the experiment group displayed progress in most variables. E.g. in function, the control group deteriorated 15% while the information group improved 3%. Because of the small effects in unequal directions, the differences in change scores showed statistical significance. As the authors stated, there might have been some selection bias, confounding the results. Information therefore seems to be a highly uncertain alternative compared to forceful traction mobilization treatment for patients with hip disability.

4.11 *Impact on health*

There are several measurement domains that are helpful in organizing outcomes with respect to the various health effect experienced by clients as means of therapy. The World Health Organization's (WHO) International Classification of the Functioning, Disability, and health (ICF); Health Related Quality of Life (HRQL); and Cost, are the 3 most valuable for evaluation of physical rehabilitation (Finch et al., 2002).

4.11.1 ICF

In the ICF, local body structure (capsular hyper stiffness) and local body function (ROM) relate to the impairment measured in this study. Much evidence pertain to the fact that hip OA patients have reduced mobility (Altman et al., 1991), and some that amending stiffness play an important part in reducing symptoms and activity restrictions (Hoeksma et al., 2004). Forceful traction mobilization and forceful manipulation might play important parts in breaking the disease processes and prohibit the development of hip OA by altering the tissue environment, the nervous-tissue function, and the local hip adhesive forces. To be able to reverse the disease process, the patients probably must be referred early to efficient physiotherapy, i.e. before non-reversible changes have taken place. Due to reports of the hip OA treatment paradigm reported amongst general practitioners (Klassbo, 1993) such early referral seems unlikely. The major problem concerned with classifying hip OA by tissue structure- and function-changes, is that these presents late in the disease process (Petersson, 1997). The only tissue-function measure assessed in this trial showed no important treatment effect, and the reason might well be improper choice of measure.

It might be that by measuring capsular oedema, intra-articular biochemical markers, and intra-capsular nerve tissue conduction instead, the tissue effect caused by forceful mobilizations might have been revealed. A more valid measure might also have been

hip joint capsule stiffness as judged by a traction tests, as opposed to ROM measures by physiological rotations. Cleary it is important to measure the construct considered to be most affected by the treatment modality (Finch et al., 2002).

Tests on impairment level mostly do not correlate highly with activity (disability) nor participant (handicap) outcome data (Finch et al., 2002). This was also the case in the present study, as the effects were moderate and high in ADL and R&S, whereas ROM increased negligible. Anyway, the positive effect on activity in this forceful mobilization study is well documented.

The Participation domain of the ICF is not measured in this trail. Participation measures whether a person is involved in meaningful, fulfilling, and satisfying activities that are socially and culturally expected of a person. Examples would include family- (provide for the family), social- (go tracking with friends) or cultural-roles (engage in voluntary communal work). In the HOOS only the category Recreation & Sport goes into this field, still indirectly. There are no questions concerning economy, education, work, community life, friendships, or the ability of helping others in this scale. Other trials have used the WOMAC and the SF-36, and as such indirect evidence in support of effect in this domain is found.

In the methodological study of HOOS in the THR surgery population (Nilsdotter et al., 2003) the correlations between Role Physical (SF-36) and all the other HOOS subscales were small. Thus, this data do not support an important change in participation as a cause of that highly effective physical intervention. On the other hand, supporting evidence of changes in participation comes from RCTs on knee OA. One assessing the effect of the injection therapy hylan G-F 20 (Raynauld et al., 2002) and another assessing 2 types of NSAIDs in hip and knee OA patients (Lohmander et al., 2005). In both trials clinical important improvement in all WOMAC subscales as well as statistically significant improved in the SF-36s aggregate Physical Component, including Role Physical were reported. The baseline scores seen in these trials were comparable to those seen in present trial, whereas the change scores were higher in the latter (results not shown). Therefore there might be moderate indirect evidence supporting similar changes in the present trial.

4.11.2 Health related quality of life

HRQL is a construct defined as "the value assigned to duration of life as modified by impairments, functional status, perceptions and opportunities influenced by disease, injury, treatment and policy" (Patrick & Erickson, 1993). In the present study the HRQL was not measured. The HR-QL, the subscale of the HOOS, was measured. This value expresses a narrow hip related view, not the broad meaning of HRQL as defined above. A construct related to the broad HRQL is Utility, which was measured in the hylan G-F 20 study (Raynauld et al., 2002). These researchers found the 3 WOMAC-subscales, the SF-36 aggregate Physical Component and the overall Utility score to be statistically significantly different between the groups. Furthermore, a RCT assessing the effect of acupuncture on knee OA, found similar changes in the WOMAC subscales and improvement in Physical Capability and Psychological Functioning (Vas et al., 2004). Lastly, the NSAID-RCT (Lohmander et al., 2005) showed changes in the 5 SF-36 domains Bodily pain, Physical functioning, Vitality, Mental health and Social functioning in addition to the WOMAC changes. Due to the larger effect magnitudes displayed in the present trial as compared to the mentioned RCTs, these data might be considered as indirect evidence supporting the value of the intervention on Utility, Physical Capability and Psychological Functioning.

4.11.3 Costs

The third main health measurement domain is cost – a construct that is becoming increasingly important in the context of the rehabilitation community. Two types of costs are relevant: direct costs to the health care system for recourses consumed as part of the treatment or program, and indirect costs to the client and families as a result of participating in the treatment or program (Finch et al., 2002). The statistically significant 33% fewer treatment sessions held together with the clearly superior treatment effects in the forceful mobilization- as compared to the standard mobilization-group might bee seen as indirect evidence supporting lower direct costs due to choice of mobilization technique. The clients in the forceful group had fewer sessions because the therapists reduced the treatment frequency due to improvement in traction-induced joint-play and symptoms. Therefore the participants had to travel less and spend less time connected with treatment sessions, thus reducing indirect costs. As most of the participants in this trial had radiographic OA, they had the treatment sessions for free.

Hence, the indirect costs probably are higher in the population than what is suggested here. More formal assessment on this domain is warranted.

5 Future directions

In the introduction of the paper, I emphasized the importance of joint-play for assessing the indication for forceful traction mobilization treatment, but most participants were successfully selected based on reduced passive ROM. Still, the ROM-results do not support stiffness reduction as the important effect mechanism. Even though these measurements were not very reliable, I would still expect differences in mean ROM within the groups if such truly existed. Anyway, by using higher standardized ROM-measurement, the impact of this treatment on stiffness allows to be solved. Whether there are correlation between changes in ROM and changes in joint-play measured by traction forces is unknown. Interesting, the therapists performing the forceful traction expressed improved joint-play in most participants during the intervention. How reliable these manual assessments are, and their value in the clinic, might be able to document in the hip joint due to its 1-1.5 cm accessory movement (Arvidsson, 1990; Samuelsen et al., 1990). Based on the presumable non-stiffness effect-mechanism, future trials might assess whether the intervention actually decrease intra-arthicular and intra-capsular oedema by using sonography (Bierma-Zeinstra et al., 2000).

The importance of early intervention in hip OA (Cibulka et al., 2004) was not assessed in this trial. It is hypothesized that the combination of manipulation, forceful traction mobilization and specific exercises can stop and even reverse the disease process in early diagnosed and treated individuals with idiopathic hip OA. The new paradigm of OA as a failed repair process (Brandt et al., 2003) and the new assessment methods using biochemical markers (Petersson, 1997) seem promising. It may be worth having an offensive attitude towards the problem based on the positive results seen in the participants who displayed in average 10 years of symptoms and obvious tissue degeneration. Lastly, the effects in the wider Participation and HRQL domains are still to be measured.

6 Conclusions

First, this RCT showed superior clinical important treatment effects of forceful traction mobilizations as compared to standard mobilization in the major outcome HOOS-t.

Second, the forceful traction mobilization treatment afforded superior post-treatment effect magnitude in Pain compared to other conservative treatment methods reported, and the ES in Function was large. Third, this thesis presents indirect evidence suggesting the treatment to be of value in the following health domains: Participation according to the ICF; Utility, Physical Capability, and Psychological function in HRQL; and Costs. I suggest general practitioners to refer patients with hip pain, hypomobility, and disability to forceful traction mobilization treatment. Politicians are asked to create incentives for physiotherapists to take the effort applying this approach. Future trials are recommended intervening early in these patients using the modalities forceful traction mobilization and forceful manipulation. The effect of the intervention is then hypothetically even higher.

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Appendices

Appendix I. Informed consent paper

Universitetet i Bergen
Ulriksdal 8c 5009 Bergen
Seksjon for fysioterapivitenskap Tlf 55586100

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

"Evaluering av manuell mobilisering i behandling av hoftedysfunksjon – en randomisert kontrollert studie"

De forespørres herved om å ta del i et forskningsprosjekt som skal evaluere effekten av et nytt behandlingsopplegg for plager med stive og smertefulle hofteledd, med eller uten tydelige slitasjetegn via røntgen. Behandling forbundet med studien skal foregå i perioden januar 2003 til mars 2005. Det finnes i dag ingen dokumentert konservativ (ikke-operativ) kur for slike plager. Vi håper at dette prosjektet kan bidra til å utvikle en mer effektiv behandling for denne pasientgruppen.

Eksperimentbehandling gis til halvparten av pasientene og kontrollterapi til den andre halvparten. Begge gruppene vil få manuelle drag i hoften , øvelser og informasjon. Kontrollgruppen (KG) får en annen type manuell behandling, og detaljene i behandlingen styres av den enkelte terapeut på et institutt som har praktisk lokalisering i forhold til Dem.

De forespørres fordi de har stiv(e) og smertefull(e) hofte(r). Deres deltakelse, dersom De etter loddtrekning havner i eksperimentgruppen (EG), vil innebære: manuelle drag i hofteleddet, informasjon og veiledet trening 2 ganger per uke; samt hjemmeøvelser. De manuelle tiltakene vil dominere i starten, og egentrening ved slutten av den 12 ukers behandlingsperioden.

Den manuelle eksperiementteknikken er trekking i hoften via ankelknokene. Trekkingen vil foretas med en kraft fra ca. 5 til 80 kilo tilpasset Deres toleranse, med hensikt å redusere smerter forbundet med drag i leddkapselen samt å myke opp hofteleddet. De to terapeutene har benyttet teknikken i 10 og 30 år, og den er meget trygg.

Øvelsene vil være tilpasset Deres toleranse etter modell av medisinsk treningsterapi. De vil få nøye oppfølging og veiledning vedrørende utførelse og dosering.

Dersom De gir Deres samtykke (dette skrivet), vil vi be Dem om å fortelle kort Deres sykdomshistorie og svare på et spørreskjema, for deretter å få målt bevegeligheten i hoftene. Så vil De, via loddtrekning, bli henvist til enten EG eller KG for fysioterapibehandling.

Kontrollterapi vil i dette tilfelle bety konvensjonell fysioterapi som også innbefatter informasjon, øvelser og manuelle drag i hoften. Forskjellen mellom EG og KG er at de manuelle teknikkene er ulike. Det er per i dag ikke dokumentert forskjell i behandlingseffekt mellom teknikkene, og det er studiens formål er å avdekke om det faktisk er forskjell. Blir De trukket til KG vil De få de behandlinger som i dag er mest utbredt for pasienter med denne type plager.

Risikoene for deltakerne i begge grupper er de samme som ved hvilken som helst annen fysioterapibehandling, det vil si uten kjente bivirkninger. Eksperimentbehandlingen kan gi noe ubehag ved ankelknokene hvor terapeuten fatter grep for drag i hoften. Skulle det bli et problem, tilbys å benytte en festeanretning med polstring. Grepet tolereres vanligvis godt. Umiddelbart etter behandling kan tilstanden helt forbigående (opptil maksimalt 1,5 timer) forverres litt.

Ved endt behandlingsperiode vil De gjennomgå testprosedyren som før behandlingsstart.

Skulle det oppstå skade som følge av feilbehandling, kan De søke oppreisning fra Norsk Pasientskadeerstatning. Prosjektadministrator (se under) kan kontaktes ved problemer eller spørsmål vedrørende studien.

Behandlingen tilknyttet studien er gratis for pasienter med diagnosen artrose (slitasje), mens andre må betale egenandel etter Rikstrygdeverkets (RTV) takster som normalt for fysikalsk behandling. Reiseutgifter knyttet direkte til behandling som overskrider kr. 96,- en vei, dekkes av RTV etter søknad med kvittering fra pasienten. Reiseutgifter forbundet med testing knyttet til prosjektet refunderes ut fra billigste reisealternativ av prosjektadministrator mot fremvisning av kvittering.

Dataene fra studien vil bli forsøkt publisert i et vitenskapelig tidsskrift. Deres deltakelse i studien vil ikke offentliggjøres, og opplysninger vedrørende Dem vil bli behandlet konfidensielt. Alle innsamlede opplysninger anonymiseres ved prosjektslutt, estimert til september 2007. Prosjektet er meldt til personvernombudet for forskning, NSD.

Deres deltakelse er frivillig, og avgjørelsen om å delta eller ei vil ikke affisere forholdet til forsker, lege eller fysioterapeut. Dersom De velger å ta del i studien, har De full rett til å trekke Dem fra den når som helst uten å måtte oppgi noen grunn. De vil også bli trukket ut av studien dersom De skulle oppleve vedvarende forverring som følge av behandlingen. De vil motta en kopi av dette skjemaet.

SAMTYKKE

Jeg,_____, har mottatt skriftlig og muntlig informasjon om studien og sier meg villig til å delta.

_____
Dato

_____
Deltakers signatur

_____

Prosjektadministrators signatur
Kjartan Vårbakken
Hovedfagsstudent
Seksjon for fysioterapivitenskap
Universitetet i Bergen
Tlf 928 88 498

Prosjektleder/veileder
Elisabeth Ljunggren, professor, dr.philos.
Seksjon for fysioterapivitenskap
Universitetet i Bergen
Kalfarveien 31
5018 Bergen

Appendix II. The Regional Ethics Committee

UNIVERSITETET I BERGEN
Det medisinske fakultet
Harald Hårfagresgt. 1,
Postboks 7800, 5020 BERGEN
Tlf: 55 58 20 84/86
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Regional komité for
medisinsk forskningsetikk
Vest-Norge (REK Vest)

Bergen, 06.02.04
Sak nr. 04/00794

Professor Anne Elisabeth Ljunggren
Seksjon for fysioterapivitenskap, UiB
Ulriksdal 8C
5009 BERGEN

Ad prosjekt: Evaluering av manuell mobilisering i behandling av hoftedysfunksjon - En randomisert kontrollert studie (REK Vest nr. 218.03)

Det vises til ditt brev datert 13.01.04 med svar på komiteens merknader.

REK Vest v/leder har vurdert saken. En har ikke ytterligere merknader og studien er da endelig klarert fra denne komité sin side.

Vi ønsker dere lykke til med gjennomføringen og minner om at komiteen setter pris på en sluttrapport, eventuell en kopi av trykt publikasjon når studien er fullført.

Vennlig hilsen

Grethe Seppola Tell
leder

Arne Salbu
sekretær

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

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Org.nr. 985 321 884

Kjartan Vårbakken
Årstadveien 25, C219
5009 BERGEN

Vår dato: 10.11.2003 Vår ref: 200301047 GHA /RH Deres dato: Deres ref:

KVITTERING FRA PERSONVERNOMBUDET

Vi viser til melding om behandling av personopplysninger, mottatt 29.10.2003. Meldingen gjelder prosjektet:

10465 Evaluering av manuell mobilisering i behandlingen av hoftedysfunksjon - en randomisert kontrollert studie

Norsk samfunnsvitenskapelig datatjeneste AS er utpekt som personvernombud av Universitetet i Bergen, jf. personopplysningsforskriften § 7-12. Ordningen innebærer at meldeplikten til Datatilsynet er erstattet av meldeplikt til personvernombudet.

Personvernombudets vurdering

Etter gjennomgang av meldeskjema og dokumentasjon finner personvernombudet at behandlingen av personopplysningene vil være regulert av § 7-25 i personopplysningsforskriften. Dette betyr at behandlingen av personopplysningene vil være unntatt fra konsesjonsplikt etter personopplysningsloven § 33 første ledd, men underlagt meldeplikt etter personopplysningsloven § 31 første ledd, jf. personopplysningsforskriften § 7-20.

Unntak fra konsesjonsplikten etter § 7-25 gjelder bare dersom vilkårene i punktene a) – e) alle er oppfylt:

a) førstegangskontakt opprettes på grunnlag av offentlig tilgjengelige registre eller gjennom en faglig ansvarlig person ved virksomheten der respondenten er registrert,
b) respondenten, eller dennes verge dersom vedkommende er umyndig, har samtykket i alle deler av undersøkelsen,
c) prosjektet skal avsluttes på et tidspunkt som er fastsatt for prosjektet settes i gang,
d) det innsamlede materialet anonymiseres eller slettes ved prosjektavslutning,
e) prosjektet ikke gjør bruk av elektronisk sammenstilling av personregistre.

Personvernombudets vurdering forutsetter at prosjektet gjennomføres slik det er beskrevet i vedlegget.

Behandlingen av personopplysninger kan settes i gang.

Avdelingskontorer / *District Offices:*
OSLO: NSD. Universitetet i Oslo, Postboks 1055 Blindern, 0316 Oslo. Tel: +47/ 22 85 52 11. nsd@uio.no
TRONDHEIM: NSD. Norges teknisk-naturvitenskapelige universitet, 7491 Trondheim. Tel: +47/ 73 59 19 07. kyrre.svarva@svt.ntnu.no
TROMSØ: NSD. SVF, Universitetet i Tromsø, 9037 Tromsø. Tel: +47/ 77 64 43 36. nsdmaa@sv.uit.no

Ny melding

Det skal gis ny melding dersom behandlingen endres i forhold til de punktene som ligger til grunn for personvernombudets vurdering.

Selv om det ikke skjer endringer i behandlingsopplegget, skal det gis ny melding tre år etter at forrige melding ble gitt dersom prosjektet fortsatt pågår.

Ny melding skal skje skriftlig til personvernombudet.

Offentlig register

Personvernombudet har lagt ut meldingen i et offentlig register, www.nsd.uib.no/personvern/register/

Ny kontakt

Personvernombudet vil ved prosjektets avslutning, 30.09.2007, rette en henvendelse angående status for prosjektet.

Vennlig hilsen

for Bjørn Henrichsen

Grethe Halvorsen

Kontaktperson: Grethe Halvorsen tlf: 55583542

Vedlegg: Personvernombudets vurdering

Kopi: Behandlingsansvarlig Anne Elisabeth Ljunggren

Appendix IV. Hip disability and Osteoarthritis Outcome Score

HOOS
Spørreskjema for personer med hofteplager

DATO:_____PERSONNUMMER:_____

NAVN:_____

Instruksjoner: Dette skjemaet inneholder spørsmål om hoften din. Informasjonen skal bidra til å følge opp hvordan du har det og hvordan du fungerer i ditt dagligliv.
Sett kryss ved det alternativet du mener stemmer best (ett alternativ for hvert spørsmål). Dersom du er usikker, kryss allikevel ved det alternativet som føles mest riktig.

Generelle symptomer, inkludert stivhet
Når du besvarer disse spørsmålene, tenk på de vanlige symptomene som du har kjent fra hoften i løpet av den siste uken.

1.s2. Kjenner du gnissing (eller skuring), hører klikking eller andre lyder fra hoften?

Aldri	Sjelden	Av og til	Ofte	Alltid
☐	☐	☐	☐	☐

2.s10. Hvor vanskelig synes du synes du det er å føre bena langt fra hverandre?

Ikke	Litt	Middels	Vanskelig	Svært vanskelig
☐	☐	☐	☐	☐

3.s11. Har du opplevd at det er vanskelig å skritte ut når du går?

Nei	Litt	Middels	Vanskelig	Svært vanskelig
☐	☐	☐	☐	☐

Leddstivhet betyr vanskeligheter med å komme i gang eller øket motstand ved bevegelser. Angi den grad av hofteleddsstivhet du har opplevd i løpet av den siste uken.

4.s6. Hvor stiv har hoften din vært når du har våknet om morgenen?

Ikke	Litt	Middels	Veldig	Ekstremt
☐	☐	☐	☐	☐

5.s7. Hvor stiv har hoften din vært når du har sittet eller ligget og hvilt i løpet av dagen?

Ikke	Litt	Middels	Veldig	Ekstremt
☐	☐	☐	☐	☐

Smerte/verking/ubehag

6.p1. Hvor ofte har du hoftesmerter?

Aldri	Hver måned	Hver uke	Hver dag	Alltid
☐	☐	☐	☐	☐

Følgende spørsmål angår hoftesmerten som du eventuelt har opplevd den siste uken. Angi graden av smerte du har kjent ved følgende aktiviteter.

7.p2. Snu på belastet ben

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

8.p5. Gå på jevnt underlag

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

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9.p11. Gå på hardt underlag, som asfalt, betong

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

10.p12. Gå på ujevnt underlag

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

11.p6. Gå oppover eller nedover trapper

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

12.p9. Stående

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

13.p8. Sittende eller liggende

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

14.p7. I sengen om natten (smerte som forstyrrer søvnen)

Ingen	Litt	Middels	Stor	Veldig stor
☐	☐	☐	☐	☐

Aktivitetsbegrensninger i dagliglivet

Følgende spørsmål angår din aktivitetsbegrensning i dagliglivet. Angi vanskelighetsgraden du har opplevd i løpet av siste uken ved følgende aktiviteter på grunn av dine hofteplager.

15.a1. Gå nedover trapper

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

16.a2. Gå oppover trapper

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

17.a3. Reise deg opp fra sittende

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

18.a4. Stå stille

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

19.a5. Bøye deg ned, eksempelvis for å plukke opp noe fra gulvet

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

20.a6. Gå på jevnt underlag

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

21.a7. Komme inn og ut av bil

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

22.a8. Handle/gjøre innkjøp

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

23.a9. Ta på strømper

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

24.a10. Gå ut av sengen

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

25.a11. Ta av strømper

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

26.a12. Ligge i sengen (snu deg, holde hoften lenge i samme stilling)

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

27.a13. Komme opp i og ut av badekar/dusj

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

28.a14. Sitte

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

29.a15. Sette og reise deg fra toalettet

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

30.a16. Utføre tungt husarbeid (snømåking, gulvvask, støvsuging etc)

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

31.a17. Utføre lett husarbeid (matlaging, støvtørring etc)

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

Aktivitetsbegrensninger, fritid og idrett

Følgende spørsmål angår dine aktivitetsbegrensninger. Angi den grad av vanskelighet du har opplevd siste uken ved følgende aktiviteter på grunn av dine hofteplager.

32.sp1. Sitte på huk

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

33.sp2. Løpe

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

34.sp4. Snu om på belastet ben

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

35.sp6. Gå på ujevnt underlag

Ingen	Liten	Moderat	Høy	Ekstrem
☐	☐	☐	☐	☐

Livskvalitet

36.q1. Hvor ofte tenker du på hoften din?

Aldri	Hver måned	Hver uke	Hver dag	Alltid
☐	☐	☐	☐	☐

37.q2. Hvor mye har du forandret din livsstil for å unngå å overbelaste hoften?

Ikke noe	Litt	Moderat	Svært mye	Totalt
☐	☐	☐	☐	☐

38.q3. I hvor stor grad kan du stole på hoften din?

Fullstendig	Stor	Middels	Noe	Ikke
☐	☐	☐	☐	☐

39.q4. Generelt sett, hvor store problemer har du med hoften?

Ingen	Små	Middels	Store	Svært store
☐	☐	☐	☐	☐

Tusen takk for at du tok deg tid til å fylle ut hele skjemaet!

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The HOOS is to be found in English, Swedish, and Norwegian at

http://www.liv.se/page.jsp?node=2370