

# Osteoarthritis of the Hip

Prevalence in Danish chiropractic practice  
Reproducibility of range of motion and muscle strength  
A proof-of-principle randomized clinical trial

PhD thesis

Erik Poulsen

Institute of Sports Science and Clinical Biomechanics  
University of Southern Denmark

Nordic Institute of Chiropractic and Clinical Biomechanics

Department of Orthopaedic Surgery and Traumatology  
Odense University Hospital



UNIVERSITY OF SOUTHERN DENMARK

Faculty of Health Sciences  
University of Southern Denmark  
2012

## Contents

Contents .....	1
PREFACE.....	4
Supervisors .....	4
List of papers .....	5
Acknowledgements .....	6
Abbreviations.....	8
Summary in English .....	9
Summary in Danish.....	10
List of Tables and Figures .....	11
INTRODUCTION .....	12
BACKGROUND .....	12
Prevalence and impact of osteoarthritis .....	12
Hip osteoarthritis.....	13
Diagnosis of hip osteoarthritis.....	14
Clinical diagnosis of hip osteoarthritis.....	14
Radiographic diagnosis of hip osteoarthritis.....	15
Management of hip osteoarthritis .....	15
Non-pharmacological treatment.....	16
Pharmacological treatment .....	18
Surgery.....	18
AIMS AND OBJECTIVES .....	19
Specific aims .....	19
Specific objectives .....	19
SUMMARY OF METHODS AND MATERIALS.....	20
Study populations and recruitment .....	20
Hip osteoarthritis in chiropractic practice, paper II.....	20
Reproducibility study, paper III and randomized clinical trial, paper IV .....	20
Participating raters for the reproducibility study, paper III.....	20
Procedures.....	20
Hip osteoarthritis in chiropractic practice.....	20
Reproducibility study and randomized clinical trial .....	21
Specific procedure for the reproducibility study.....	22
Randomization for the randomized clinical trial .....	22
Sample size for the randomized clinical trial.....	22

Interventions for the randomized clinical trial .....	22
Dependent variables for the reproducibility study .....	23
Outcome measures and time points for the randomized clinical trial.....	23
Adverse reactions or unintended effects for the randomized clinical trial.....	23
STATISTICS .....	24
Hip osteoarthritis in chiropractic practice .....	24
Reproducibility study.....	24
Randomized clinical trial.....	24
ETHICS AND REGISTRATIONS.....	24
SUMMARY OF RESULTS .....	25
Hip osteoarthritis in chiropractic practice.....	25
Reproducibility study.....	26
Randomized clinical trial.....	27
DISCUSSION .....	31
Summary of findings.....	31
Comparison with other studies .....	32
Methodological considerations .....	34
Hip osteoarthritis in chiropractic practice.....	34
Reproducibility of hip range of motion and muscle strength .....	34
Participants for the reproducibility study and randomized clinical trial .....	36
Radiographic hip osteoarthritis .....	37
Sample size .....	38
Randomization and allocation.....	38
Interventions .....	38
Blinding.....	39
Outcome measures .....	39
Clinical implications .....	40
Research implications.....	40
CONCLUSIONS .....	42
REFERENCES.....	43
PAPERS.....	54

## PREFACE

### Supervisors

Professor Jan Hartvigsen, DC, PhD (main supervisor)  
Institute of Sports Science and Clinical Biomechanics  
Part of Clinical Locomotion Network  
University of Southern Denmark  
*and*  
Nordic Institute of Chiropractic and Clinical Biomechanics

Director Henrik Wulff Christensen, DC, MD, PhD  
Nordic Institute of Chiropractic and Clinical Biomechanics  
Part of Clinical Locomotion Network

Professor Søren Overgaard, MD, DMSc  
Department of Orthopedic Surgery and Traumatology  
Odense University hospital  
*and*  
Institute of Clinical Science  
University of Southern Denmark

## List of papers

This thesis is based on the following papers:

### Paper I

Erik Poulsen, Henrik W Christensen, Ewa M Roos, Werner Vach, Søren Overgaard, Jan Hartvigsen.  
Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: Protocol for a three-armed randomized clinical trial.

BMC Musculoskelet Disord 2011;**12**:88

### Paper II

Erik Poulsen, Henrik W Christensen, Søren Overgaard, Jan Hartvigsen.

Prevalence of hip osteoarthritis in chiropractic practice in Denmark – a descriptive cross-sectional and prospective study.

JMPT, accepted for publication

### Paper III

Erik Poulsen, Henrik Wulff Christensen, Jeannette Østergaard Penny, Søren Overgaard, Werner Vach, Jan Hartvigsen.

Reproducibility of range of motion and muscle strength measurements in patients with hip osteoarthritis – an inter-rater study

Submitted

### Paper IV

Erik Poulsen, Henrik W. Christensen, Ewa M. Roos, Jan Hartvigsen, Werner Vach, Søren Overgaard  
Effectiveness of patient education and manual therapy compared to a minimal control intervention in patients with osteoarthritis of the hip – a proof of principle randomized clinical trial.

## Acknowledgements

The individual studies, manuscripts and this PhD thesis would not have been without the collaboration, advice, and support from my supervisors, institutions and everyone who, in any shape or form, have been involved in this project.

Specifically, I wish to thank:

Jan Hartvigsen, my main supervisor, for your never ending commitment and support both professionally and personally. For continually pushing and widening my boundaries, for your sincere enthusiasm and for your general calm and collectiveness. Thank you, in particular, for demonstrating leadership and keeping perspective throughout the last month and last but not least, I have had the pleasure of experiencing your truly superb cooking skills.

Henrik Wulff Christensen, co-supervisor, for believing in this project prior to day one, for your continuous support and advice, for our discussions on a wide range of challenges pertaining to practical aspects of this project, our numerous debates concerning clinical and professional practice and for leading the Nordic institute forward.

Søren Overgaard, co-supervisor, for seeing the potential and making this project possible by opening the doors to your world of research, your group at the Orthopedic Research Department, and for making the contacts and truly making the project multidisciplinary.

A very special and deeply felt thank you to Jytte Johannesen, our research secretary at the Nordic Institute of Chiropractic and Clinical Biomechanics. Your tireless efforts, your constant interest and your continuous support have been invaluable. This project has truly benefitted from your organizational management and typesetting skills and I truly believe the project would have suffered without. Thank you also for proofreading all manuscripts. It has really been a pleasure and an inspiration to work with you.

Without Annie Gam-Pedersen, Bodil L. Pedersen and Lisa Hargreaves at the Department of Orthopedics at Odense University hospital, the hip school, the clinical measurements, the reproducibility studies, and the control group would have suffered. Your invaluable people skills made the participating patients comply and feel important. So a deep and sincere thank you.

I also want to thank Werner Vach for your statistical expertise to paper III and IV and for your practical approach to the universe of statistics. Ewa M. Roos for introducing us to the hip school, the Hip Osteoarthritis disability and Outcome Score and for your excellent advice on paper I and IV. Specifically for inviting me to participate and present the concept of manual therapy at

international conferences. Gert Brønfort for your invaluable advice on design, methodology and statistics for paper I and IV and for letting me spend time with your group in Minneapolis.

I want to send a little extra thank you to Alice Kongsted and Mette Jensen Stochkendahl, for never getting tired of my questions, for understanding and your empathy.

Thanks to Henrik Hein Lauridsen for your expert advice and assistance with patient reported outcomes for paper IV. Rune Mieritz for our inspiring discussions on variance components, homogeneity, mean squares and within and without group differences. Your patience is very much appreciated. Eleanor Boyle for stepping in at the right time and for working at the speed of light producing output after output for paper IV and Michael Busse for designing the pain drawing mannequin.

My appreciation and gratitude go to everybody at the Nordic Institute of Chiropractic and Clinical Biomechanics for your continuous support and interest in the project and for being able to have fun while at work.

Let me also thank my colleagues at the Research unit for Clinical Biomechanics at University of Southern Denmark for inspirational and stimulating conversations at the weekly research meetings. The same goes for everybody at the Research unit for Orthopedics at the Department of Orthopedic Surgery and Traumatology for a time well spent at our Friday meetings and bi-yearly seminars throughout the last four years, and thanks also to the entire staff at the Department of Orthopedic Surgery and Traumatology, Odense University Hospital for initially welcoming me and continuously showing an interest in the project. Special thanks to Rigmor and Lone for your assistance in scheduling patients. I also would like to thank everybody at the Institute of Sports Science and Clinical Biomechanics who have been in some shape or form involved in this project and particular Lone Berens Pedersen for keeping track of accounts.

My appreciation to the chiropractic clinics participating in the descriptive study (paper II) and the general practitioners and private chiropractors referring patients for the reproducibility study and the randomized clinical trial (paper III and IV).

Last but not least, my gratitude goes to all the participating patients in this project who have increased and improved my knowledge about hip osteoarthritis. You have made me understand your thoughts, speculations and concerns.

Erik Poulsen, Odense, 2012

## Abbreviations

OA	Osteoarthritis
JSW	Joint space width
SD	Standard deviation
CI	Confidence interval
ICC	Intra-class correlation coefficient
HOOS	Hip disability and osteoarthritis outcome score
ROM	Range of motion
MT	Manual therapy
PE	Patient education
MCI	Minimal control intervention

## Summary in English

This PhD thesis is about the clinical diagnosis and non-pharmacological treatment of patients with hip osteoarthritis. The overall aims were to report on the prevalence of hip osteoarthritis in chiropractic practice, to examine the reproducibility of two clinical examination procedures commonly used in the assessment of hip OA, and to investigate the feasibility of a three-arm randomized clinical trial in a Danish setting including patients with mild to moderate hip osteoarthritis.

Results from the first part of the thesis indicate that hip osteoarthritis is a condition both diagnosed and treated by Danish chiropractors, although the proportion is low. For the patients diagnosed with the condition, approximately half has not previously been diagnosed with hip osteoarthritis.

Besides pain, reduced hip mobility and muscle strength are two important clinical signs associated with the diagnosis of hip osteoarthritis. Therefore in the second part of the thesis, we found it relevant to examine if clinicians of the same profession (orthopedists and chiropractors) were able to agree on findings when measuring hip range of motion with a goniometer and muscle strength with a dynamometer. For the two orthopedists and the two chiropractors we found that agreement was in general poor to moderate for all measurements. When using all measurements to decide on the degree of osteoarthritis of the examined hip, both orthopedists and chiropractors were to a moderate level able to differentiate between hips with no, mild or severe osteoarthritis.

Hip osteoarthritis is a chronic debilitating disease with a lifetime risk of 25% but only 20% of sufferers end up having hip replacement surgery. Therefore, it is important to investigate whether non-surgical treatments can reduce pain, improve function and quality of life for the group of patients not needing surgery. Patient education programs such as the Swedish based hip school and manual therapy have shown promising results. Therefore, we wanted to see if a Danish set-up with a three-arm randomized trial involving multiple professional disciplines was feasible in measuring significant change in pain severity when patients with hip osteoarthritis received a patient education program, a combined program of patient education and manual therapy or a home exercise program with minimal instruction. The results indicate that the combined treatment program of patient education and manual therapy was superior to the minimal home exercise program as patients experienced greater pain reduction. When patients evaluated the overall effect of the treatment, a majority felt the combined treatment had improved their situation compared to before treatment. When comparing the patient education without the manual therapy to the home exercise program, we found no differences in pain severity between the two treatments. By comparing the group receiving the patient education alone to the group receiving the combined treatment of patient education and manual therapy, the manual therapy is likely responsible for the improvement in pain.

## Summary in Danish

Denne ph.d.-afhandling omhandler klinisk diagnose og ikke-kirurgisk behandling af patienter med hofteartrose. De overordnede mål er at rapportere forekomsten af hofteartrose i kiropraktorpraksis, at undersøge pålideligheden af to kliniske undersøgelsesprocedurer benyttet i udredningen af hofteartrose samt at vurdere gennemførligheden af en lodtræknings-undersøgelse under danske forhold; en undersøgelse, hvor patienter med hofteartrose tilbydes én af tre typer behandling.

Resultater fra første del af afhandlingen viser, at patienter med hofteartrose både diagnosticeres og behandles i kiropraktorpraksis, men andelen er lille. Af de patienter, som her får konstateret hofteartrose, har halvdelen ikke tidligere fået diagnosen.

Ved udredningen af patienter med hofteartrose er måling af hoftens bevægeudslag og muskelstyrke væsentlige elementer i den kliniske diagnose. Derfor er pålideligheden af disse målinger vigtig, dvs. om to eller flere personer kan opnå ens målinger med det samme måleredskab. Da patienter med hofteartrose undersøges både i primær og sekundær sektor, valgte vi i anden del af afhandlingen at undersøge, om to ortopæder indbyrdes og to kiropraktorer indbyrdes kan opnå tilfredsstillende pålidelighed. De målte bevægeudslag med et goniometer og muskelstyrke med et dynamometer og vores resultater viser, at både mellem ortopæder og mellem kiropraktorer er der stor måleusikkerhed, dvs. begrænset pålidelighed. Ved vurdering af graden af hofteartrose ud fra hoftens samlede bevægeudslag og muskelstyrke viste undersøgelsen at for både ortopæder og kiropraktorer er det muligt at skelne mellem hofter uden, let eller svær grad af artrose.

Hofteartrose er en kronisk sygdom, hvor patienter kan være stærkt smerteplagede og have besvær med udføre selv simple dagligdags aktiviteter. Det er vurderet at 25 % af befolkningen på et tidspunkt får hofteartrose, men det er kun ca. 20 %, som bliver opereret og får en ny hofte. Det er derfor vigtigt at undersøge ikke-kirurgiske behandlingsformer som potentielt kan give smertelindring og forbedre funktionsniveauet for den store gruppe, som ikke bliver opereret. Patientuddannelse, som den svenske hofteskole og manuel behandling, har vist lovende resultater, så vi valgte derfor, under danske forhold at undersøge gennemførligheden af en lodtrækningsundersøgelse med involvering af flere faggrupper samt om det var muligt at måle signifikante forskelle, når patienter med hofteartrose fik enten hofteskole, hofteskole kombineret med manuel behandling eller et hjemmeøvelsesprogram. Undersøgelsen viste, at hofteskole kombineret med manuel behandling forbedrede patienternes smerteniveau væsentligt i sammenligning med øvelses-programmet. De patienter, som kun fik hofteskole, havde derimod ingen relevant forbedring i smerteniveauet i sammenligning med dem, som fik hjemmeøvelser. Ved at sammenligne de patienter, som kun fik hofteskole med dem som fik både hofteskole og manuel behandling, er der indikation for, at det er manuelle behandling som er ansvarlig for ændringen i smerteniveauet.

## List of Tables and Figures

### List of Tables

1. Kellgren & Lawrence classification of radiographic osteoarthritis
2. Croft classification of radiographic osteoarthritis
3. Inclusion and exclusion criteria for participants in paper III and IV
4. Proportions off clinical and radiographic hip osteoarthritis

### List of Figures

1. Limits of agreement for internal rotation range of motion between orthopedists
2. Limits of agreement for internal rotation range of motion between chiropractors
3. Limits of agreement for abduction muscle strength between orthopedists
4. Limits of agreement for abduction muscle strength between chiropractors
5. Flow of patients participating in paper III and IV
6. Pain severity on an 11-box numerical rating scale
7. Global perceived effect of interventions

## **INTRODUCTION**

The World Health Organization considers musculoskeletal conditions the most common cause of long-term pain and physical disability (1). In Denmark, it is estimated that a 20 year old will lose between five and eight quality adjusted life years due to these disorders (2) and the National Ministry of Health has commissioned musculoskeletal conditions as an important target area for both prevention and treatment (3).

In 2005 the Danish National Institute of Public Health documented that at any given time within a two-week period, half of the Danish population reported pain or physical activity limitations due to musculoskeletal complaints and 8% had visited their general practitioner for their complaint (2). Musculoskeletal conditions are often chronic and not related to a single anatomical area and 15% of the Danish adult population have one or more musculoskeletal condition of more than six months' duration (2).

The economic impact of musculoskeletal conditions on societies is considerable as total cost in the western world is estimated to 2.5-5% of the gross national product (1). In Denmark this correlates to around DKK 70 billion in 2011 (€ 9 billion), the majority being related to loss of productivity because of sick leave and health related pension (2). In 2005, musculoskeletal conditions accounted for 24% of health related pensions (2) and the Danish National Board of Industrial Injuries reported that in the year 2010, musculoskeletal conditions accounted for 40% of all reported work related diseases (4).

## **BACKGROUND**

### **Prevalence and impact of osteoarthritis**

Osteoarthritis (OA) is the leading musculoskeletal disorder in seniors and the most common joint disease (5-7) and it is estimated from surveys that worldwide, between 10 and 20% of people 60 years or older have symptomatic OA (8). Recently, hip and knee OA have been linked to increased mortality (9).

In Denmark, the number of people affected by severe OA is reported to 165.000 in 2010 and is predicted by the Danish National Institute of Public Health to increase by 17% over the coming decade totalling 193.000 (10).

Consequently, the economic burden of OA is substantial. Specific cost-of-illness relating to OA has not been determined in Denmark but in five other industrialized and comparable countries, the total cost is estimated to 1-2.5% of the gross national product (11). In the United States estimated

total cost is as high as \$90 billion every year (12) and indirect yearly costs for loss of wages and loss of productivity amount to \$7 billion (13). Total cost in relation to patients eligible for total hip replacement has recently been studied in Sweden and is estimated to \$7,700 per patient (14). The majority of cost relates to loss of productivity.

Osteoarthritis is a disease where focus for many years was on cartilage and bone as the major tissues involved. Today, however, focus is directed to all joint structures (15-17). Synovial tissue displays chronic synovial inflammation (18), collateral ligaments demonstrate histological changes even where radiographs are considered normal (19), and periarticular muscles are weakened in both knee and hip OA (20-24). Consequently, it has been proposed that treatment and preventive measures should include all areas of the joint (15).

## Hip osteoarthritis

In the lower extremity, the hip is the second most common joint affected by OA (25;26) and the lifetime risk of symptomatic hip OA has been estimated to 25% (27). When symptomatic, hip OA is responsible for pain, functional disability and reduced health related quality of life (28-30) and recently Bieleman et al. reported a negative association with work participation (31).

Prevalence rates for hip OA vary and are dependent on the definitions applied, i.e. self-reported, radiographic or clinical, and even rates on radiographic hip OA depend on the classification system (26). According to systematic reviews, radiographic hip OA is estimated to affect 5-11% in the adult population (26;32;33). In Denmark, the prevalence of radiographic hip OA in adults has been estimated to be 4.4-5.3% (34) whereas the prevalence of radiographic hip OA in Island was estimated to 10-12% in roughly the same age group probably reflecting a large genetic component (35). In Icelandic seniors over 85 years of age, the rate was as high as 35%.

The etiology of hip OA is multi-causal with an interaction of genetic, biomechanical, systemic, and biochemical factors (17;36). In recent decades focus has been on minor structural changes in the acetabulum and femur referred to as *cam and pincer deformities* affecting biomechanics of the joint and causing femoroacetabular impingement (37;38). Risk factors for development of hip OA are further related to lifestyle and occupation. In a systematic review by Bierma-Zeinstra and Koes, the authors reported that ranging from strongest to weakest age, obesity, history of trauma, heavy physical labour, farming > 10 years, certain sport participation on an elite level, and congenital deformations were proven risk factors (39). Few studies have examined prognostic factors but strong evidence is found for age and radiographic findings of superior migration of the femoral head into the acetabulum, subchondral bone cyst formation and a grade 3 or more on the Kellgren & Lawrence scale (39;40).

## Diagnosis of hip osteoarthritis

Hip OA is diagnosed based on symptomatology, clinical examination findings and diagnostic imaging and is commonly categorized into clinical and radiographic OA (41-43). Thus, clinical hip OA being based on findings from the case history and clinical examination and radiographic hip OA demonstrating bone or cartilage reaction visible on radiographs. Differential diagnoses include bursitis, tendinitis, muscular sprains, “snapping hip syndrome”, labral damage, femoroacetabular impingement, severe dysplasias, inflammatory arthritises, fractures, neoplasms, or pain originating from other musculoskeletal structures like the low back, sacroiliac or pubic joints (41;42).

## Clinical diagnosis of hip osteoarthritis

Pain is the dominant symptom in hip OA (44;45) but many patients find it difficult to define and describe exactly where the pain is located, because the hip is positioned deep in the groin (46). The most common areas are the trochanter major, groin, buttock and anterior or lateral thigh (46-48). Patients can further describe distribution to the knee, lower back or upper posterior pelvis area.

A triad where pain is present or aggravated on movement initiation, eases with moderate activity and returns after prolonged activity is commonly used to describe pain in patients with hip OA (49).

Common symptoms other than pain include joint stiffness, joint crepitus, restricted mobility of the hip and difficulties with normal daily activities like putting socks on, walking on stairs, getting in and out of the car or up on their bicycle (50;51).

Clinical examination in hip OA include the following: Visual inspection of gait and general movement from sitting to standing and kneeling, assessment of range of motion (ROM) and muscle strength, evaluation of leg length and palpatory assessment of soft tissue structures where accessible (muscle, tendon insertion, bursae and ligaments) and elicitation of pain by these procedures (41;42;49;52).

The procedures demonstrating the highest correlation with a diagnosis of hip OA are ROM and muscle strength and these are therefore recommended as core components in the evaluation (41;53).

## Radiographic diagnosis of hip osteoarthritis

Radiographs are the most common type of imaging modality used for assessing OA of the hip because it is accessible and relative inexpensive (54), however radiographs are not recommended as the sole modality for confirming the diagnosis (50;55).

Different definitions are used to classify radiographic hip OA. The most common being the Kellgren and Lawrence classification which categorizes OA into five categories as illustrated in table 1 (56).

**Table 1. Kellgren and Lawrence classification of radiographic osteoarthritis**

<b>Grade 0</b>	No OA
<b>Grade 1</b>	Questionable narrowing of joint space width (JSW) and possible osteophytoses
<b>Grade 2</b>	Definite JSW narrowing and definite osteophytoses
<b>Grade 3</b>	Definite JSW narrowing, moderate osteophytoses, some subchondral sclerosis and possible deformation of the femoral head
<b>Grade 4</b>	Marked JSW narrowing, large osteophytoses, severe subchondral sclerosis and definite deformation of the femoral head

The reliability and validity of the Kellgren and Lawrence classification have however been questioned (57;58) and Croft et al. proposed a modified definition of the Kellgren and Lawrence to be used in population research which emphasizes the measurement of JSW (59) (table 2).

**Table 2. Croft classification of radiographic osteoarthritis**

<b>Grade 0</b>	No OA
<b>Grade 1</b>	Osteophytoses only
<b>Grade 2</b>	JSW narrowing only
<b>Grade 3</b>	Two of: osteophytoses, JSW narrowing, subchondral sclerosis and cyst formation
<b>Grade 4</b>	Three of: osteophytoses, JSW narrowing, subchondral sclerosis and cyst formation
<b>Grade 5</b>	As grade 4 and deformation of the femoral head

## Management of hip osteoarthritis

Currently, clinical guidelines for the management of hip OA are not published or implemented in Denmark but in the recent decade, international and national evidence-based guidelines have been published elsewhere. General recommendations emphasize initial focus on self-help and patient driven interventions and less focus on passive clinician/therapist administered treatment. Patient driven interventions include education for disease understanding, self-management strategies, empowerment, advice on appropriate activity levels, and exercises for improvement in

aerobic, mobility and strength capacity. In addition, weight loss is recommended when indicated (60;60-63).

As pain levels fluctuate during different stages of the disease, treatment differentiation is recommended pending disease stages and acute episodes (64). Treatment should further be tailored to short or long term goals regarding pain management and improvement in physical function.

Clinician/therapist administered treatment for hip OA can be categorized into non-pharmacological, pharmacological and surgical procedures and should all incorporate the patient's overall clinical picture including age, co-morbidities, medication use, employment status, recreational activities and also account for patient preferences (50).

## Non-pharmacological treatment

### *Self-management and patient education*

Self-management, education and specific disease information are recommended as core interventions even though effectiveness in terms of improvement in pain and function appears to be rather small (60;62;65). Systematic reviews are contradictory in conclusions as the authors of one review reports no effect when patient education (PE) is compared to no or standard care (66), whereas patient education in combination with exercise therapy has demonstrated effectiveness in terms of pain reduction (67). These reviews are however difficult to interpret because both incorporate studies with patients suffering from OA from several anatomic areas.

At the moment patient education offered as standardized programs is not part of hip OA management in Denmark but in Sweden such programs are implemented nationwide (68). Of particular interest is a program specific for the hip termed "hip school" consisting of individual and group sessions with trained physiotherapists and covers information on basic anatomy, disease knowledge, the natural course of OA, recommendations on physical activity, pain mechanisms and self-management, treatment options and optimal contact with the health care system. Exercises for balance, stretching and mobility are demonstrated (69). The hip school has shown promising results in one non-randomized trial when compared to standard medical care and in a recent trial small improvement in pain was noted at 10 and 16 months follow-up in two groups receiving the hip school intervention (69;70). There are however, many unanswered questions in relation to patient education and self-care in general and the hip school in particular in the Danish health care setting. For instance how it compares to standard care or in combination with other non-pharmacological interventions?

### *Exercise therapy*

In addition to self-management and patient education, strengthening and water based exercises are recommended (60;64;65). Small effects for pain reduction are reported in a recent meta-analysis for land-based exercises but no effect was reported for self-reported physical function (71). Water based exercises have demonstrated moderate effects for improvement in pain and function (72). In a recently published long-term follow-up study comparing behavioural graded activity to usual exercise therapy, the group receiving behavioural graded therapy demonstrated significant greater improvement in pain, physical function and self-rated global assessment of intervention compared to the usual exercise group at nine months follow-up and had fewer hip replacement surgeries than the usual exercise therapy group at five years follow-up (73). Behavioural graded activity is an individual oriented program targeting specific activities limiting the individual and includes long-term follow-up sessions with a physiotherapist (74).

### *Manual therapy*

Some of the more recent guidelines recommend manual therapy (MT) as an adjunct intervention for patients with hip OA (60;63;64). In contrast, authors of recent systematic review conclude that currently, manual therapy for hip OA cannot be recommended as an individual treatment due to limited amount of quality trials (75).

The term “manual therapy” has not clearly been defined and depends mainly on the tradition and scope of the professional group utilizing it (76;77). The concept implies an application of physical treatment by hand from a health care provider to a general or specific anatomic area on a patient with the purpose of obtaining a therapeutic effect.

For the musculoskeletal system, manual therapy comprises a variety of techniques with the purpose of affecting tissue structures such as muscles, tendons, ligaments and joints, resulting in pain reduction and improvement in function. The mechanisms of action leading to pain reduction and improvement in physical function are not known.

Manual therapy techniques for the hip joint include most commonly joint mobilization and manipulation and stretching (63). The purpose of joint mobilization and manipulation is to affect the joint surface and create movement and improve mobility by stretching the joint capsule and ligaments (78;79). The aim of stretching is to release muscular tension and improve mobility (80).

Joint mobilization is by definition different from manipulation (78;79;81). Both attempt to separate the articular surfaces through passive forces but joint manipulation aims at obtaining a joint “gapping” which produces an audible “crack” (81-83) whereas mobilization passively moves the joint through its active and passive ranges of motion (78). To obtain this joint “gapping” in manipulation, force must be generated (84-86). For the hip joint this force is considerable and has

in healthy hip joints been estimated to a minimum of 400-600 Newton (84). The required force of course varies according to size and gender of the individual patient.

Studies where patients with hip OA have been subjected to mobilization techniques have not demonstrated effectiveness whereas trials incorporating joint manipulation have shown significant improvement in pain reduction and improvement in physical function and hip ROM (75;86-88). Current trials reporting on manual therapy of the hip involve stretching of some kind but specific effect of the stretching component alone is not known. Stretching can be applied in a variety of forms either passively by the therapist or in corporation with the patient (80).

### Pharmacological treatment

Paracetamol (acetaminophen) is recommended as the initial drug of choice due to low risk of side effects and lesser risk of gastro-intestinal complications than non-steroidal anti-inflammatory drugs (60-62;64). The effect is however reported as being small for pain reduction (62;64). If ineffective, non-steroidal anti-inflammatory drugs are recommended, and if risks of gastro-intestinal complications are present, cox-2 inhibitors or mild opioids combined with paracetamol can be administered. Effects are reported as small to moderate (62;64). Intra-articular injections with corticoid steroid are effective for pain reduction demonstrating moderate effects (64;65). For patients with moderate to severe pain and no effect of the previous drugs, stronger opioids are recommended for a limited time period. The effect is reported as moderate for pain reduction (64;65).

Products containing glucosamine and chondroitin sulphate have been extensively tested and studies have reported moderate effects (65). Recently however, it has been suggested that there is considerable publication bias in the area and effectiveness is being questioned (62).

### Surgery

If non-surgical interventions have been ineffective and/or has the disease progressed to the end stages of severe joint disease, joint replacement surgery is the treatment of choice and has demonstrated large effect but results are limited to prospective cohort studies (65;89).

## **AIMS AND OBJECTIVES**

### **Specific aims**

This PhD project deals with diagnosis and non-pharmacological treatment of patients with hip OA. The overall aims are to 1) report on the prevalence of hip OA in chiropractic practice 2) examine the reproducibility of two clinical examination procedures and 3) investigate the feasibility of a three-arm randomized clinical trial in a Danish setting.

### **Specific objectives**

1. Examine the prevalence of clinical and radiographic hip OA in consecutive patients presenting in Danish chiropractic practice
2. Report on the occurrence of first time diagnosis of hip OA in consecutive patients presenting in chiropractic practice
3. Report on the components of the initial treatment rendered by the chiropractor
4. Examine the inter-rater reproducibility of passive range of motion and muscle strength measurements in patients with unilateral hip OA
5. Examine the inter-rater reliability of the overall assessment of clinical hip OA based on findings of range of motion and strength measurements
6. Investigate the feasibility of a three-arm randomized clinical trial for primary care patients with hip osteoarthritis (OA) in a Danish setting
7. Determine the effectiveness, in terms of pain reduction, of a patient education program with or without the added effect of manual therapy compared to a minimal control intervention
8. Explore any benefit of the addition of manual therapy to the patient education program

## **SUMMARY OF METHODS AND MATERIALS**

### **Study populations and recruitment**

#### **Hip osteoarthritis in chiropractic practice, paper II**

Twenty randomly selected Danish chiropractic clinics participated in the study. At each clinic 100 consecutive patient records and 50 consecutive radiographs of the pelvis of patients over 40 years of age were reviewed retrospectively from August 31<sup>st</sup> 2007. Then during a 2 week period in November 2007, chiropractors at each clinic participated in a prospective survey on all new patients presenting to the clinic.

#### **Reproducibility study, paper III and randomized clinical trial, paper IV**

Patients with a clinical and radiographic diagnosis of hip OA or with a working diagnosis of clinical hip OA were referred from general practitioners or chiropractors in primary care to the Department of Orthopedic Surgery and Traumatology at Odense University Hospital. Inclusion criteria were 1) unilateral hip pain of more than three months' duration, 2) age 40 – 80 years, 3) radiographic hip OA defined by minimal joint space width (JSW)  $\leq$  2.00 mm (34) or a side difference in JSW  $>$  10%, 4) Able to speak and read Danish. Paper I is the published study protocol for paper IV.

#### **Participating raters for the reproducibility study, paper III**

Four clinicians participated as raters: Two orthopaedists from secondary hospital care and two chiropractors from primary care.

### **Procedures**

#### **Hip osteoarthritis in chiropractic practice**

In the retrospective review, patient records were reviewed and data collected for the following information: age, sex, primary complaint, case history, clinical and radiographic examination findings related to hip OA and information on whether patients had received treatment from the chiropractor or had been referred to the general practitioner.

Radiographs were reviewed for the following signs of hip OA: measurement of minimal JSW  $\leq$  2.00 mm (34), side difference of JSW of more than 1.00 mm when comparing right and left hip (90) or

minimal JSW  $\leq$  3.00 mm and minimum one of three findings: subcondral cyst formation, osteophytosis or acetabular sclerosis (59).

The prospective survey used a standardized questionnaire collecting information from consecutive new patients presenting to the clinic: age, sex, primary complaint and if the case history, physical examination and/or radiographs indicated hip OA. It was recorded if patients received treatment and which treatment modalities were used, if a referral was made to the general practitioner, and if it was a first time diagnosis of hip OA.

### Reproducibility study and randomized clinical trial

All referred patients were interviewed initially by phone according to a standardized form including questions related to specific hip symptomatology and in order to differentiate hip OA from other musculoskeletal conditions. Specific questions related to complaints from knees, low back and legs were asked. The full list of inclusion and exclusion criteria is displayed in table 3. If eligible for inclusion, an appointment was made for a clinical examination at the Department of Orthopedic Surgery and Traumatology and a radiographic examination at one of two private chiropractic clinics. The principal investigator assessed radiographs. At the first hospital consultation a clinical examination was performed by a physiotherapist according to a standardized protocol including ROM measurements and an appointment was scheduled for completion of baseline self-reported outcome measures and subsequent randomization. If the physiotherapist obtained information related to the exclusion criteria, this was conferred with the principal investigator. Patients were informed by telephone about results of the radiographic examination and whether radiographic inclusion criteria were present.

**Table 3. Inclusion and exclusion criteria for participants in paper III and IV**

Inclusion criteria	Exclusion criteria
- 40-80 years of age	- Bilateral hip pain
- Unilateral hip pain > 3 months	- Hip OA due to hip fracture or infection
- Radiographic measurement of joint space width < 2.00 mm or side difference > 10%	- Previous hip or knee joint replacement surgery
- Able to speak and read Danish	- Indication for hip joint replacement surgery within the next 6 months
	- Rating of worst hip pain during the last week as $\leq$ 2 on 11-box rating scale
	- Manual therapy for the hip within the last 12 months
	- Hip dysplasia, Center Edge angle < 25 and Acetabular index Angle > 10
	- Local knee pain originating from the knee on the same side as the hip OA
	- Low back pain dominating over the hip symptoms
	- Inflammatory joint disease
	- Polyarthritis defined as > 3 regional sites
	- Cerebrovascular disease
	- Polyneuropathy or neuromuscular disease
	- Malignant disease
	- Other conditions than hip osteoarthritis (OA) appearing to be the cause of the patient's symptoms
	- Refusal to participate

### Specific procedure for the reproducibility study

Examinations took place at the university hospital on the day of randomization. Raters were blind to patient information and examined participants in random order. Raters were allowed to communicate with patients regarding examination procedures only. Range of motion was measured with a standard two-arm goniometer and muscle strength was measured using a hand-held dynamometer. Each rater independently classified assessed each hip into one of three categories: “no hip OA”, “mild hip OA”, and “severe hip OA”. The detailed examination protocol is attached in paper III.

### Randomization for the randomized clinical trial

Patients were randomized and allocated to one of three treatment groups (see below). The randomization sequence was computer generated containing a letter corresponding to each group. Block sizes of three, six or nine were used. On days of randomization, sealed opaque envelopes containing the appropriate letter were generated for the corresponding number of patients eligible for inclusion. The randomization list and envelopes were created individually by two persons not otherwise involved in the study.

### Sample size for the randomized clinical trial

To demonstrate a statistically significant difference of minimum 17 percentage points on the primary outcome after treatment with a 5% significance level and 80% power between the group of PE vs. minimal control intervention (MCI) and PE/MT vs. MCI, 30 patients needed to be included in each group assuming a joint normal distribution for baseline and 6-weeks follow-up with a correlation of 0.3 and equal variances. Allowing for a 15% drop out per group it was decided to include a minimum of 106 patients.

### Interventions for the randomized clinical trial

#### *Patient education*

The patient program, developed and standardized in Sweden and originally termed “hip school” (69), was translated into Danish with permission from the author. A specially trained physiotherapist taught the program which included two individual sessions and three group sessions taught during a 6-weeks period according to the original protocol (paper I)(91).

### *Manual therapy*

The manual therapy protocol was developed and administered by the principal investigator. It included three separate manual therapy techniques: joint manipulation, muscle energy technique and trigger point release therapy and was administered twice a week over a 6-weeks period.

### *Minimal intervention control*

The minimal control intervention included a leaflet with exercises from the patient education program and instruction to “live as usual”. It was administered by a project nurse during a one time encounter and lasted 5-10 minutes.

Protocols for the patient education program, manual therapy and minimal control intervention are attached in paper IV.

### *Dependent variables for the reproducibility study*

Reproducibility for ROM and muscle strength was reported as agreement and reliability between pair-wise raters of the same profession (orthopedists and chiropractors) and reliability of the overall assessment of the presence of clinical OA.

### *Outcome measures and time points for the randomized clinical trial*

The primary outcome was pain severity rated on an eleven-box numerical rating scale at six weeks (92) and patients rated their “worst possible” pain experience during the previous week. Secondary outcomes were the Hip disability and Osteoarthritis Outcome Score (HOOS)(93), patients’ global perceived effect of interventions, ROM measurements of flexion, abduction, adduction and internal and external rotation, use of pain medication at 12-months and hip replacement surgery within the 12-months follow-up period. Assessments were performed at baseline, 6-weeks (immediately following the intervention period) and at 3- and 12-months.

### *Adverse reactions or unintended effects for the randomized clinical trial*

A standardized questionnaire was used for all three groups to collect information on adverse reactions. Information was collected at the end of the 6-weeks intervention period and included: 1) location of pain/discomfort, 2) time of appearance, 3) severity, 4) frequency, 5) duration and 6) did it affect activities of daily living.

## STATISTICS

### Hip osteoarthritis in chiropractic practice

Descriptive data were presented as numbers and percentages. Proportions were presented with 95% confidence intervals (CIs).

### Reproducibility study

For each rater, means and standard deviations (SD) were presented for all measurements. Comparisons between raters of the same profession were presented with mean differences and SD. Measurement error was reported as standard error of the measurement (94). Agreement was reported as 95% limits of agreement (95) and as percent agreement for ROM within 10 degrees for flexion and 5 degrees for all other ROMs (94). Reliability was reported with the intra-class correlation coefficient (ICC<sub>2,1</sub>) including 95% CIs. The reliability of the overall assessment of clinical hip OA was reported with Cohen's weighted kappa.

### Randomized clinical trial

Group differences for all outcomes on a continuous scale were analyzed using ANCOVA with adjustment for baseline values with a significant level of 0.05. For the pair-wise comparisons between the two active treatments and the minimal control intervention, both primary and secondary outcomes were analyzed using Dunnett's test. Post-hoc secondary exploratory analysis of the difference between the PE group and PE/MT was performed using Bonferroni corrected ANCOVA. A longitudinal analysis of primary and secondary outcomes incorporating data from baseline, 6-weeks, 3- and 12-months, was conducted using a linear mixed model approach. Binary outcomes were analyzed by pair-wise application of Fisher's exact. Effect sizes reporting Cohen's d including 95% CIs were displayed for the comparison between PE and MCI, PE/MT and MCI and PE and PE/MT. Adverse events were presented as descriptive information.

## ETHICS AND REGISTRATIONS

### Hip osteoarthritis in chiropractic practice

According to Danish Law, collection of data from records and surveys without disclosure of patient identification does not require ethical approval (96).

## Reproducibility study and randomized clinical trial

An information package about the study including a protocol for lay persons, copy of written consent form and individual's rights for participation was mailed to each patient prior to the initial hospital appointment and radiographic examination. Ethics approval was granted by the Regional Ethics Committee of Southern Denmark, approval number S-20080027 and the Danish Data Protection Agency registered and approved the study J.nr. 2008-41-1910. The study was registered with clinicaltrials.gov ID NCT01039337.

## SUMMARY OF RESULTS

### Hip osteoarthritis in chiropractic practice

#### Retrospective review of records

Records were included for 1,015 males and 985 females with a mean age of 38.9 years. A diagnosis of clinical hip OA was indicated in 27 cases (1.4%) applying the above criteria. The diagnosis of radiographic OA was confirmed in 16 cases (0.8%) of the total records (52% of patients with clinical OA). Of the 16 patients, nine were treated by the chiropractor, six were referred to their general practitioner without treatment and one was referred to a physiotherapist for treatment. Proportions of clinical and radiographic hip OA including 95% CIs are presented in table 4.

**Table 4. Proportions of clinical and radiographic hip osteoarthritis**

	Retrospective			Prospective		
	n	(%)	95% CIs*	n	(%)	95% CIs*
Suspected hip OA from case history alone	72	(3.6)	2.9 – 4.3	18	(4.7)	2.6 – 6.8
Clinical hip OA	27	(1.4)	0.9 – 2.0	13	(3.4)	1.8 – 5.7
Radiographic hip OA	16	(0.8)	0.5 – 1.3	7	(1.8)	0.7 – 3.7

\*confidence intervals

#### Retrospective review of radiographs

A total of 19.2% of radiographs reviewed demonstrated radiographic hip OA according to the criteria.

#### Prospective survey

A total of 387 new patients were registered in the twenty chiropractic clinics during the two-week period including 201 males and 186 females with a mean age of 38.6 years. The diagnosis of clinical hip OA was made in thirteen patients (3.4%) and of these, seven (2.4%) were diagnosed with radiographic OA. A first time diagnosis was made in five of the seven patients. Of the thirteen patients with clinical OA, five were treated at the first visit by the chiropractor, five did not receive

treatment at the first visit and three were referred to the general practitioner for further evaluation without treatment. Treatment by the chiropractor included different types of manual therapy and advice on over-the-counter medication and glucosamine products. Proportions of clinical and radiographic hip OA including 95% CIs for the prospective survey are presented in table 4.

### Reproducibility study

Between January 2009 and September 2009, five days were scheduled for examinations. The senior orthopedic surgeon was not available for one day of examination so a total of 48 patients were assessed for comparison between the two orthopedists versus 61 for the two chiropractors. Twenty-nine males and 32 females with a mean age of 66 years participated.

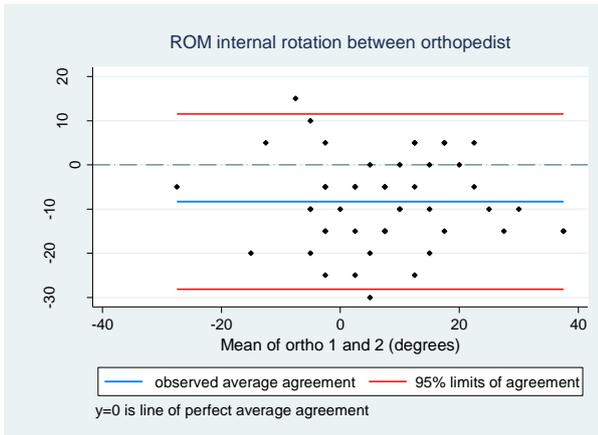
Systematic differences between the two orthopaedists and between the two chiropractors were found for almost all measurements however for ROM measurements no consistent pattern was noted. For hip muscle strength, recordings for one chiropractor were systematically higher for all measurements.

For ROM measurements, limits of agreement were wide between both the two orthopedists and the two chiropractors. Limits of agreement for internal rotation between orthopedists are illustrated in figure 1 and between chiropractors in figure 2. Reliability was highest for flexion between both the two orthopedists,  $ICC_{2,1}$  0.73 (95% CI 0.38-0.87) and the two chiropractors, 0.79 (0.63-0.88). All other ROM measurements between the two orthopedists and the two chiropractors were lower with wide 95% CIs.

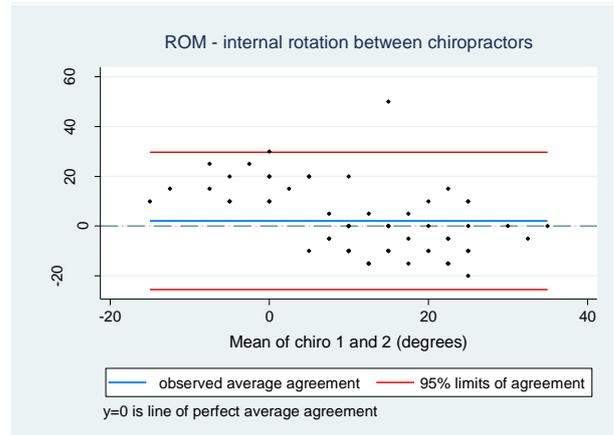
For muscle strength, limits of agreement were wide between both the two orthopedists and the two chiropractors. Limits of agreement for abduction between orthopedists are illustrated in figure 3 and between chiropractors in figure 4. Reliability between the two orthopedists was highest for abduction, 0.85 (0.74-0.91) whereas between the two chiropractors it was highest for flexion, 0.81 (0.69-0.88). All other strength measurements between the two orthopedists and the two chiropractors were lower with wide 95% CIs.

Reliability (weighted kappa) for the assessment of clinical hip OA based on the combined information on ROM and muscle strength was 0.52 between orthopedists and 0.65 between chiropractors.

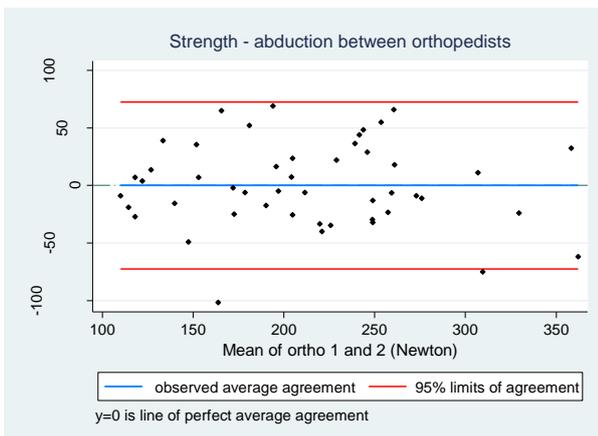
**Figure 1. Limits of agreement between orthopedist for ROM internal rotation**



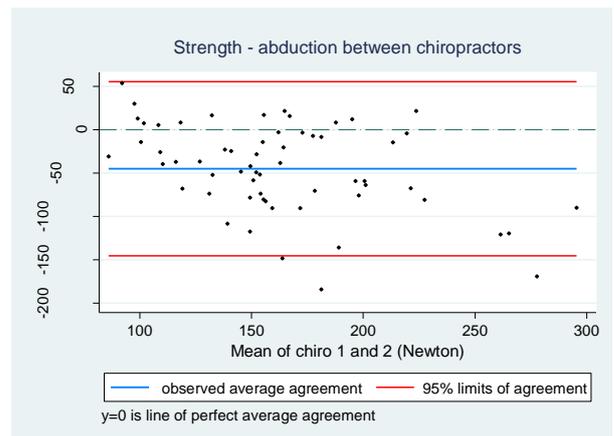
**Figure 2. Limits of agreement between chiropractors for ROM internal rotation**



**Figure 3. Limits of agreement between orthopedist for abduction strength**



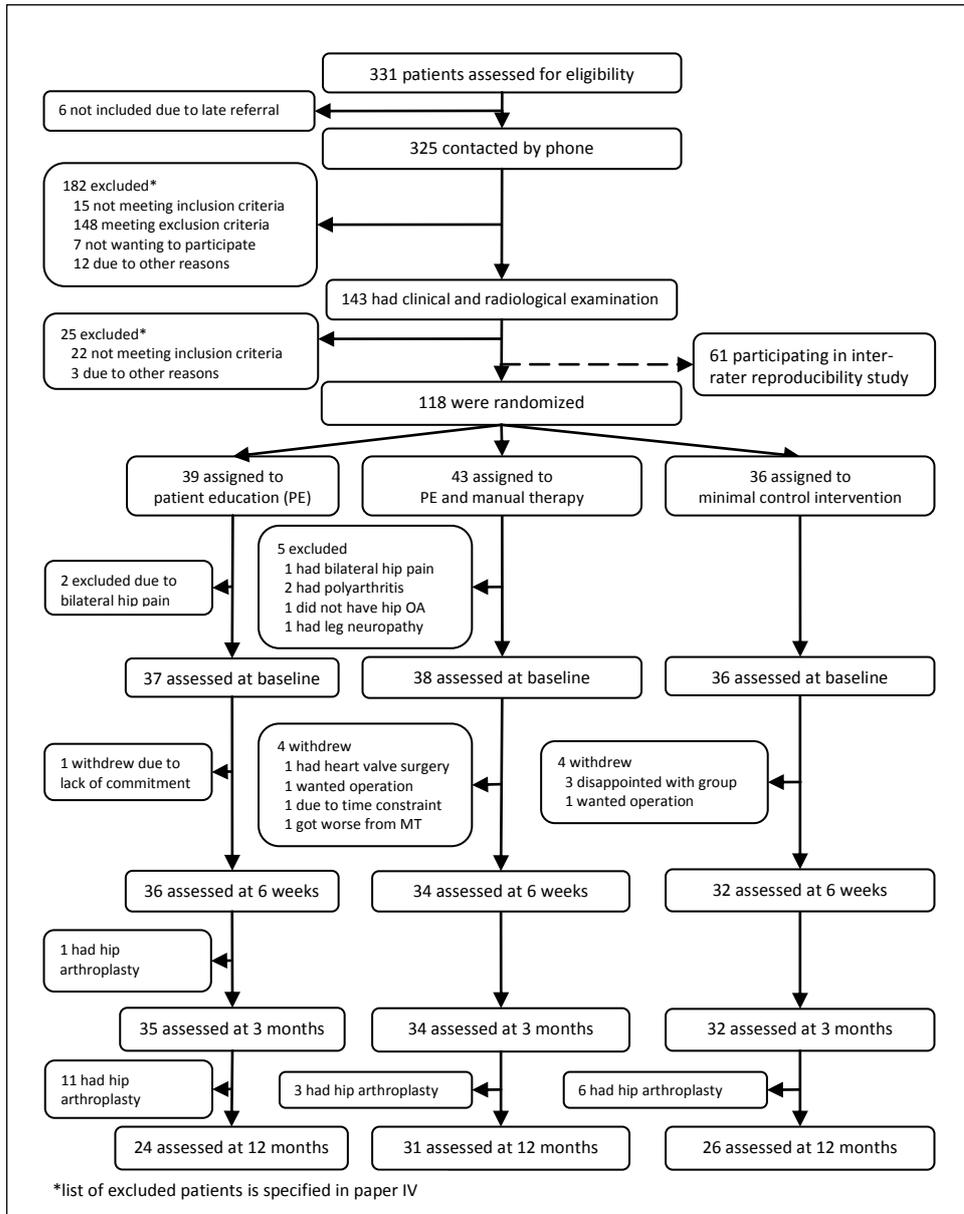
**Figure 4. Limits of agreement between chiropractors for abduction strength**



## Randomized clinical trial

Three-hundred and thirty-one eligible patients were referred from December 2008 to May 2010. Patient flow through the study is illustrated in figure 5. Two-hundred and thirteen patients did not fulfil the inclusion criteria or did fulfil at least one exclusion criteria, so 118 were randomized and allocated into the three groups. Following randomization but before initiation of interventions, seven patients were excluded due to detection of exclusion criteria. Hence, a total of 111 were included in the analyses at six weeks for the primary outcome. At 6-weeks nine patients (8.1%) had withdrawn. Group distribution and reason for withdrawal are presented in paper IV. In addition, twenty-three (21%) of patients had undergone hip replacement surgery before the 12 months follow-up.

**Figure 5. Flow of patients participating in paper III and IV**



### Primary outcome at 6-weeks

At the primary end-point at 6-weeks no overall statistically significant differences were found between groups for pain severity (ANCOVA). However, baseline adjusted reduction in pain severity on the 11-point NRS was -1.9 points (95% CI -2.9 – -0.9) greater for the PE/MT group when compared to the MCI group, whereas no difference was found between the PE and MCI group (-1.0 – 1.0) (Dunnett’s). Effect size between PE/MT and MCI was 0.92 (0.41 – 1.42) and between PE and MCI 0.02 (-0.49 – 0.46).

### Secondary outcomes at 6-weeks

Differences between groups were statistically significant for the HOOS subscales Pain, Function in sport and recreation, and Hip related quality of life but not for the subscales Symptoms and Function in daily living. All baseline adjusted improvements in HOOS subscales were statistically significantly greater for the PE/MT group when compared to the MCI group: 17 points (11-23) for Pain; 13 points (5-20) for Symptoms; 14 points (7-22) for Function in daily living; 17 points (8-25) for Function in sport and recreation and 13 points (6-20) for Hip related quality of life. No differences were found between the PE and MCI groups. Effect sizes for HOOS subscales between PE/MT and MCI ranged between 0.75 – 1.08 with wide 95% CIs. For ROM measurements group differences were not statistically significant and there were no change in pair-wise comparisons between PE/MT and MCI or PE and MCI.

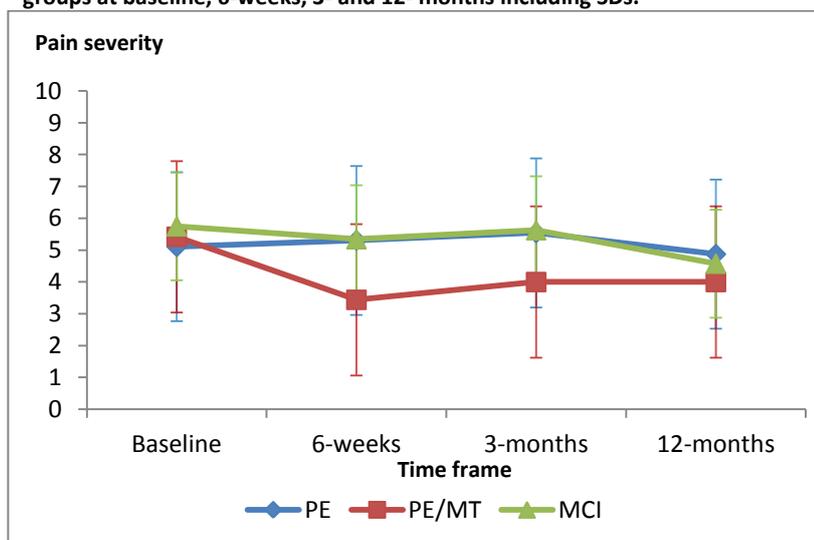
### Post-hoc secondary exploratory analysis between PE and PE/MT groups at 6-weeks

Baseline adjusted reduction in pain severity on the 11-point NRS was -1.9 points (-2.9 – -0.8) greater for the PE/MT group by comparison to the MCI group (ANCOVA – Bonferroni corrected). The same pattern was demonstrated for all HOOS subscales. No differences were found for ROM measurements.

### Pair-wise comparison between PE and MCI and PE/MT and MCI including all time-points

Incorporating all time-points, the reduction in pain severity on the 11-point NRS was -1.1 points (-2.1 – -0.1) greater for the PE/MT group when compared to the MCI group (Dunnett - linear mixed model) and the same pattern was noted for all HOOS subscales when comparing the PE/MT group to the MCI group. Conversely, no differences were demonstrated for any of the ROM measurements or between PE and MCI for NRS pain, HOOS subscales or ROM measurements. Mean scores and SDs for NRS pain severity for the three groups at all time-points are presented in figure 6.

Figure 6. Pain severity on an 11-box numerical rating scale between the three groups at baseline, 6-weeks, 3- and 12- months including SDs.



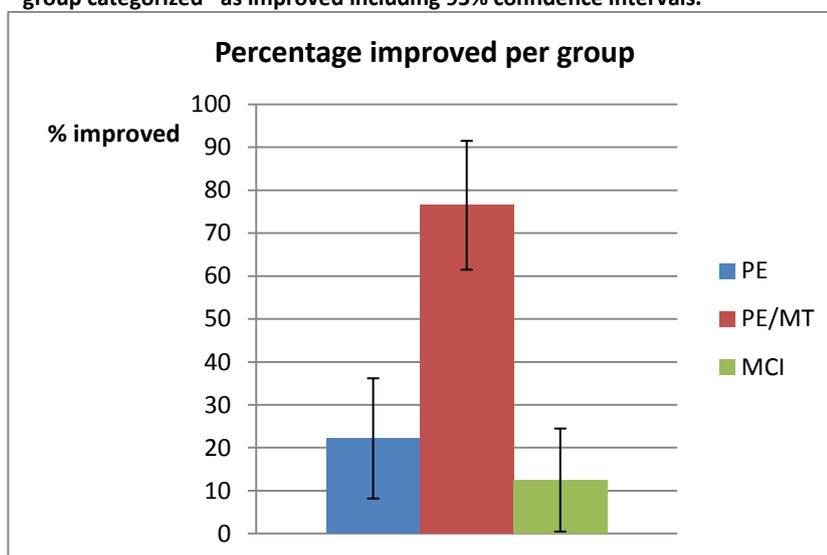
PE = patient education, MT = manual therapy, MCI = minimal control intervention

Post-hoc secondary exploratory comparison between PE and PE/MT including all time-points  
Incorporating all time-points, the reduction in pain severity on the NRS was -1.0 points (-2.1 – 0.0) greater for the PE/MT group when compared to the PE group (ANCOVA - linear mixed model).

### Patients' global perceived effect of intervention

At 6-weeks, 76.5% of patients in the PE/MT group had classified themselves as improved compared to 22.2% in the PE group and 12.5% in the MCI group demonstrating statistical significance between PE/MT vs. PE and PE/MT vs. MCI (figure 7).

Figure 7. Global perceived effect of interventions. Percentage of patients per group categorized\* as improved including 95% confidence intervals.



PE = patient education, MT = manual therapy, MCI = minimal control intervention

\*Improved (much better and better). Not improved (little better, no change, little worse, worse and much worse)

### Pain medication and hip surgery at 12-months

Use of pain medication at 12-months was statistically significant lower in the PE/MT group (n=10) than the PE group (n=23) but there were no statistically significant differences between groups with respect to hip surgery (PE=12, PE/MT=4, MCI=7).

### Adverse reactions or unintended effects

Reaction to interventions occurred primarily in the group receiving MT. Eight patients experienced discomfort, muscle soreness or mild pain appearing up to 24 hours after treatment. One patient withdrew as the hip complaint got worse from MT. In the MCI group two patients terminated specific exercises as hip symptoms got worse or created low back pain.

## DISCUSSION

### Summary of findings

The overall aims of this thesis were to 1) report on the prevalence of hip OA in chiropractic practice 2) examine the reproducibility of two clinical examination procedures in hip OA patients and 3) investigate the feasibility of a three-arm randomized clinical trial involving non-pharmacological interventions in a Danish setting.

We found that hip OA is a condition both diagnosed and managed in Danish chiropractic practice with a prevalence estimation of clinical hip OA to be around 3.5%. Results further indicate that a first time diagnosis of radiographic verified hip OA is made in 40% of these patients.

For measurements of range of motion and muscle strength in patients with unilateral hip OA, limits of agreement between pairs of orthopedists and chiropractors were wide and the reliability were generally low.

For both orthopedists and chiropractors, acceptable reliability was nevertheless found for hip range of motion in flexion. In addition for orthopedists, strength assessment in abduction demonstrated acceptable reliability and for chiropractors, this was found for strength assessment in flexion.

Reliability of the overall assessment of the presence clinical hip OA is moderate and equal between orthopedists and between chiropractors when based on range of motion and muscle strength assessment.

With the applied setting for a three-arm randomized clinical trial, a statistical significant improvement in pain severity on the numerical rating scale, HOOS subscales and patients' global perceived effect of interventions was found when a combined non-pharmacological intervention of patient education and manual therapy were applied to patients with unilateral hip OA.

In addition, statistically significant differences for improvement in pain, physical function measures, and hip related quality of life were found in the group receiving a combined intervention of patient education and manual therapy when compared to a minimal control intervention following a 6-weeks intervention period.

When comparing the combined intervention group to the patient education group alone, pain reduction and improvement in physical function measures and hip related quality of life were statistically significantly lower in the combined group after the intervention period.

## Comparison with other studies

Characteristics of patients presenting to chiropractic practice have been described in several European studies but they have focused mainly on spine related conditions (97-100). Hence, this is the first time specific prevalence estimates of hip OA or diagnosis and management have been systematically described in this setting.

Inter-rater agreement and/or reliability of ROM measurements and muscle strength in patients with hip OA have been investigated in a range of studies but direct comparison between those and our study is difficult because of variation in patient and rater characteristics, measurement equipment, methods and statistics applied and in reporting and interpretation. Theiler et al. reported similar results as ours for ROM measurements using a goniometer. However, they reported Pearson's correlation coefficients which do not incorporate systematic differences between raters and no agreement measures were reported (101).

Steultjens et al. examined active assisted ROM and reported acceptable reliability (>0.75) but again Pearson's was reported (102). Holm et al. studied teams of raters but results for mean measurements of each ROM were combined from all raters (103). Sutlive et al. reported better reliability than our study. They used two physiotherapists as raters and incorporated several training sessions, however testing procedures were not described for four of the six ROMs and agreement between examiners was not reported (104). Cibere et al. concluded they had found clinically acceptable reliability of ROM measurements before and after a rigorous standardisation process but neither variance components for the patients nor random error were incorporated and again agreement between examiners was not reported (105).

The only study reporting on reliability of passive ROM measurements using clinicians from primary care is by Croft et al. who found results similar to ours. However, only six patients were assessed and a pleurimeter was used for measurements and results from healthy and diseased hips were pooled (106).

Arnold et al. reported excellent inter-rater reliability for hip muscle strength using a model of hand-held dynamometer different from the one we used and results were not differentiated between patients with hip and knee OA (107). Steultjens et al. used a model of dynamometer like in our study and found acceptable reliability (>0.75) but Pearson's was again reported (108).

Manual therapy for patients with hip OA was first described in textbooks dating back to the fifties and sixties (109;110). Later, case reports, case series and pilot studies were published but it is only recently that controlled trials evaluating the effectiveness of manual therapy have emerged (111-117).

In 2004, Hoeksma et al. published a randomized clinical trial comparing manual therapy to exercise therapy and reported results similar to ours for the combined PE/MT group regarding improvement in pain, physical function measures and patients' global perceived effect of treatment (75). The manual therapy intervention included joint manipulation, joint mobilization and stretching exercises administered over nine treatment sessions during a five week period. In addition to the self-reported improvements, Hoeksma et al. reported significant improvement in hip ROM lasting 6 months post intervention. This finding differs from our results and may be explained by differences in the manual treatment intervention.

Finally, Vaarbakken and Ljunggren reported results similar to ours in a small randomized clinical trial including only nineteen participants (86). They applied a forceful distraction technique in one group in comparison to joint mobilization in another. But patients were diagnosed with hip dysfunction and not all had radiographic diagnosed hip OA. Average treatment sessions were thirteen during a 5-12 week period.

Therefore, even with a limited amount of controlled trials the results of our trial are concurrent with the two mentioned above.

Self-management and patient education for hip OA patients have been promoted during the last two decades and are considered a core intervention in management (60;64;65;118). Interestingly, the authors of a meta-analysis found little or no effect on pain and function of self-management programs when compared to controls and the effectiveness of these interventions on patients with hip OA are dominantly studied where patients with both hip and knee OA have been included (66).

Allen et al. reported on a trial examining a telephoned-based self-management program including written and video material but without educational classes and found no differences in pain reduction when compared to usual care at 12 months follow-up (119). Patel et al. reported on another self-management program demonstrating no cost effectiveness when compared to an education booklet alone (120). In patients with mild hip and knee OA, Wetzels et al. reported no differences in pain or function at 6 months when comparing a nurse supported self-management program to an education booklet (121). Finally, Buszewicz et al. found no difference in pain or physical function at 4 or 12 months when comparing a six session self-management program including an education booklet to the booklet alone (122). Using a program similar to ours in content and duration, Hansson et al. found no change in pain or functional measures at 6-months follow-up when compared to patients told to live as usual, but patients with hip, knee and hand OA were included (123). A study including just hip OA patients by Fernandes et al. compared the patient education program identical to ours to a combined patient education and exercise therapy program and reported no differences in pain severity between groups at 10 and 16 months follow-ups (70). So in summary, findings from our study are very similar to the current literature when

comparing self-management or patient education programs to usual care or minimal control interventions.

## Methodological considerations

### Hip osteoarthritis in chiropractic practice

We included approximately 10% of all chiropractic clinics in Denmark from urban, suburban and rural parts of the country, and with the number of reviewed records and the compliance from all participating clinics and chiropractors, we consider the estimates of the prevalence of hip OA accurate and reasonable. The prevalence rates between the retrospective review and prospective survey were based on clinical and radiographic information. However, the exact timeframe for the retrospective review was not recorded.

The prevalence estimates in the retrospective review may be inflated because information was collected by only one person, the principal investigator, with a possible interpretation bias in favor of hip OA. In addition, estimates in the prospective survey are potentially inflated because participating chiropractors had an increased awareness of the condition. For the future, electronic patient records are now a requirement from the Danish National Health Insurance and radiographs from chiropractic clinics are now being stored centrally. Therefore, research of this type will be made easier and less prone to bias from hand written records. This type of electronic record keeping, will further improve research possibilities into correlations between case history information and clinical and radiographic findings.

We do not consider the information pertaining to treatment administered by the chiropractor a fair representation of daily practice because it was collected for only a limited number of patients over a short period of time. Almost half of the patients diagnosed with clinical hip OA did not receive treatment on the first visit. But it is not uncommon for chiropractors to not administer treatment on the first visit if patients present with chronic conditions and imaging procedures are required for differential diagnosis. Therefore, it is unknown if they later received treatment or were referred to their general practitioner.

### Reproducibility of hip range of motion and muscle strength

The diagnosis of hip OA is initially made predominantly in primary care based on clinical information (44;55;124). Therefore, we found it important to include clinicians from primary care when examining agreement and reliability of clinical procedures considered important for the diagnosis. Thus, we included both chiropractors (primary care) and orthopedists (secondary care) as raters to further investigate differences between the two groups. Presumably more

experienced and specialized examiners would be able to obtain better levels of agreement and reliability.

We did not include raters from a random selection but chose two from each profession based on convenience and practicality, hence generalizability of the study can be questioned (125). But we still consider results reflecting current levels of reproducibility among orthopedists and chiropractors in Denmark as the standardization is not common in clinical practice. The two orthopedists had different levels of experience and of opposite sex but we did not find systematic differences between the two as has been suggested and reported elsewhere (126;127). The two chiropractors had similar levels of experience, so the poor agreement and reliability is likely a result of habitual practice despite the standardized protocol.

Commonly, studies on reproducibility of ROM and strength measurements reports better intra-rater agreement and reliability compared to inter-rater because between-rater variability is eliminated (22;128). We chose to focus on inter-rater reproducibility because when different clinicians are assessing the same patient on follow-up consultations or when diagnoses are agreed on between clinicians, inter-rater reproducibility becomes essential.

For ROM measurements, internal rotation has been reported as a predictor for both moderate and severe hip OA (52;53). But reproducibility when using a goniometer is questioned because of use and interpretation and systematic differences between raters (129). As reported in our study, reproducibility for internal rotation was poor for both orthopedists and chiropractors. Systematic differences were relatively large and standard error of the measurements was the highest compared to all ROMs. Part of this error is likely due to the supine patient position we chose causing minimal femoral stability. Textbooks and other studies on ROM measurements recommend a sitting position for evaluation so the procedure should be further evaluated for optimal positioning (106;130). For external rotation the same would be expected as we found poor reproducibility, but Cibere et al. found better reliability in the supine position for external rotation compared to the sitting position (105). Flexion ROM has also been reported as a predictor for hip OA and demonstrated acceptable reproducibility like most studies involving hip OA patients (52;53;106;131). But maybe these findings needs reconsidering as Büttner and Müller argues that the wider the possible range for the measurement analysed, the higher the reliability coefficients (132). This is specifically true for ROM in flexion as it is the movement reflecting the widest possible range.

We incorporated a “break” test for strength measurements to optimize detection of differences between the population of early and mild OA. This method has been recommended especially in the larger muscle groups (126;133). But the “break” test is considered more prone to measurements error as it requires a stronger force from both the participant and the rater (134;135). Our results indicate that systematic differences between raters are a major contributor

to the overall measurement error which is concurrent with another study on hip strength measurements using a hand-held dynamometer but on healthy subjects (126).

For diagnosing patients with hip OA, a preliminary clinical prediction rule has been proposed based on findings from the clinical examination (104). This method incorporates a range of examination procedures and calculates a pre- and post-test probability of having hip OA based on the number of positive tests. The strength of this method includes resemblance to clinical practice by identifying procedures with the strongest predictors for the condition but individual procedures still need to demonstrate adequate reproducibility to be included. The appropriate place for clinical prediction rules is when uncertainty exists about the diagnosis so this would be true for patients with early and mild hip OA (136).

We decided to include an overall assessment of clinical hip OA based on the raters' evaluation of ROM and strength and categorizing the assessment into "no", "mild" or "severe OA". We are aware that the diagnosis of hip OA is not based on solely these two clinical evaluations but we were interested in the overall reliability as they are considered essential in the clinical examination (41). The inclusion of a third category of "moderate" OA is commonly applied in radiographic assessments but reliability coefficients becomes smaller when a category is added in the weighted kappa analysis (137). Therefore, interpretation should be made with care and results likely not applicable to practice. We further consider the results of the overall assessment likely influenced by interpretation bias as raters were aware of inclusion and exclusion criteria for the study.

Finally, good to excellent intra- and inter-rater reliability for ROM and strength measurements has been reported using goniometer and hand-held dynamometer in healthy subjects (126;133;138-141). However, age and disease characteristics influence the variation between subjects and therefore both agreement and reliability can therefore not be directly compared.

### Participants for the reproducibility study and randomized clinical trial

When defining inclusion criteria for patients with hip OA for research trials, several methods have been proposed but clinical and imaging signs correlates poorly and reliability of the applied measurements are not convincing (16;26). The American College of Rheumatology criteria are commonly used (43) but they are based on secondary care patients and the validity for their clinical criteria in primary care has been questioned (142;143). Furthermore, to our knowledge, the American College of Rheumatology criteria are not commonly used in trials on OA patient in Denmark.

We included patients aged 40 to 80 years with hip pain for more than 3 months which is common in trials of hip OA (70;144). Interestingly, we found patients under 40 years of age and over 80 who

were eligible and with increased longevity future trials should consider extending the age limits (145). The case history information was collected through a standardized protocol and contained information relevant for patients with hip OA (42;49). The definition of hip pain was inspired by studies on pain distribution and included the groin, buttock, trochanter major, anterior or lateral thigh area which have been reported to increase sensitivity and specificity in this patient group (46-48). But it is still a possibility, although considered small, that patients without hip OA were included. This is supported by the findings in paper II which demonstrated patients with hip OA being categorized into groups of “low back pain”, “low back with referring leg pain” and “leg pain”.

in clinical trials, it is common that mostly highly motivated individuals are included affecting generalizability (146). This trial is probably no exception because it received extensive media coverage through national television and magazines during the initial months of inclusion and in addition, referrals from general practitioners and chiropractors were based on the opinion of each clinician and likely did not result in a group of consecutive and eligible patients. Since most trials are faced with challenges of recruitment especially when conducted over years, this bias is considered unavoidable.

### Radiographic hip osteoarthritis

We decided to use radiographic findings of hip OA as an inclusion criteria since radiographs are easy accessible and inexpensive (50). The radiographic examination was performed according to a standardized procedure which should improve reliability and radiographs were assessed for minimal JSW according to a standardized protocol and measured using digital software (147;148). This method is reported to be reliable (149). All measurements were performed by the principal investigator and since the person was not blind to patient characteristics, it could be a source of selection bias. But the person was not aware of group allocation at time of measurements, so it is anticipated that randomization would have minimized this bias.

The inclusion criterion of minimal JSW < 2.00 mm was based on results from Jacobsen et al. who reported this cut-off of JSW narrowing to correlate the most with self-reported hip pain (150). This finding is supported by a study by Bierma-Zeinstra et al. (52) although correlation between JSW and hip pain remains controversial (151). We included a side difference in JSW in order to include patients with early to mild hip OA based on results from Danielsson et al. who used a criterion of a side difference of > 1.00 mm (90). This method using relative small differences could have included patients without hip OA as measuring error alone could account for this difference. However, only seven patients were included with minimal JSW difference > 10% and < 25% and they were equally distributed between the three groups and therefore it is unlikely to have influenced our results.

## Sample size

Sample size calculations prior to the study were successful because we had sufficient power to detect statistically significant differences in changes for all patient reported outcomes in the combined intervention group when compared to the minimal control. Although the patient education group alone was not able to demonstrate significant improvement for any of the outcome measures when compared to the minimal control, this could be due to lack of power and our extensive list of exclusion criteria but on the other hand could also reflect that patient education as performed in this trial is not effective in this clinical population.

## Randomization and allocation

The two major benefits of using randomization are to avoid selection bias and to improve the likelihood that differences observed between groups does not happen by chance (146). In our trial, group allocation took place on the day of baseline evaluation so that the number of patients would match the number of sealed opaque envelopes. Therefore it did not match the computer generated sequence exactly in all cases. We do not anticipate this procedure to have introduced bias to group allocation but the effect is not truly known.

Because patients allocated to the minimal intervention group were left on their own for the intervention period in contrast to the two active interventions groups, it is possible that, in spite of careful and standardized baseline examinations, patients who did not fulfil inclusion or had exclusion criteria were allowed to remain in this group. Seven patients were identified in the two active groups and the exclusion of those immediately after randomization may have introduced selection bias (146).

## Interventions

In Denmark, primary care treatment for patients with hip OA is not standardized or registered so we considered including a minimal control intervention both optimal and ethical. We further found it relevant to examine the effectiveness of the patient education program because it is recommended and implemented in neighbouring Sweden but not in Denmark. Manual therapy is one of the few non-pharmacological interventions for hip OA that has documented convincing effects but only in two clinical trials (75;86). We therefore found it timely and relevant to compare the relative effectiveness of these interventions in a proof-of-principle trial. Whether a large-scale randomized clinical trial is feasible will depend on careful scrutiny of the results of the current trial as well as careful considerations of practical and logistical aspects. To optimize treatment effect for the manual therapy, it was administered by the principal investigator who has extensive experience in manual therapy for this patient group but it reduces generalizability.

## Blinding

Blinding participants involved in an randomized clinical trial to group allocation is necessary to measure the true effect of an intervention (146). However, for trials involving non-pharmacological interventions this is often not possible and consequently, results may be influenced by or even caused by factors indirectly related to the interventions (152). For instance, the treatment effect observed in the PE/MT group could be influenced by performance bias because the group received twelve sessions with a chiropractor in addition to the patient education. In addition, differences observed between the PE and PE/MT group could be influenced by expertise bias because the physiotherapist teaching the patient education was relatively inexperienced in running this particular program even though the person had 11-years of experience involving patient education and rehabilitation of orthopedic hospital patients. In contrast, the treating chiropractor had extensive experience and clinical interest in treating patients with OA of the hip.

The initial objective was to blind the physiotherapist measuring ROM of the hips but for patients not to converse about their group allocation proved difficult as instructions were not strict enough. Therefore, ROM measurements could be bias but difference was not observed between groups.

Finally, the independent statistician performing the analyses was not blind to group allocation because it was necessary to know the identity of the control group to perform the Dunnett's analyses. Analysis bias is however considered minimal as the statistician was not otherwise involved in the study.

## Outcome measures

Composite measures of pain and function are recommended as outcome measures by OMERACT – OARSI (Outcome Measures in Rheumatology – Osteoarthritis Research Society International) in trials involving patients with hip or knee OA (153). We chose a single measure for pain severity (11-box numerical rating scale) as it has been shown to be valid and responsive in chronic pain patients and in this trial it was able to measure a significant change in the combined intervention group (92;154). Recently, this measure of pain is supported by Perrot et al. who examined daily and weekly pain levels in hip and knee OA patients (144). They conclude the “worst pain experience” to be used in OA clinical trials but if patients are asked about the pain experience during the last week or month, it is strongly influenced by pain levels on the day asked.

We included ROM measurements because it is a common belief that joint manipulation improves ROM but results from pilot- and case studies and controlled trials are conflicting (75;86;113-116). Hoeksma et al. were able to demonstrate significant changes in ROM up to 6-months following treatment (75) whereas Vaarbakken & Ljunggren did not report on improvement in ROM but demonstrated similar results as ours for the improvement in HOOS subscales (86). In this study,

we did not find significant between-group or within-group differences and thus could not confirm that manual therapy significantly increases ROM. The conflicting results could be due to differences in the applied method of joint manipulation and traction forced applied to the hip joint but it has probably more to do with the reliability of the ROM measurements.

## **Clinical implications**

Postgraduate education for practising chiropractors in addition to greater focus on osteoarthritis of the hip in undergraduate education is recommended based on the findings in this thesis. This should include courses based on international clinical guidelines and current evidence on diagnostic test accuracies, clinical predictors and treatment.

When using range of motion and strength measurements for diagnostic assessment or evaluation of disease progression in patients with hip OA, it appears that both orthopedists and chiropractors require rigorous training to improve reproducibility, however it is not known if such training will lead to better patient outcomes.

When measuring internal hip rotation in patients with OA, patients should be seated on an examination table instead of being supine in order to minimize measurement error.

The combined intervention of patient education and manual therapy appears to be an effective and safe treatment option for patients with hip OA but these initial results need to be verified in a large scale clinical trial.

Patients receiving manual therapy for the hip should be informed about possible short term discomfort, muscle soreness or pain lasting up to 48 hours. A small proportion of patients may not tolerate manual therapy.

## **Research implications**

Further descriptive studies dealing with the management of hip OA in chiropractic practices are recommended. These should include detailed description of the diagnostic process and complete management plans including information on specific clinical diagnostic procedures and type, duration and frequency of interventions. Through the practice-based network of chiropractic clinics in Denmark, such studies appear to be feasible.

Recently, specific ranges of hip motion have been associated with specific radiographic findings in patients with early symptomatic hip OA. Therefore, primary care clinicians (general medical practitioners, physiotherapists and chiropractors) should be involved in the assessment of

agreement and reliability. This should include the impact of standardization and training and identification of specific causes of measurement error when evaluating this patient group. Of course agreement and reliability by itself is not important if tests are not predictive of outcome or prognosis of patients.

The effect of treatment involving manual therapy either alone or in combination with other types of treatment should be tested in future large scale trials based on the results of our proof-of-principle trial. Effect sizes and standard deviations from the current trial will assist in determining the optimal number of participants. Based on our experiences the following is recommended for improvement and to be implemented in future trial protocols: 1) The inclusion process should involve a physical examination performed by one or more expert clinicians experienced in the area of differential diagnosis of hip pain. 2) The randomization sequence should be matched to consecutive included patients. 3) The HOOS-pain subscale can substitute the 11-point numerical rating scale because it appears to be more responsive. 4) Pending the physical surroundings of the trial, objective measures for physical performance, i.e. 6-min walk test, timed-up-and-go etc., should be included and correlated to patient-reported physical function measures. 5) Investigating predictors for responders and non-responders regardless of interventions should be explored. 6) The manual therapy and patient education should be delivered by three or more clinicians/therapists in order to avoid therapist bias. Any bias from therapists can then be assessed and controlled in the subsequent analysis. 7) Introducing follow-up or “booster” treatment sessions could be included for both patient education and manual therapy as treatment effect appears to gradually diminish over the 12-months follow-up. This approach probably reflects clinical practice in many cases of chronic conditions and would give a more realistic picture of the true long term value of these interventions.

## CONCLUSIONS

Patients with hip OA are diagnosed and treated in chiropractic practice in Denmark and the condition is likely under diagnosed.

First time diagnosis of hip OA in chiropractic practice is common among new presenters with clinical and radiographic signs of OA.

In general, when examining patients with hip OA, orthopedists and chiropractors have within their own profession difficulty in agreeing on measurements of range of motion and muscle strength when using a goniometer and a dynamometer.

Orthopedists and chiropractors are within their own professions able to discriminate between hips with or without hip OA when the evaluation is based on findings from range of motion and strength measurements.

Our current trial set-up is feasible in the Danish health care setting for investigating three non-pharmacological interventions for patients with hip OA.

A combined patient education and manual therapy intervention is an effective and safe treatment option for patients with hip OA.

When evaluating the combined intervention of patient education and manual therapy, it appears that manual therapy is the active treatment.

## REFERENCES

1. Woolf AD, Pfleger B. Burden of major musculoskeletal conditions. *Bull. World Health Organ* 2003;81(9):646-56.
2. Muskel og skeletsygdomme. Folkesundhedsrapporten. København: Statens Institut for Folkesundhed: 2007.
3. Vi kan leve længere og sundere. Forebyggelseskommissionens anbefalinger til en styrket forebyggende indsats. Forebyggelseskommissionen; 2009.
4. Erhvervs sygdomme oprettet i perioden 2006-10 opgjort på anmeldediagnose København: Arbejdsskadestyrelsen: 2011.
5. Bijlsma JW, Knahr K. Strategies for the prevention and management of osteoarthritis of the hip and knee. *Best. Pract. Res. Clin. Rheumatol.* 2007 Feb;21(1):59-76.
6. Elders MJ. The increasing impact of arthritis on public health. *J Rheumatol. Suppl* 2000 Oct;60:6-8.
7. Moskowitz RW. The burden of osteoarthritis: clinical and quality-of-life issues. *Am. J. Manag. Care* 2009 Sep;15(8 Suppl):S223-S229.
8. Murray CJL, Lopez AD. The global burden of disease. A comprehensive assessment of mortality and disability from diseases, injuries, and risk factors in 1990 and projected to 2010. Cambridge, Massachusetts, USA: Harvard School of Public Health on behalf of the World Health Organization and The World Bank: 1996.
9. Nuesch E, Dieppe P, Reichenbach S, Williams S, Iff S, Juni P. All cause and disease specific mortality in patients with knee or hip osteoarthritis: population based cohort study. *BMJ* 2011;342:d1165.
10. Helweg-Larsen K, Davidsen M, Laursen B, Anderson GM. Slidgigt. Forekomst og risikofaktorer. Udvikling i Danmark. Statens Institut for Folkesundhed. Syddansk Universitet; 2009.
11. March LM, Bachmeier CJ. Economics of osteoarthritis: a global perspective. *Baillieres. Clin. Rheumatol.* 1997 Nov;11(4):817-34.
12. Leigh JP, Seavey W, Leistikow B. Estimating the costs of job related arthritis. *J. Rheumatol.* 2001 Jul;28(7):1647-54.
13. Ricci JA, Stewart WF, Chee E, Leotta C, Foley K, Hochberg MC. Pain exacerbation as a major source of lost productive time in US workers with arthritis. *Arthritis Rheum.* 2005 Oct 15;53(5):673-81.
14. Rolfson O, Strom O, Karrholm J, Malchau H, Garellick G. Costs Related to Hip Disease in Patients Eligible for Total Hip Arthroplasty. *J. Arthroplasty* 2011 Dec 30.
15. Brandt KD, Radin EL, Dieppe PA, van de PL. Yet more evidence that osteoarthritis is not a cartilage disease. *Ann. Rheum. Dis.* 2006 Oct;65(10):1261-4.

16. Busija L, Bridgett L, Williams SR, Osborne RH, Buchbinder R, March L, Fransen M. Osteoarthritis. *Best.Pract.Res.Clin.Rheumatol.* 2010 Dec;24(6):757-68.
17. Hunter DJ. Osteoarthritis. *Best.Pract.Res.Clin.Rheumatol.* 2011 Dec;25(6):801-14.
18. Sellam J, Berenbaum F. The role of synovitis in pathophysiology and clinical symptoms of osteoarthritis. *Nat.Rev Rheumatol.* 2010 Nov;6(11):625-35.
19. Tan AL, Grainger AJ, Tanner SF, Shelley DM, Pease C, Emery P, McGonagle D. High-resolution magnetic resonance imaging for the assessment of hand osteoarthritis. *Arthritis Rheum.* 2005 Aug;52(8):2355-65.
20. Slemenda C, Brandt KD, Heilman DK, Mazzuca S, Braunstein EM, Katz BP, Wolinsky FD. Quadriceps weakness and osteoarthritis of the knee. *Ann.Intern.Med.* 1997 Jul 15;127(2):97-104.
21. Rydevik K, Fernandes L, Nordsletten L, Risberg MA. Functioning and disability in patients with hip osteoarthritis with mild to moderate pain. *J.Orthop.Sports Phys.Ther.* 2010 Oct;40(10):616-24.
22. Pua YH, Wrigley TV, Cowan SM, Bennell KL. Intrarater test-retest reliability of hip range of motion and hip muscle strength measurements in persons with hip osteoarthritis. *Arch.Phys Med.Rehabil.* 2008 Jun;89(6):1146-54.
23. Arokoski MH, Haara M, Helminen HJ, Arokoski JP. Physical function in men with and without hip osteoarthritis. *Arch.Phys Med.Rehabil.* 2004 Apr;85(4):574-81.
24. Roos EM, Herzog W, Block JA, Bennell KL. Muscle weakness, afferent sensory dysfunction and exercise in knee osteoarthritis. *Nat.Rev Rheumatol.* 2011 Jan;7(1):57-63.
25. Felson DT. An update on the pathogenesis and epidemiology of osteoarthritis. *Radiol.Clin.North Am.* 2004 Jan;42(1):1-9, v.
26. Pereira D, Peleteiro B, Araujo J, Branco J, Santos RA, Ramos E. The effect of osteoarthritis definition on prevalence and incidence estimates: a systematic review. *Osteoarthritis.Cartilage.* 2011 Nov;19(11):1270-85.
27. Murphy LB, Helmick CG, Schwartz TA, Renner JB, Tudor G, Koch GG, Dragomir AD, Kalsbeek WD, Luta G, Jordan JM. One in four people may develop symptomatic hip osteoarthritis in his or her lifetime. *Osteoarthritis.Cartilage.* 2010 Nov;18(11):1372-9.
28. Salaffi F, Carotti M, Stancati A, Grassi W. Health-related quality of life in older adults with symptomatic hip and knee osteoarthritis: a comparison with matched healthy controls. *Aging Clin.Exp.Res.* 2005 Aug;17(4):255-63.
29. Dominick KL, Ahern FM, Gold CH, Heller DA. Health-related quality of life and health service use among older adults with osteoarthritis. *Arthritis Rheum.* 2004 Jun 15;51(3):326-31.
30. Jakobsson U, Hallberg IR. Quality of life among older adults with osteoarthritis: an explorative study. *J.Gerontol.Nurs.* 2006 Aug;32(8):51-60.

31. Bieleman HJ, Bierma-Zeinstra SM, Oosterveld FG, Reneman MF, Verhagen AP, Groothoff JW. The effect of osteoarthritis of the hip or knee on work participation. *J.Rheumatol.* 2011 Sep;38(9):1835-43.
32. Dagenais S, Garbedian S, Wai EK. Systematic review of the prevalence of radiographic primary hip osteoarthritis. *Clin.Orthop.Relat Res.* 2009 Mar;467(3):623-37.
33. Lawrence RC, Felson DT, Helmick CG, Arnold LM, Choi H, Deyo RA, Gabriel S, Hirsch R, Hochberg MC, Hunder GG, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part II. *Arthritis Rheum.* 2008 Jan;58(1):26-35.
34. Jacobsen S, Sonne-Holm S, Soballe K, Gebuhr P, Lund B. Radiographic case definitions and prevalence of osteoarthrosis of the hip: a survey of 4 151 subjects in the Osteoarthritis Substudy of the Copenhagen City Heart Study. *Acta Orthop Scand.* 2004 Dec;75(6):713-20.
35. Ingvarsson T, Hagglund G, Lohmander LS. Prevalence of hip osteoarthritis in Iceland. *Ann.Rheum.Dis.* 1999 Apr;58(4):201-7.
36. Brandt KD, Dieppe P, Radin EL. Etiopathogenesis of osteoarthritis. *Rheum.Dis.Clin.North Am.* 2008 Aug;34(3):531-59.
37. Troelsen A, Soballe K. [Idiopathic osteoarthritis of the hip]. *Ugeskr.Laeger* 2007 Jan 29;169(5):390.
38. Ganz R, Leunig M, Leunig-Ganz K, Harris WH. The etiology of osteoarthritis of the hip: an integrated mechanical concept. *Clin.Orthop.Relat Res.* 2008 Feb;466(2):264-72.
39. Bierma-Zeinstra SM, Koes BW. Risk factors and prognostic factors of hip and knee osteoarthritis. *Nat.Clin.Pract.Rheumatol.* 2007 Feb;3(2):78-85.
40. Wright AA, Cook C, Abbott JH. Variables associated with the progression of hip osteoarthritis: a systematic review. *Arthritis Rheum.* 2009 Jul 15;61(7):925-36.
41. Cibulka MT, White DM, Woehrl J, Harris-Hayes M, Ensey K, Fagerson TL, Slover J, Godges JJ. Hip pain and mobility deficits--hip osteoarthritis: clinical practice guidelines linked to the international classification of functioning, disability, and health from the orthopaedic section of the American Physical Therapy Association. *J.Orthop.Sports Phys.Ther.* 2009 Apr;39(4):A1-25.
42. Lane NE. Clinical practice. Osteoarthritis of the hip. *N.Engl.J Med.* 2007 Oct 4;357(14):1413-21.
43. Altman R, Alarcon G, Appelrouth D, Bloch D, Borenstein D, Brandt K, Brown C, Cooke TD, Daniel W, Feldman D, et al. The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hip. *Arthritis Rheum.* 1991 May;34(5):505-14.
44. Bierma-Zeinstra SM, Lipschart S, Njoo KH, Bernsen R, Verhaar J, Prins A, Bohnen AM. How do general practitioners manage hip problems in adults? *Scand.J Prim.Health Care* 2000 Sep;18(3):159-64.
45. Birrell F, Croft P, Cooper C, Hosie G, Macfarlane GJ, Silman A. Radiographic change is common in new presenters in primary care with hip pain. PCR Hip Study Group. *Rheumatology.(Oxford)* 2000 Jul;39(7):772-5.

46. Birrell F, Lunt M, Macfarlane GJ, Silman AJ. Defining hip pain for population studies. *Ann.Rheum.Dis.* 2005 Jan;64(1):95-8.
47. Khan AM, McLoughlin E, Giannakas K, Hutchinson C, Andrew JG. Hip osteoarthritis: where is the pain? *Ann.R.Coll.Surg.Engl.* 2004 Mar;86(2):119-21.
48. Khan NQ, Woolson ST. Referral patterns of hip pain in patients undergoing total hip replacement. *Orthopedics* 1998 Feb;21(2):123-6.
49. Overgaard S, Fredberg U. [The clinical examination of hip joints in adults]. *Ugeskr.Laeger* 2004 Jun 21;166(26-31):2544-7.
50. Bijlsma JW, Berenbaum F, Lafeber FP. Osteoarthritis: an update with relevance for clinical practice. *Lancet* 2011 Jun 18;377(9783):2115-26.
51. Guccione AA, Felson DT, Anderson JJ, Anthony JM, Zhang Y, Wilson PW, Kelly-Hayes M, Wolf PA, Kreger BE, Kannel WB. The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *Am.J Public Health* 1994 Mar;84(3):351-8.
52. Bierma-Zeinstra SM, Oster JD, Bernsen RM, Verhaar JA, Ginai AZ, Bohnen AM. Joint space narrowing and relationship with symptoms and signs in adults consulting for hip pain in primary care. *J Rheumatol.* 2002 Aug;29(8):1713-8.
53. Holla JF, Steultjens MP, van der Leeden M, Roorda LD, Bierma-Zeinstra SM, den Broeder AA, Dekker J. Determinants of range of joint motion in patients with early symptomatic osteoarthritis of the hip and/or knee: an exploratory study in the CHECK cohort. *Osteoarthritis.Cartilage.* 2011 Apr;19(4):411-9.
54. Altman RD, Gold GE. Atlas of individual radiographic features in osteoarthritis, revised. *Osteoarthritis.Cartilage.* 2007;15 Suppl A:A1-56.
55. Cibere J. Do we need radiographs to diagnose osteoarthritis? *Best.Pract.Res.Clin.Rheumatol.* 2006 Feb;20(1):27-38.
56. KELLGREN JH, Lawrence JS. Radiological assessment of osteo-arthritis. *Ann.Rheum.Dis.* 1957 Dec;16(4):494-502.
57. Sun Y, Sturmer T, Gunther KP, Brenner H. Reliability and validity of clinical outcome measurements of osteoarthritis of the hip and knee--a review of the literature. *Clin.Rheumatol.* 1997 Mar;16(2):185-98.
58. Ingvarsson T, Hagglund G, Lindberg H, Lohmander LS. Assessment of primary hip osteoarthritis: comparison of radiographic methods using colon radiographs. *Ann.Rheum.Dis.* 2000 Aug;59(8):650-3.
59. Croft P, Cooper C, Wickham C, Coggon D. Defining osteoarthritis of the hip for epidemiologic studies. *Am.J Epidemiol.* 1990 Sep;132(3):514-22.
60. National Collaborating Centre for Chronic Conditions. Osteoarthritis: national clinical guidelines for care and management in adults. London: Royal College of Physicians; 2008.

61. Zhang W, Doherty M, Arden N, Bannwarth B, Bijlsma J, Gunther KP, Hauselmann HJ, Herrero-Beaumont G, Jordan K, Kaklamanis P, et al. EULAR evidence based recommendations for the management of hip osteoarthritis: report of a task force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). *Ann.Rheum.Dis.* 2005 May;64(5):669-81.
62. Zhang W, Nuki G, Moskowitz RW, Abramson S, Altman RD, Arden NK, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, et al. OARSI recommendations for the management of hip and knee osteoarthritis: part III: Changes in evidence following systematic cumulative update of research published through January 2009. *Osteoarthritis.Cartilage.* 2010 Apr;18(4):476-99.
63. Peter WF, Jansen MJ, Bloo H, Dekker-Bakker LMMCJ, Dilling RG, Hilberdink WKHA, Kersten-Smit C, de Rooij M, Veenhof C, Vermeulen HM, et al. KNGF Guideline for Physical Therapy in patients with Osteoarthritis of the hip and knee. 2010.
64. Guideline for the non-surgical management of hip and knee osteoarthritis. The Royal Australian College of General Practitioners. 2009 [cited 2011 Oct 4] Available from [http://www.racgp.org.au/Content/NavigationMenu/ClinicalResources/RACGPGuidelines/Guidelineforthenonsurgicalmanagementofhipandkneeosteoarthritis/RACGP\\_OA\\_guideline.pdf](http://www.racgp.org.au/Content/NavigationMenu/ClinicalResources/RACGPGuidelines/Guidelineforthenonsurgicalmanagementofhipandkneeosteoarthritis/RACGP_OA_guideline.pdf).
65. Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis.Cartilage.* 2008 Feb;16(2):137-62.
66. Chodosh J, Morton SC, Mojica W, Maglione M, Suttrop MJ, Hilton L, Rhodes S, Shekelle P. Meta-analysis: chronic disease self-management programs for older adults. *Ann.Intern.Med.* 2005 Sep 20;143(6):427-38.
67. Walsh NE, Mitchell HL, Reeves BC, Hurley MV. Integrated exercise and self-management programmes in osteoarthritis of the hip and knee: a systematic review of effectiveness. *Phys Ther Rev* 2006;11:289-97.
68. BOA - Better management of patients with OsteoArthritis 2008 [cited 2012 Jan 29] Available from <https://www.boaregistret.se/en/Default.aspx>.
69. Klassbo M, Larsson G, Harms-Ringdahl K. Promising outcome of a hip school for patients with hip dysfunction. *Arthritis Rheum.* 2003 Jun 15;49(3):321-7.
70. Fernandes L, Storheim K, Sandvik L, Nordsletten L, Risberg MA. Efficacy of patient education and supervised exercise vs patient education alone in patients with hip osteoarthritis: a single blind randomized clinical trial. *Osteoarthritis.Cartilage.* 2010 Oct;18(10):1237-43.
71. Fransen M, McConnell S, Hernandez-Molina G, Reichenbach S. Does land-based exercise reduce pain and disability associated with hip osteoarthritis? A meta-analysis of randomized controlled trials. *Osteoarthritis.Cartilage.* 2010 May;18(5):613-20.
72. Fransen M, McConnell S, Hernandez-Molina G, Reichenbach S. Exercise for osteoarthritis of the hip. *Cochrane.Database.Syst.Rev* 2009;(3):CD007912.

73. Pisters MF, Veenhof C, Schellevis FG, de Bakker DH, Dekker J. Long-term effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: a randomized controlled trial comparing two different physical therapy interventions. *Osteoarthritis.Cartilage*. 2010 Aug;18(8):1019-26.
74. Veenhof C, Koke AJ, Dekker J, Oostendorp RA, Bijlsma JW, van Tulder MW, van den Ende CH. Effectiveness of behavioral graded activity in patients with osteoarthritis of the hip and/or knee: A randomized clinical trial. *Arthritis Rheum*. 2006 Dec 15;55(6):925-34.
75. Hoeksma HL, Dekker J, Runday HK, Heering A, van der LN, Vel C, Breedveld FC, van den Ende CH. Comparison of manual therapy and exercise therapy in osteoarthritis of the hip: a randomized clinical trial. *Arthritis Rheum*. 2004 Oct 15;51(5):722-9.
76. Gatterman MI, Hansen DT. Development of chiropractic nomenclature through consensus. *J.Manipulative Physiol Ther* 1994 Jun;17(5):302-9.
77. Farrell JP, Jensen GM. Manual therapy: a critical assessment of role in the profession of physical therapy. *Phys Ther* 1992 Dec;72(12):843-52.
78. Peterson DH, Bergmann TF. *Chiropractic Technique: Principles and Procedures*. 2nd ed. ed. St. Louis, Missouri: Mosby, Inc.; 2002.
79. Broome RT. The evaluation of joint play and adjustive procedures for the peripheral joints. In: Broome RT, editor. *Chiropractic Peripheral Joint Technique*. Oxford: Butterworth-Heinemann; 2000. p. 91-3.
80. Chaitow L. MET and the treatment of joints. In *Muscle Energy Technique*. 2 ed. Edinburgh: Churchill Livingstone; 2001. p. 159-95.
81. Evans DW, Lucas N. What is 'manipulation'? A reappraisal. *Man.Ther* 2010 Jun;15(3):286-91.
82. Cramer G, Budgell B, Henderson C, Khalsa P, Pickar J. Basic science research related to chiropractic spinal adjusting: the state of the art and recommendations revisited. *J.Manipulative Physiol Ther* 2006 Nov;29(9):726-61.
83. Mierau D, Cassidy JD, Bowen V, Dupuis P, Noftall F. Manipulation and mobilization of the third metacarpophalangeal joint. *Manual Medicine* 1988;3:135-40.
84. Arvidsson I. The hip joint: forces needed for distraction and appearance of the vacuum phenomenon. *Scand.J.Rehabil.Med*. 1990;22(3):157-61.
85. Evans DW. Why do spinal manipulation techniques take the form they do? Towards a general model of spinal manipulation. *Man.Ther* 2010 Jun;15(3):212-9.
86. Vaarbakken K, Ljunggren AE. Superior effect of forceful compared with standard traction mobilizations in hip disability? *Adv.Physiother*. 2007 Sep;9(3):117-28.
87. Nyfos L. [Traction therapy of osteoarthrosis of the hip. A controlled study]. *Ugeskr.Laeger* 1983 Sep 12;145(37):2837-40.

88. Marques B, Toldbod M, Ostrup EL, Bentzen L, Gjørup T, Gylding-Sabroe JP, Leopold M, Riis P. [The effect of naproxen compared with that of traction in patients with osteoarthritis of the hip. A single-blind controlled study]. *Ugeskr.Laeger* 1983 Sep 12;145(37):2840-4.
89. Rasanen P, Paavolainen P, Sintonen H, Koivisto AM, Blom M, Ryyanen OP, Roine RP. Effectiveness of hip or knee replacement surgery in terms of quality-adjusted life years and costs. *Acta Orthop.* 2007 Feb;78(1):108-15.
90. Danielsson L, Lindberg H. Prevalence of coxarthrosis in an urban population during four decades. *Clin.Orthop.Relat Res.* 1997 Sep;(342):106-10.
91. Poulsen E, Christensen HW, Roos EM, Vach W, Overgaard S, Hartvigsen J. Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: Protocol for a three-armed randomized clinical trial. *BMC.Musculoskelet.Disord.* 2011;12:88.
92. Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, Kerns RD, Stucki G, Allen RR, Bellamy N, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain* 2005 Jan;113(1-2):9-19.
93. Nilsson AK, Lohmander LS, Klassbo M, Roos EM. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. *BMC.Musculoskelet.Disord.* 2003 May 30;4:10.
94. de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. *J.Clin.Epidemiol.* 2006 Oct;59(10):1033-9.
95. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986 Feb 8;1(8476):307-10.
96. The Danish National Committee on Biomedical Research Ethics 2011 Aug 11 [cited 2011 Oct 4] Available from <http://www.cvk.sum.dk/English/guidelinesaboutnotification.aspx>.
97. Humphreys BK, Peterson CK, Muehleman D, Haueter P. Are swiss chiropractors different than other chiropractors? Results of the job analysis survey 2009. *J Manipulative Physiol Ther* 2010 Sep;33(7):519-35.
98. Rubinstein S, Pfeifle CE, van Tulder MW, Assendelft WJ. Chiropractic patients in the Netherlands: a descriptive study. *J Manipulative Physiol Ther* 2000 Oct;23(8):557-63.
99. Hartvigsen J, Sorensen LP, Graesborg K, Grunnet-Nilsson N. Chiropractic patients in Denmark: a short description of basic characteristics. *J.Manipulative Physiol Ther.* 2002 Mar;25(3):162-7.
100. Leboeuf-Yde C, Hennius B, Rudberg E, Leufvenmark P, Thunman M. Chiropractic in Sweden: a short description of patients and treatment. *J Manipulative Physiol Ther* 1997 Oct;20(8):507-10.
101. Theiler R, Stucki G, Schutz R, Hofer H, Seifert B, Tyndall A, Michel BA. Parametric and non-parametric measures in the assessment of knee and hip osteoarthritis: interobserver reliability and correlation with radiology. *Osteoarthritis.Cartilage.* 1996 Mar;4(1):35-42.

102. Steultjens MP, Dekker J, van Baar ME, Oostendorp RA, Bijlsma JW. Range of joint motion and disability in patients with osteoarthritis of the knee or hip. *Rheumatology.(Oxford)* 2000 Sep;39(9):955-61.
103. Holm I, Bolstad B, Lutken T, Ervik A, Rokkum M, Steen H. Reliability of goniometric measurements and visual estimates of hip ROM in patients with osteoarthrosis. *Physiother.Res.Int.* 2000;5(4):241-8.
104. Sutlive TG, Lopez HP, Schnitker DE, Yawn SE, Halle RJ, Mansfield LT, Boyles RE, Childs JD. Development of a clinical prediction rule for diagnosing hip osteoarthritis in individuals with unilateral hip pain. *J Orthop.Sports Phys Ther* 2008 Sep;38(9):542-50.
105. Cibere J, Thorne A, Bellamy N, Greidanus N, Chalmers A, Mahomed N, Shojania K, Kopec J, Esdaile JM. Reliability of the hip examination in osteoarthritis: effect of standardization. *Arthritis Rheum.* 2008 Mar 15;59(3):373-81.
106. Croft PR, Nahit ES, Macfarlane GJ, Silman AJ. Interobserver reliability in measuring flexion, internal rotation, and external rotation of the hip using a plurimeter. *Ann.Rheum.Dis.* 1996 May;55(5):320-3.
107. Arnold CM, Warkentin KD, Chilibeck PD, Magnus CR. The reliability and validity of handheld dynamometry for the measurement of lower-extremity muscle strength in older adults. *J.Strength.Cond.Res.* 2010 Mar;24(3):815-24.
108. Steultjens MP, Dekker J, van Baar ME, Oostendorp RA, Bijlsma JW. Muscle strength, pain and disability in patients with osteoarthritis. *Clin.Rehabil.* 2001 Jun;15(3):331-41.
109. Mennell JM. *Joint Pain: Diagnosis and Treatment using Manipulative Techniques.* Boston: Little Brown; 1964.
110. Cyriax J. *Textbook of Orthopaedic Medicine: Treatment by Manipulation, Massage and Injection v.2.* 11 ed. Bailliere Tindall; 1984.
111. Loudon JK. Case report: Manual Therapy Management of Hip Osteoarthritis. *The Journal of Manual & Manipulative Therapy* 1999;7(4):203-8.
112. Vaux P. Hip Osteoarthritis: a chiropractic approach. *European Journal of Chiropractic* 1998;46:17-22.
113. Brantingham JW, Williams AM, Parkin-Smith GF, Weston P, Wood T. A controlled, prospective pilot study of the possible effects of chiropractic manipulation in the treatment of osteo-arthritis of the hip. *European Journal of Chiropractic* 2003;51:149-66.
114. MacDonald CW, Whitman JM, Cleland JA, Smith M, Hoeksma HL. Clinical outcomes following manual physical therapy and exercise for hip osteoarthritis: A case series. *J Orthop Sports Phys Ther* 2006 Aug;36(8):588-99.
115. Brantingham JW, Globe GA, Cassa TK, Globe D, de LK, Pollard H, Lee F, Bates C, Jensen M, Mayer S, et al. A single-group pretest posttest design using full kinetic chain manipulative therapy with rehabilitation in the treatment of 18 patients with hip osteoarthritis. *J Manipulative Physiol Ther* 2010 Jul;33(6):445-57.

116. de LK, Pollard H, Brantingham J, Globe G, Cassa T. Chiropractic management of the kinetic chain for the treatment of hip osteoarthritis: an Australian case series. *J Manipulative Physiol Ther* 2010 Jul;33(6):474-9.
117. Thorman P, Dixner A, Sundberg T. Effects of chiropractic care on pain and function in patients with hip osteoarthritis waiting for arthroplasty: a clinical pilot trial. *J Manipulative Physiol Ther* 2010 Jul;33(6):438-44.
118. Brand CA. The role of self-management in designing care for people with osteoarthritis of the hip and knee. *Med.J.Aust.* 2008 Nov 17;189(10 Suppl):S25-S28.
119. Allen KD, Oddone EZ, Coffman CJ, Datta SK, Juntilla KA, Lindquist JH, Walker TA, Weinberger M, Bosworth HB. Telephone-based self-management of osteoarthritis: A randomized trial. *Ann.Intern.Med.* 2010 Nov 2;153(9):570-9.
120. Patel A, Buszewicz M, Beecham J, Griffin M, Rait G, Nazareth I, Atkinson A, Barlow J, Haines A. Economic evaluation of arthritis self management in primary care. *BMJ* 2009;339:b3532.
121. Wetzels R, van WC, Grol R, Wensing M. Family practice nurses supporting self-management in older patients with mild osteoarthritis: a randomized trial. *BMC.Fam.Pract.* 2008;9:7.
122. Buszewicz M, Rait G, Griffin M, Nazareth I, Patel A, Atkinson A, Barlow J, Haines A. Self management of arthritis in primary care: randomised controlled trial. *BMJ* 2006 Oct 28;333(7574):879.
123. Hansson EE, Jonsson-Lundgren M, Ronnheden AM, Sorensson E, Bjarnung A, Dahlberg LE. Effect of an education programme for patients with osteoarthritis in primary care--a randomized controlled trial. *BMC.Musculoskelet.Disord.* 2010;11:244.
124. Birrell F, Afzal C, Nahit E, Lunt M, Macfarlane GJ, Cooper C, Croft PR, Hosie G, Silman AJ. Predictors of hip joint replacement in new attenders in primary care with hip pain. *Br.J Gen.Pract.* 2003 Jan;53(486):26-30.
125. Kottner J, Audige L, Brorson S, Donner A, Gajewski BJ, Hrobjartsson A, Roberts C, Shoukri M, Streiner DL. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *J Clin.Epidemiol.* 2011 Jan;64(1):96-106.
126. Thorborg K, Bandholm T, Schick M, Jensen J, Holmich P. Hip strength assessment using handheld dynamometry is subject to intertester bias when testers are of different sex and strength. *Scand.J.Med.Sci.Sports* 2011 Oct 28.
127. Wikholm JB, Bohannon RW. Hand-held Dynamometer Measurements: Tester Strength Makes a Difference. *J.Orthop.Sports Phys.Ther.* 1991;13(4):191-8.
128. Klassbo M, Harms-Ringdahl K, Larsson G. Examination of passive ROM and capsular patterns in the hip. *Physiother.Res.Int.* 2003;8(1):1-12.
129. Reichenbach S, Juni P, Nuesch E, Frey F, Ganz R, Leunig M. An examination chair to measure internal rotation of the hip in routine settings: a validation study. *Osteoarthritis.Cartilage.* 2010 Mar;18(3):365-71.

130. Norkin CC, White C. Measurement of Joint Motion: A Guide to Goniometry. 4th ed. Philadelphia: F.A. Davis Company; 2009.
131. Birrell F, Croft P, Cooper C, Hosie G, Macfarlane G, Silman A. Predicting radiographic hip osteoarthritis from range of movement. *Rheumatology.(Oxford)* 2001 May;40(5):506-12.
132. Muller R, Buttner P. A critical discussion of intraclass correlation coefficients. *Stat.Med.* 1994 Dec 15;13(23-24):2465-76.
133. Lu YM, Lin JH, Hsiao SF, Liu MF, Chen SM, Lue YJ. The relative and absolute reliability of leg muscle strength testing by a handheld dynamometer. *J.Strength.Cond.Res.* 2011 Apr;25(4):1065-71.
134. Burns SP, Breuninger A, Kaplan C, Marin H. Hand-held dynamometry in persons with tetraplegia: comparison of make- versus break-testing techniques. *Am.J.Phys.Med.Rehabil.* 2005 Jan;84(1):22-9.
135. Bohannon RW. Hand-held dynamometry: factors influencing reliability and validity. *Clin.Rehabil.* 1997 Aug;11(3):263-4.
136. Herbert RD, Sherrington C, Maher C, Moseley AM. Evidence-based practice - imperfect but necessary. *Physiother.Theory.Pract.* 2001;17:201-11.
137. Kirkwood BR, Sterne JAC. Measurement error: assessment and implications. In *Essential Medical Statistics*. 2nd. ed. Oxford: Blackwell Publishing Ltd.; 1988. p. 429-46.
138. Thorborg K, Petersen J, Magnusson SP, Holmich P. Clinical assessment of hip strength using a hand-held dynamometer is reliable. *Scand.J.Med.Sci.Sports* 2010 Jun;20(3):493-501.
139. Prather H, Harris-Hayes M, Hunt DM, Steger-May K, Mathew V, Clohisy JC. Reliability and agreement of hip range of motion and provocative physical examination tests in asymptomatic volunteers. *PM.R.* 2010 Oct;2(10):888-95.
140. Fulcher ML, Hanna CM, Raina EC. Reliability of handheld dynamometry in assessment of hip strength in adult male football players. *J.Sci.Med.Sport* 2010 Jan;13(1):80-4.
141. Bierma-Zeinstra SM, Bohnen AM, Ramlal R, Ridderikhoff J, Verhaar JA, Prins A. Comparison between two devices for measuring hip joint motions. *Clin.Rehabil.* 1998 Dec;12(6):497-505.
142. Reijman M, Hazes JM, Koes BW, Verhagen AP, Bierma-Zeinstra SM. Validity, reliability, and applicability of seven definitions of hip osteoarthritis used in epidemiological studies: a systematic appraisal. *Ann.Rheum.Dis.* 2004 Mar;63(3):226-32.
143. Bierma-Zeinstra S, Bohnen A, Ginai A, Prins A, Verhaar J. Validity of American College of Rheumatology criteria for diagnosing hip osteoarthritis in primary care research. *J Rheumatol.* 1999 May;26(5):1129-33.
144. Perrot S, Rozenberg S, Moyse D, Legout V, Marty M. Comparison of daily, weekly or monthly pain assessments in hip and knee osteoarthritis. A 29-day prospective study. *Joint Bone Spine* 2011 Oct;78(5):510-5.
145. Vaupel JW, Carey JR, Christensen K, Johnson TE, Yashin AI, Holm NV, Iachine IA, Kannisto V, Khazaeli AA, Liedo P, et al. Biodemographic trajectories of longevity. *Science* 1998 May 8;280(5365):855-60.

146. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. *J.Clin.Epidemiol.* 2010 Aug;63(8):e1-37.
147. Rowe LJ, Yochum TR. Radiographic Positioning and Normal Anatomy. In *Essentials of Skeletal Radiology*. 2nd ed. Baltimore: Williams & Wilkins; 1996. p. 1-138.
148. Lequesne MG, Laredo JD. The faux profil (oblique view) of the hip in the standing position. Contribution to the evaluation of osteoarthritis of the adult hip. *Ann.Rheum.Dis.* 1998 Nov;57(11):676-81.
149. Pessis E, Chevrot A, Drape JL, Leveque C, Sarazin L, Minoui A, Le BG, Chemla N, Dupont AM, Godefroy D. Study of the joint space of the hip on supine and weight-bearing digital radiographs. *Clin.Radiol.* 1999 Aug;54(8):528-32.
150. Jacobsen S, Sonne-Holm S, Soballe K, Gebuhr P, Lund B. The relationship of hip joint space to self reported hip pain. A survey of 4.151 subjects of the Copenhagen City Heart Study: the Osteoarthritis Substudy. *Osteoarthritis.Cartilage.* 2004 Sep;12(9):692-7.
151. Kinds MB, Welsing PM, Vignon EP, Bijlsma JW, Viergever MA, Marijnissen AC, Lafeber FP. A systematic review of the association between radiographic and clinical osteoarthritis of hip and knee. *Osteoarthritis.Cartilage.* 2011 Jan 31.
152. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann.Intern.Med.* 2008 Feb 19;148(4):295-309.
153. Bellamy N, Kirwan J, Boers M, Brooks P, Strand V, Tugwell P, Altman R, Brandt K, Dougados M, Lequesne M. Recommendations for a core set of outcome measures for future phase III clinical trials in knee, hip, and hand osteoarthritis. Consensus development at OMERACT III. *J Rheumatol.* 1997 Apr;24(4):799-802.
154. Farrar JT, Young JP, Jr., LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001 Nov;94(2):149-58.

## PAPERS

### Paper I

Erik Poulsen, Henrik W Christensen, Ewa M Roos, Werner Vach, Søren Overgaard, Jan Hartvigsen.  
Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: Protocol for a three-armed randomized clinical trial.

BMC Musculoskelet Disord 2011;**12**:88

### Paper II

Erik Poulsen, Henrik W Christensen, Søren Overgaard, Jan Hartvigsen.

Prevalence of hip osteoarthritis in chiropractic practice in Denmark – a descriptive cross-sectional and prospective study.

JMPT, accepted for publication

### Paper III

Erik Poulsen, Henrik Wulff Christensen, Jeannette Østergaard Penny, Søren Overgaard, Werner Vach, Jan Hartvigsen.

Reproducibility of range of motion and muscle strength measurements in patients with hip osteoarthritis – an inter-rater study

Submitted

### Paper IV

Erik Poulsen, Henrik W. Christensen, Ewa M. Roos, Jan Hartvigsen, Werner Vach, Søren Overgaard  
Effectiveness of patient education and manual therapy compared to a minimal control intervention in patients with osteoarthritis of the hip – a proof of principle randomized clinical trial.

**STUDY PROTOCOL**

**Open Access**

# Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: Protocol for a three-armed randomized clinical trial

Erik Poulsen<sup>1,2\*</sup>, Henrik W Christensen<sup>2</sup>, Ewa M Roos<sup>1</sup>, Werner Vach<sup>3</sup>, Søren Overgaard<sup>4,5</sup> and Jan Hartvigsen<sup>1,2</sup>

## Abstract

**Background:** Hip osteoarthritis is a common and chronic condition resulting in pain, functional disability and reduced quality of life. In the early stages of the disease, a combination of non-pharmacological and pharmacological treatment is recommended. There is evidence from several trials that exercise therapy is effective. In addition, single trials suggest that patient education in the form of a hip school is a promising intervention and that manual therapy is superior to exercise.

**Methods/Design:** This is a randomized clinical trial. Patients with clinical and radiological hip osteoarthritis, 40-80 years of age, and without indication for hip surgery were randomized into 3 groups. The active intervention groups A and B received six weeks of hip school, taught by a physiotherapist, for a total of 5 sessions. In addition, group B received manual therapy consisting of joint manipulation and soft-tissue therapy twice a week for six weeks. Group C received a self-care information leaflet containing advice on "live as usual" and stretching exercises from the hip school. The primary time point for assessing relative effectiveness is at the end of the six weeks intervention period with follow-ups after three and 12 months.

Primary outcome measure is pain measured on an eleven-point numeric rating scale. Secondary outcome measures are the hip dysfunction and osteoarthritis outcome score, patient's global perceived effect, patient specific functional scale, general quality of life and hip range of motion.

**Discussion:** To our knowledge this is the first randomized clinical trial comparing a patient education program with or without the addition of manual therapy to a minimal intervention for patients with hip osteoarthritis.

**Trial registration:** ClinicalTrials NCT01039337

## Background

Osteoarthritis (OA) of the hip is a major contributor to pain, decreased physical function and decline in health related quality of life (QoL) [1]. In the western world, it is estimated that 5-11% of the adult population are affected by hip OA, with even higher prevalence rates in the senior population [2-4]. Consequently, an increasing

aging population is expected to lead to a steep increase in the number of people affected by hip OA in the coming decades.

Recent international evidence-based guidelines dealing with the management of hip and knee OA recommend a combination of pharmacological and non-pharmacological interventions as first line treatment [5-7]. Initially, patient information and weight reduction are recommended, followed by exercise. If warranted this can be supplemented by pharmacological treatment in the form of paracetamol and/or non-steroid anti-inflammatory

\* Correspondence: e.poulsen@nikkb.dk

<sup>1</sup>Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Denmark

Full list of author information is available at the end of the article

drugs (NSAID). In selected patients, when such non-surgical interventions are no longer sufficiently effective, arthroplasty is considered an appropriate treatment option [5].

There is evidence from several trials that exercise therapy is effective [8,9].

Patient education programs have become popular in a range of chronic conditions over the past two decades [10-13]. In the case of OA, authors of a meta-analysis concluded that patients receiving disease specific education in addition to NSAID achieved an added effect of 20% pain reduction when this was compared to NSAID alone [12]. An example of such a disease specific patient information program is the so-called "hip school" which has been shown to be a promising intervention [14]. Fernandes et al have compared the hip school to a group receiving both hip school and supervised exercise therapy and although a small reduction in pain scores was observed within groups at four, 10 or 16 months follow-up, no statistical significant difference was observed between groups at any of the follow-up points [15].

Manual therapy is an umbrella term comprising different manual techniques aimed at decreasing pain and improving function of the musculoskeletal system [16]. Examples include joint manipulation and mobilization, muscular, ligament and capsular stretching and trigger point therapy. Historically, practitioners of manual medicine, chiropractic, physiotherapy and osteopathy have been treating patients with musculoskeletal complaints resulting from OA using these techniques [16-19]. Recently, results from a randomized clinical trial (RCT) showed that patients receiving such manual therapy compared to exercise resulted in more pain reduction, improvement in activities of daily living and general health status after a series of treatments and at 6 months follow-up [20]. There is currently an increased interest in further evaluating the effectiveness of patient education, exercise and manual therapy in this group of patients but few results are available at this time [21-23].

The primary objective of this proof-of-concept study is to assess the effectiveness of hip school with or without the addition of manual therapy in terms of pain severity reduction when compared to a minimal intervention. Second, we will explore if adding manual therapy to the hip school is associated with added benefit.

## Methods

### Study design

Randomized clinical trial

### Participants and recruitment procedure

Patients from primary care with a clinical and radiological diagnosis of hip OA, or with a working diagnosis of clinical hip OA (defined as pain in the groin, buttock or

proximal thigh area and restriction on passive hip range of motion) could be referred to the study. General medical practitioners (GPs) and practicing chiropractors from the island of Funen, Denmark were invited to an information meeting about the project followed by an information letter. Subsequently, the principal investigator (EP) personally paid most GP practices on the island a visit, and information about the project was made available on a closed web site for health care professionals by the Region of Southern Denmark. Referrals of eligible patients were made to the Department of Orthopedic Surgery and Traumatology, Odense University Hospital, Denmark either in a written form or by telephone. The referring clinician had the opportunity to hand out a short information leaflet about the study. Eligible patients were then contacted by phone by the principal investigator and asked about symptom location, mode of onset, duration, pain severity, improving and worsening factors, medication use and questions related to the exclusion criteria. If inclusion criteria and none of the exclusion criteria were met, an appointment was made for a clinical examination at the Department of Orthopedic Surgery and Traumatology and a radiographic examination at one of two chiropractic clinics. The radiographic examination included an AP pelvic series and a false profile of the involved hip.

Inclusion and exclusion criteria are listed in table 1.

At the first consultation at the hospital, participants were given time for questions and would sign the informed consent form. An appointment was then scheduled for completion of the baseline self-reported outcome measures and randomization.

Figure 1 (study flow chart) illustrates the flow of participants through the study.

### Setting

Initial examination, randomization, manual therapy, and follow-up examinations took place at the outpatient clinic at the Department of Orthopedic Surgery and Traumatology, Odense University Hospital, Denmark. The hip school was taught at the Rehabilitation Unit, Odense University Hospital, Denmark.

Radiographs were taken at one of two pre-selected chiropractic clinics in the town of Odense, Denmark. Clinicians were specially trained for the purpose of this project.

### Randomization

Block randomization was performed using a computer generated list containing a sequence of the letters A - referring to the hip school, B - referring to hip school and manual therapy and C - referring to the minimal information intervention. Block sizes vary with three, six or nine letters. Each letter was written on a piece of paper which was folded and placed in a sealed opaque

**Table 1 Criteria for inclusion and exclusion**

Inclusion criteria	Exclusion criteria
- 40-80 years of age	- Other conditions than hip OA appearing to be the cause of the patient's symptoms
- Unilateral hip pain > 3 months	- Bilateral hip pain
- Radiographic measurement of joint space width < 2.00 mm or side difference > 10%	- Indication for hip joint replacement surgery within the next 6 months
- Able to speak and read Danish	- Previous hip or knee joint replacement surgery
	- Hip OA due to hip fracture or infection
	- Rating of worst hip pain during the last week as ≤ 2 on 11-box rating scale
	- Hip dysplasia, Center Edge angle < 25 and Acetabular index Angle > 10
	- Local knee pain originating from the knee on the same side as the hip OA
	- Low back pain dominating over the hip symptoms
	- Inflammatory joint disease
	- Cerebrovascular disease
	- Polyneuropathy or neuromuscular disease
	- Malignant disease
	- Refusal to participate

envelope. The list was generated by a person not involved in the study who is unaware of any information pertaining to the participants. For practical purposes randomization was performed every 8-10 weeks when it was anticipated a sufficient number of patients were

referred from primary care to create the two groups involving hip school. The number of envelopes matched the number of patients ready for the randomization and followed the sequential numbers on the generated list. The patient opened the envelope in front of a project nurse who then made an appointment corresponding to the relevant group. The project nurse is not involved in assessment of the patients.

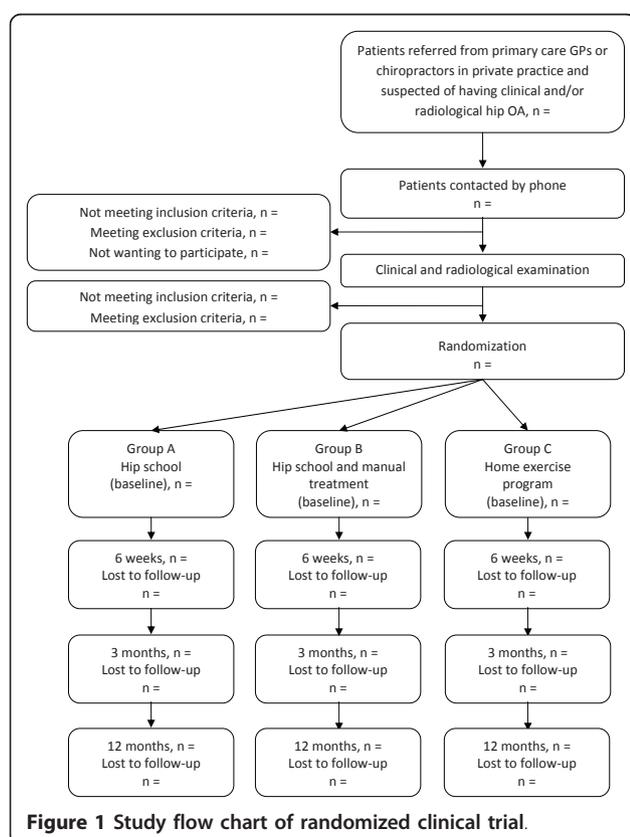
### Interventions

#### Group A: Hip school

The hip school is designed to educate the participants about hip OA. The school was taught over 5 sessions during the 6 weeks intervention period and consisted of one initial personal interview, three group sessions and one follow-up personal session. A specially trained physiotherapist was responsible for teaching the hip school. The content is well described and includes information about epidemiology of hip OA, anatomy of the hip joint and adjacent functional structures, pain distribution and diagnosis of hip OA, recommended activity levels, natural course of the disease, and finally information about treatment options [14]. Stretching exercises for the hip are taught and instructions are given on how to incorporate these into a daily routine. Teaching aids in the form of power point presentations and anatomic models are used. In this study, the original illustrations, with the text translated into Danish (with permission M. Klässbo 03.08.2008), were used.

#### Group B: Hip school and manual therapy

In addition to hip school the patients received manual therapy. The protocol for manual therapy includes a



combination of manual soft tissue therapy, stretching and joint manipulation. The soft tissue therapy is trigger point pressure release as described by Travell and Simons [24]. The soft tissue stretching is based on muscle energy techniques as described by Chaitow [25]. The joint manipulation is one of high velocity low amplitude as described by Bergmann, Peterson and Lawrence [26]. The purpose of the manual therapy is to improve elasticity of the muscular, ligamentous and capsular tissue of the hip and posterior joints of the pelvis. Combination of treatment modalities was individualized to each patient according to examination findings at the discretion of the treating clinician. Treatment sessions lasted 15-20 minutes each and treatment was administered twice a week during the six weeks intervention period. The principle investigator EP was the treating clinician in the manual therapy group.

#### **Group C: Minimal intervention**

A leaflet describing the stretching exercises from the hip school was used as a minimal intervention control. The patients received a short 5 minutes instruction in self-care immediately after randomization by the project nurse and were subsequently handed the exercise leaflet and instructed to incorporate the exercises into their daily routines. Patients were further instructed to live as usual, not to make any changes to use of possible pain medication or initiate other treatment during the following 6 weeks.

The project nurse was making appointments for the participants in group A and B to attend the hip school and for group B the additional manual therapy.

#### **Period of intervention**

Group A and B receiving hip school with or without the addition of manual therapy completed their intervention within a 6 weeks period. All three groups received instructions in a daily stretching program from the hip school and were expected to continue the program after the end of the intervention period.

#### **Outcome measures**

A range of self-reported and clinical outcome measures has been chosen. These include:

##### **Primary outcome measure**

The CONSORT statement for reporting of randomized trials recommends the use of one primary outcome due to risk of multiplicity of analysis followed by bias in interpretation [27]. The majority of patients in the Hoeksma et al trial rated their main complaint as pain (62% with a mean score of 55.2/100 on a visual analogue scale, standard deviation 22.0) [20]. Therefore we chose pain as the primary outcome.

**Pain rated on a 0-10 numerical rating scale (NRS)** In hip OA research, OMERACT- OARSI (Outcome

Measures in Rheumatology - Osteoarthritis Research Society International) has identified pain as one of three important outcome measure domains [28]. We measure pain using an eleven-point box scale. Patients are asked to rate their "worst" experienced pain during the last week. The eleven-point box scale is a reliable, valid and responsive tool and has been shown to be superior to a visual analogue scale when used in seniors [29].

##### **Secondary outcome measures**

**The Hip disability and Osteoarthritis Outcome Score (HOOS)** HOOS is a self-reported patient-relevant outcome measure which includes 5 subscales 1) pain 2) other symptoms 3) function in daily living (ADL) 4) function in sport and recreation and 5) hip related QoL [30]. A 5-point Likert-scale is used and converted into a 100-point scale with zero indicating the worst possible health. The questionnaire and a user's guide, including scoring instructions, are available from <http://www.koos.nu>.

**Global assessment of the effect of interventions** The assessment by the patient of a global perceived effect of the treatment is another of the three responder criteria recommended by OMERACT-OARSI [28]. A 7-point Likert-scale is used with the "no change" being the neutral response.

**Patient Specific Functional Scale (PSFS)** It has been argued that current standardized outcome scores in OA research have the possibility of missing important patient specific disabilities [31]. The PSFS is designed so patients chose up to three activities specifically important to him or her and influenced by their specific condition [32]. An 11-point numerical rating scale is used ranging from "having no problems at all" performing the activity to "is not able to perform the activity".

**General health status** EuroQoL (EQ-5D) is a self-reported generic general health questionnaire. It includes the following 5 dimensions; mobility, self care, normal activities, pain/discomfort and anxiety/depression and uses a 3-point Likert scale for each dimension [33,34]. It is in this study included for purposes of health economic evaluation and comparison to other hip OA populations.

**Hip mobility** Correlation has been shown between the amount of radiological defined hip OA and the amount of decline in passive hip range of movement (ROM) [35-37]. Passive hip ROM is defined as the range of movement measured in degrees that an observer is able to move a joint through its full range with no active participation from the patient [26]. Since one of the few studies on the effect of manual therapy has documented a considerable change in ROM following manual therapy, ROM is measured using a standard hand held goniometer [20]. Goniometric measurements of the hip have been examined extensively for reliability in all six ranges

of motion and are considered very good (ICC between 0.82 and 0.94 or Pearson correlation coefficients between 0.91 and 0.94) [36,38]. In this study, ROM in extension is not measured for practical reasons, since it requires an assistant to place the goniometer when the patient is lying prone.

**Use of pain medication** The use of pain medication is recommended as an outcome measure in the most recent evidence-based guidelines for management of hip and knee OA [6]. The patients are asked about type, dosage and frequency.

**Hip surgery within the follow-up period** Hip surgery within a 12 month follow-up period will be obtained through self-report from the patients. It will be analyzed whether the number of hip surgeries at 12 months follow-up, and the time of surgery, is statistically significantly different between the groups. Hip surgery is defined as total hip arthroplasty.

#### **Adverse events**

Little is known about reactions or adverse events following manual therapy for the extremities or from performing a standardized stretching exercise program. We decided to record occurrence of any reaction or event in the three groups categorized as follows 1) is the reaction related around the hip? 2) mild, moderate or severe 3) when did it start? 4) how long did it last? 5) did it affect activities of daily living? At the end of the 6 week intervention period, a standardized questionnaire was used for each group to record adverse events or reactions to either the hip school, manual therapy or the minimal intervention. The physiotherapist teaching the hip school asked the patient at the last session and completed the questionnaire for participants in group A, the principal investigator administering the manual therapy asked and completed the questionnaire for participants in group B at their last treatment session. A research secretary contacted group C by phone to ask about adverse reaction and completed the questionnaire for them.

#### **Follow-up**

Assessment of the patients is performed at baseline, 6 weeks (after intervention period), 3 and 12 months. The assessments are in the form of self-reported patient questionnaires and a physical examination identical to the baseline examination at all time points. The clinical measurements of the physical examination are performed by the same assessor throughout the study. This assessor is a physical therapist. She is blind to the group allocation of the patients at the time of assessment and is not involved in other parts of the study.

The short term follow-up directly after the 6-weeks intervention is chosen to examine any immediate effect

following the manual treatment and the hip school as a maximal effect is anticipated to occur around this time. Any effect due to the high level of interaction with the physiotherapist or chiropractor would further be expected immediately following the intervention period. Three month follow-up is to examine any lasting effect from manual therapy and hip school. Hoeksma et al were able to demonstrate a significant change in pain, hip function and hip range of motion between groups after six months following manual therapy [20]. All three groups are expected to comply with the exercise regimes from the hip school but it is anticipated that the minimal intervention group might not comply at the same level as the other two groups due to lack of continuous positive reinforcement during the intervention period. Twelve months follow-up is important for examining any long term effect. Hip arthroplasty is the ultimate end stage intervention for sufferers of hip OA and it is currently not known if any interventions, pharmacological or non-pharmacological are able to postpone or prevent total hip arthroplasty.

#### **Blinding**

Blinding to treatment allocation (patients, physiotherapist, chiropractor and project nurse involved in the interventions) is not possible due to the nature of the interventions. The assessor analyzing the data (the principle investigator EP) will be blinded as patients are analyzed using recoded identification numbers and group allocation will be unknown when analyzing the data. The recoding will be performed by a person not otherwise involved in the study.

#### **Statistical analyses**

Double data entry will be done by assistants not participating in the study. Baseline characteristics will be described and compared for all 3 groups and between responders and non-responders.

The primary statistical analysis is performed at the end of the 6-week intervention period. This time point was chosen, as we expect the largest treatment effect directly after end of the treatment, and we are interested in a proof-of-principle. The group differences (A vs. C and B vs. C) in pain severity will be analyzed using ANCOVA with adjustment for the baseline values. A significant level of 0.05 will be used. The pre-specified pairwise comparisons between the two active treatments and the self-care control will be analysed using the Dunnett's test and not require the ANCOVA omnibus test to be significant. A post-hoc secondary exploratory analysis of the difference between group A and B will also be performed. The secondary statistical analysis will include the same approach as described above for all the secondary patient rated outcomes. In addition a

longitudinal analysis of the primary and secondary patient rated outcomes, incorporating data from baseline, week six, three months and twelve months, will be conducted using a linear mixed model approach [39]. A multiple imputation model will be used for missing data accounting for data missing at random and data missing due to attrition [40,41]. All analyses will follow the intention to treat principle.

Finally, analysis will include calculating the minimal clinically important difference (MCID) based on the change in the primary outcome measure and the patients' global assessment of the overall treatment effect using receiver operating curve (ROC) statistics. Patients' global assessment will be categorized into 1) better 2) no change and 3) worse. The MCID will then be used to estimate how many patients in each group have reached a clinically relevant improvement. Numbers needed to treat (NNT) and odds ratio (OR) for a positive effect of treatment in each group will be presented. All statistical analyses are blinded and will be performed using Stata 10 software (StataCorp, Texas, USA).

#### Sample size

For this proof of concept trial, when comparing both A vs. C and B vs. C, we aim to be able to have 80% power (alpha at 0.05) to demonstrate a statistically significant difference of at least 17 percentage points in pain severity at the end of treatment (corresponding to a large effect size of 0.8). Using variability estimates for pain severity from the Hoeksma et al. and other relevant hip osteoarthritis trials as the basis for the sample size calculation, 30 participants in each treatment group are needed, assuming a joint normal distribution for baseline and 6-weeks follow-up with a correlation of 0.3 and equal variances. Allowing for a drop-out of 15% per group, we decided to recruit 106 participants.

#### Time line

Inclusion of participants to the main study took place from February 2009 until June 2010. Six weeks and 3 months follow-up have been concluded on all patients. The last group of patients will conclude their 12 months follow-up in June 2011.

#### Ethics

Prior to the first hospital appointment, eligible patients received an information package about the study. The package included a thorough explanation of the study, rights when participating in a research project, a copy of the written informed consent form, and directions.

Ethics approval has been granted by the Regional Ethics Committee of Southern Denmark, approval number S-20080027 and the study is registered and approved by the Danish Data Protection Agency, J.nr.

2008-41-1910. The study is registered with clinicaltrials.gov ID NCT01039337 and results will be registered with the same trial register in due time.

#### Discussion

To our knowledge this is the first randomized clinical trial comparing the effect of a patient specific education program and manual therapy to a minimal intervention consisting of a simple home stretching exercise regimen in patients diagnosed with unilateral hip OA.

Such a trial is warranted because the vast majority of trials in hip OA until now have been dealing with surgery (73%) or pharmacological interventions (20%) in spite of the fact that recent guidelines for the management of this condition recommend a combination of non-pharmacological and pharmacological interventions as first line treatment [4-7].

The relevance of this research is further based on the continuous increase in the number of patients suffering from OA which is anticipated during the coming decades when both life expectancy and the elder population will rise accordingly [42]. With exploding health care costs and maybe even increased mortality for this patient population the evaluation of simple interventions with proven beneficial effect on functional disability, pain and quality of life should be high on the agenda both from an individual and societal perspective [43,44].

The results so far of the effect of hip school or manual therapy have been based on only a few RCTs [15,20,45] or uncontrolled pre-post comparisons [46,47], and with respect to the direct comparison of manual therapy versus hip school no studies have been performed until now. Our long term interest is in the effect of manual therapy in addition to hip school versus hip school alone, so we included these two groups in our trial. However, for several reasons it is uncertain how well these two therapies will work in our setting: First, the results published so far may reflect publication bias. Second, none of the studies have been performed in Denmark. The hip school does not yet have a tradition in Denmark and manual therapy for hip OA is, to our knowledge, not a common line of intervention. Third, our measurement instruments for success are not identical to those used in the previous studies. Hence we decided to start with a small study assessing the efficacy of the two active treatments. Deciding on a primary outcome in OA research is challenging as it is common for OA patients to rate different domains of the disease experience, e.g. pain and/or reduction in activities of daily living, as their primary complaint. We have decided on pain as the primary outcome which is measured on an eleven-point NRS. At initial contact patients are phoned and asked about possible criteria for exclusion and to avoid a large floor effect on the primary

outcome patients are excluded if their pain experience is rated as two or less on the eleven-point NRS.

Strictly speaking the intervention period applies only for the manual therapy and the hip school groups. For the minimal intervention group it is arbitrary because they only receive a one time, five to ten minutes instruction on the exercise program. The purpose of the hip school is to teach the patients an understanding of their condition, to cope with it as well as improve and adapt activities of daily living. This learned effect is of course expected to continue after the intervention period. Any effect of the stretching exercises is expected in all three groups and will not favor any one group over another.

For practical purposes all three groups have a follow-up immediately after the hip school and manual therapy interventions and are then followed at 3 and 12 months to detect changes between groups over time. This does however not reflect common practice as patients with chronic conditions often are followed and treated over months and even years with varying time between consultations depending on symptom severity and flare-ups. Specifically regarding the hip school follow-up sessions would likely encourage modifications of activities of daily living as well as adjustments of exercise regimes. Specifically regarding the manual therapy, it is not uncommon to schedule future consultations for evaluation and treatment if this is perceived beneficial by the chiropractor/therapist and the patient in order to maintain the obtained progress. This practice of follow-up visits is also performed with exercise regimes and patient education programs for reinforcement of confidence and positive behavior as well as adjustments and progression of exercises.

The reasons for inclusion of a control intervention are threefold. First, home programs delivered in the form of a leaflet are often given to this patient group at the time of first diagnosis and our group C thus reflects common practice in many settings. Second, including a control group or minimal intervention group is common in clinical trials that examine the effectiveness of non-pharmacological interventions particularly when long-term follow-up is performed in order to investigate efficiency and cost-effectiveness [48-51]. Third, the effect of a hip school has not previously been compared to a minimal non-pharmacological intervention. It is however possible that patients ending up in the minimal intervention group will feel they are missing out on "treatment" and on their own seek care similar to the hip school or the manual therapy. In order to prevent this, patients in all three groups are encouraged NOT to seek other interventions from baseline to the three months follow-up. This information is provided both in the written material and it is repeated orally at the baseline clinical examination, at randomization and at the 6 weeks

clinical examination. Furthermore, patients will be asked specifically at all follow-up points if they have initiated other treatments for their hip condition since the last examination and follow-up.

Any added effect in the group receiving hip school with or without the addition of manual therapy in comparison to the minimal control intervention is of course not necessarily directly linked to the physical component of the interventions. Empathy, social and psychological interactions are important factors in any clinician/therapist patient relationship but the ratio of each to the effect of the physical components is not known. Any measured effect regarding increase in the secondary outcome hip range of motion is however less likely to be influenced by any verbal or empathic contact between patient and clinician/therapist.

The internal validity of the trial is influenced by a positive performance bias by patients participating in the groups receiving hip school with or without the addition of manual therapy whereas patients ending up in the minimal intervention group may experience negative performance bias and feel neglected and not subjected to a "real" treatment. Finally, the list of exclusion criteria may limit the external validity and generalizability, for example, the results may not be directly transferable to patients with hip OA who have a variety of comorbidities or have hip OA due to moderate or severe hip dysplasia.

Blinding of participants and the providers of the three interventions is another potential problem that may influence the results of the trial. The results from the groups are likely to be influenced by the complex interactions between participants and providers. This includes the verbal communication, physical interaction and empathy between participant and provider. Blinding of the assessor is however possible and this will be done by coding the ID numbers of the participants by a person not involved in the study.

We have designed a study with the main purpose of comparing a patient education program with or without the addition of manual therapy to a minimal intervention in patients with hip OA. The results of this proof of principle study will further inform the design of future RCTs involving non-pharmacological interventions and potentially also the management of patients with early unilateral hip OA.

The results of the study will be submitted to a peer-reviewed journal for publication irrespective of the outcome in accordance with the CONSORT guidelines for reporting of clinical trials [52].

#### Acknowledgements

The protocol for the hip school is developed by Maria Klässbo and was translated into Danish with assistance from Morten Thorup, Hanne Rönn and

Mats Johansson. We would like to acknowledge Gert Bronfort for advice on the sample size and statistical analysis sections and the manuscript in general.

The study is funded by the Danish Foundation for Chiropractic Research and Postgraduate Education, The Danish Rheumatism Association, The Region of Southern Denmark, University of Southern Denmark, Odense University Hospital and Nordic Institute of Chiropractic and Clinical Biomechanics.

#### Author details

<sup>1</sup>Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Denmark. <sup>2</sup>Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark. <sup>3</sup>Institute of Medical Biometry and Medical Informatics, University of Freiburg, Germany. <sup>4</sup>Institute of Clinical Research, University of Southern Denmark, Denmark. <sup>5</sup>Department of Orthopedic Surgery and Traumatology, Odense University Hospital, Denmark.

#### Authors' contributions

All authors participated in the design of the study. EP developed the manual treatment protocol, is serving as project manager for the trial and responsible for drafting this paper. JH revised the first draft and JH, HWC, WV, ER and SO commented and revised subsequent drafts. All authors have read and approved the final manuscript.

#### Competing interests

The authors declare that they have no competing interests.

Received: 9 March 2011 Accepted: 4 May 2011 Published: 4 May 2011

#### References

- Salaffi F, Carotti M, Stancati A, Grassi W: Health-related quality of life in older adults with symptomatic hip and knee osteoarthritis: a comparison with matched healthy controls. *Aging Clin Exp Res* 2005, **17**:255-263.
- Ingvarsson T, Hagglund G, Lohmander LS: Prevalence of hip osteoarthritis in Iceland. *Ann Rheum Dis* 1999, **58**:201-207.
- Jacobsen S, Sonne-Holm S, Soballe K, Gebuhr P, Lund B: Radiographic case definitions and prevalence of osteoarthritis of the hip: a survey of 4 151 subjects in the Osteoarthritis Substudy of the Copenhagen City Heart Study. *Acta Orthop Scand* 2004, **75**:713-720.
- Zhang W, Doherty M, Arden N, Bannwarth B, Bijlsma J, Gunther KP, et al: EULAR evidence based recommendations for the management of hip osteoarthritis: report of a task force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCIIT). *Ann Rheum Dis* 2005, **64**:669-681.
- National Collaborating Centre for Chronic Conditions: Osteoarthritis: national clinical guidelines for care and management in adults. London, Royal College of Physicians; 2008. Ref Type: Report.
- Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, et al: OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage* 2008, **16**:137-162.
- Guideline for the non-surgical management of hip and knee osteoarthritis: The Royal Australian College of General Practitioners. 2011. Ref Type: Online Source.
- Pisters MF, Veenhof C, van Meeteren NL, Ostelo RW, de Bakker DH, Schellevis FG, et al: Long-term effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: a systematic review. *Arthritis Rheum* 2007, **57**:1245-1253.
- Fransen M, McConnell S, Hernandez-Molina G, Reichenbach S: Does land-based exercise reduce pain and disability associated with hip osteoarthritis? A meta-analysis of randomized controlled trials. *Osteoarthritis Cartilage* 2010, **18**:613-620.
- Deakin TA, Cade JE, Williams R, Greenwood DC: Structured patient education: the diabetes X-PERT Programme makes a difference. *Diabet Med* 2006, **23**:944-954.
- Effing T, Monninkhof EM, van der Valk PD, van der Palen J, van Herwaarden CL, Partidge MR, et al: Self-management education for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2007, CD002990.
- Superio-Cabuslay E, Ward MM, Lorig KR: Patient education interventions in osteoarthritis and rheumatoid arthritis: a meta-analytic comparison with nonsteroidal antiinflammatory drug treatment. *Arthritis Care Res* 1996, **9**:292-301.
- Coleman S, Briffa K, Conroy H, Prince R, Carroll G, McQuade J: Short and medium-term effects of an education self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals: a quality assurance study. *BMC Musculoskelet Disord* 2008, **9**:117.
- Klassbo M, Larsson G, Harms-Ringdahl K: Promising outcome of a hip school for patients with hip dysfunction. *Arthritis Rheum* 2003, **49**:321-327.
- Fernandes L, Storheim K, Sandvik L, Nordsletten L, Risberg MA: Efficacy of patient education and supervised exercise vs patient education alone in patients with hip osteoarthritis: a single blind randomized clinical trial. *Osteoarthritis Cartilage* 2010, **18**:1237-1243.
- Peterson DH, Bergmann TF: *Chiropractic Technique: Principles and Procedures*. 2 edition. St. Louis, Missouri: Mosby, Inc; 2002.
- Mennell JM: *Joint Pain: Diagnosis and Treatment using Manipulative Techniques* Boston: Little Brown; 1964.
- Cyriax J: *Textbook of Orthopaedic Medicine: Treatment by Manipulation, Massage and Injection* v.2. 11 edition. Bailliere Tindall; 1984.
- Stoddard A: *Manual of osteopathic practice* New York: Harper & Row, Publishers, Inc; 1969.
- Hoeksma HL, Dekker J, Ronday HK, Heering A, van der LN, Vel C, et al: Comparison of manual therapy and exercise therapy in osteoarthritis of the hip: a randomized clinical trial. *Arthritis Rheum* 2004, **51**:722-729.
- French HP, Cusack T, Brennan A, White B, Gilsenan C, Fitzpatrick M, et al: Exercise and manual physiotherapy arthritis research trial (EMPART): a multicentre randomised controlled trial. *BMC Musculoskelet Disord* 2009, **10**:9.
- Abbott JH, Robertson MC, McKenzie JE, Baxter GD, Theis JC, Campbell AJ: Exercise therapy, manual therapy, or both, for osteoarthritis of the hip or knee: a factorial randomised controlled trial protocol. *Trials* 2009, **10**:11.
- Osborne RH, Buchbinder R, Ackerman IN: Can a disease-specific education program augment self-management skills and improve Health-Related Quality of Life in people with hip or knee osteoarthritis? *BMC Musculoskelet Disord* 2006, **7**:90.
- Simons DG, Travell JG, Simons LS: General Overview. In *Myofascial Pain and Dysfunction, The Trigger Point Manual, Upper Half of Body. Volume 1*. second edition. Williams & Wilkins; 1999:11-93.
- Chaitow L: MET and the treatment of joints. *Muscle Energy Technique*. 2 edition. Edinburgh: Churchill Livingstone; 2001, 159-195.
- Bergmann TF, Peterson DH, Lawrence DJ: *Extraspinal Techniques. Chiropractic Technique* New York: Churchill Livingstone Inc; 1993, 523-722.
- Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, et al: The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001, **134**:663-694.
- Bellamy N, Kirwan J, Boers M, Brooks P, Strand V, Tugwell P, et al: Recommendations for a core set of outcome measures for future phase III clinical trials in knee, hip, and hand osteoarthritis. Consensus development at OMERACT III. *J Rheumatol* 1997, **24**:799-802.
- Bergh I, Sjostrom B, Oden A, Steen B: An application of pain rating scales in geriatric patients. *Aging (Milano)* 2000, **12**:380-387.
- Nilsdotter AK, Lohmander LS, Klassbo M, Roos EM: Hip disability and osteoarthritis outcome score (HOOS)-validity and responsiveness in total hip replacement. *BMC Musculoskelet Disord* 2003, **4**:10.
- Wright JG: Evaluating the outcome of treatment. Shouldn't We be asking patients if they are better? *J Clin Epidemiol* 2000, **53**:549-553.
- Chatman AB, Hyams SP, Neel JM, Binkley JM, Stratford PW, Schomburg A, et al: The Patient-Specific Functional Scale: measurement properties in patients with knee dysfunction. *Phys Ther* 1997, **77**:820-829.
- Brazier J, Deverill M, Green C: A review of the use of health status measures in economic evaluation. *J Health Serv Res Policy* 1999, **4**:174-184.
- EuroQol-a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health Policy* 1990, **16**:199-208.
- Fox KM, Hochberg MC, Resnik CS, Kenzora JE, Hebel JR, Zimmerman SI, et al: Severity of radiographic findings in hip osteoarthritis associated with total hip arthroplasty. *J Rheumatol* 1996, **23**:693-697.
- Arokoski MH, Haara M, Helminen HJ, Arokoski JP: Physical function in men with and without hip osteoarthritis. *Arch Phys Med Rehabil* 2004, **85**:574-581.

37. Bierma-Zeinstra SM, Oster JD, Bernsen RM, Verhaar JA, Ginai AZ, Bohnen AM: **Joint space narrowing and relationship with symptoms and signs in adults consulting for hip pain in primary care.** *J Rheumatol* 2002, **29**:1713-1718.
38. Holm I, Bolstad B, Lutken T, Ervik A, Rokkum M, Steen H: **Reliability of goniometric measurements and visual estimates of hip ROM in patients with osteoarthritis.** *Physiother Res Int* 2000, **5**:241-248.
39. Littell RC, Pendergast J, Natarajan R: **Modelling covariance structure in the analysis of repeated measures data.** *Stat Med* 2000, **19**:1793-1819.
40. Little RJA, Rubin DB: *Statistical Analysis with Missing Data*. 2 edition. Hoboken, New Jersey: Wiley-Blackwell; 2002.
41. Rubin DB: **Inference and missing data.** *Biometrika* 1979, **63**:581-592.
42. Elders MJ: **The increasing impact of arthritis on public health.** *J Rheumatol Suppl* 2000, **60**:6-8.
43. Vaupel JW, Carey JR, Christensen K, Johnson TE, Yashin AI, Holm NV, *et al*: **Biodemographic trajectories of longevity.** *Science* 1998, **280**:855-860.
44. Weiner DK: **Improving pain management for older adults: an urgent agenda for the educator, investigator, and practitioner.** *Pain* 2002, **97**:1-4.
45. Vaarbakken K, Ljunggren AE: **Superior effect of forceful compared with standard traction mobilizations in hip disability?** *Adv Physiother* 2007, **9**:117-128.
46. Brantingham JW, Globe GA, Cassa TK, Globe D, de LK, Pollard H, *et al*: **A single-group pretest posttest design using full kinetic chain manipulative therapy with rehabilitation in the treatment of 18 patients with hip osteoarthritis.** *J Manipulative Physiol Ther* 2010, **33**:445-457.
47. de LK, Pollard H, Brantingham J, Globe G, Cassa T: **Chiropractic management of the kinetic chain for the treatment of hip osteoarthritis: an Australian case series.** *J Manipulative Physiol Ther* 2010, **33**:474-479.
48. Cherkin DC, Deyo RA, Battie M, Street J, Barlow W: **A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain.** *N Engl J Med* 1998, **339**:1021-1029.
49. Hondras MA, Long CR, Cao Y, Rowell RM, Meeker WC: **A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain.** *J Manipulative Physiol Ther* 2009, **32**:330-343.
50. Karjalainen K, Malmivaara A, Pohjolainen T, Hurri H, Mutanen P, Rissanen P, *et al*: **Mini-intervention for subacute low back pain: a randomized controlled trial.** *Spine (Phila Pa 1976)* 2003, **28**:533-540.
51. Paatelma M, Kilpikoski S, Simonen R, Heinonen A, Alen M, Videman T: **Orthopaedic manual therapy, McKenzie method or advice only for low back pain in working adults: a randomized controlled trial with one year follow-up.** *J Rehabil Med* 2008, **40**:858-863.
52. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P: **Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration.** *Ann Intern Med* 2008, **148**:295-309.

#### Pre-publication history

The pre-publication history for this paper can be accessed here:  
<http://www.biomedcentral.com/1471-2474/12/88/prepub>

doi:10.1186/1471-2474-12-88

**Cite this article as:** Poulsen *et al*: Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: Protocol for a three-armed randomized clinical trial. *BMC Musculoskeletal Disorders* 2011 **12**:88.

**Submit your next manuscript to BioMed Central  
and take full advantage of:**

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at  
[www.biomedcentral.com/submit](http://www.biomedcentral.com/submit)



# PREVALENCE OF HIP OSTEOARTHRITIS IN CHIROPRACTIC PRACTICE IN DENMARK: A DESCRIPTIVE CROSS-SECTIONAL AND PROSPECTIVE STUDY

Erik Poulsen, DC, MSc,<sup>a,b</sup> Henrik W. Christensen, DC, MD, PhD,<sup>c</sup> Søren Overgaard, MD, DMSc,<sup>d,e</sup> and Jan Hartvigsen, DC, PhD<sup>f,g</sup>

## ABSTRACT

**Objective:** The purposes of this study were to measure the prevalence of clinical and radiographic hip osteoarthritis (OA) and first-time diagnosis of hip OA in consecutive patients presenting to chiropractic practices in Denmark and to report the components of the initial treatment rendered by the chiropractic practitioner.

**Methods:** A total of 2000 patient records and 1000 radiographs were reviewed retrospectively in 20 chiropractic clinics throughout Denmark. Information obtained included patients' primary complaint, physical examination and radiographic findings of hip OA, and treatment. Subsequently, the 20 clinics participated in a prospective survey where they collected equivalent information over a 2-week period.

**Results:** Retrospective review of records revealed that 1.4% of patients in Danish chiropractic practice had signs of clinical hip OA. Of these, 59% demonstrated radiographic signs of hip OA. Prospective data collection revealed that 3.4% of new patients had signs of clinical hip OA. Fifty-four percent of these demonstrated radiographic signs of hip OA, and of these 70% were diagnosed as having OA of the hip for the first time. Initial treatment involved manual treatment and advice on over-the-counter pain medication and/or supplements. Of all 1000 retrospectively reviewed radiographs in patients 40 years or older, 19.2% demonstrated radiographic signs of hip OA.

**Conclusion:** Osteoarthritis of the hip is diagnosed and managed in primary care chiropractic practice in Denmark; however, it is likely underdiagnosed. In those newly presenting to chiropractic practitioners, first-time diagnosis with clinical and radiographic signs of hip OA appears to be common. (*J Manipulative Physiol Ther* 2012;35:263-271)

**Key Indexing Terms:** *Osteoarthritis; Hip; Chiropractic; Diagnosis; Prevalence*

<sup>a</sup> PhD Fellow, Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark.

<sup>b</sup> Researcher, Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark.

<sup>c</sup> Research Director, Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark.

<sup>d</sup> Professor, Department of Orthopedic Surgery and Traumatology, Odense University Hospital, Odense, Denmark.

<sup>e</sup> Professor, Institute of Clinical Research, University of Southern Denmark, Odense, Denmark.

<sup>f</sup> Professor, Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark.

<sup>g</sup> Senior Researcher, Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark.

Submit requests for reprints to: Erik Poulsen, DC, MSc, NIKKB, Forskerparken 10A, 5230 Odense M, Denmark (e-mail: [e.poulsen@nikkb.dk](mailto:e.poulsen@nikkb.dk)).

Paper submitted July 6, 2011; in revised form October 19, 2011; accepted October 27, 2011.

0161-4754/\$36.00

Copyright © 2012 by National University of Health Sciences. doi:10.1016/j.jmpt.2012.01.010

Repeated studies have shown that most patients consult a chiropractic practitioner for problems related to the musculoskeletal system and, particularly, the spine.<sup>1-6</sup> However, in 3% to 12% of complaints relating to the extremities, neither the exact anatomical distribution of these problems nor the extremity-specific conditions have been described in detail. This is unfortunate because chiropractic and manual treatments are recommended for a range of extremity conditions,<sup>7</sup> and diagnosis and management of such conditions are part of the curriculum in most chiropractic teaching institutions.<sup>8</sup>

Osteoarthritis (OA) of the hip is a common musculoskeletal problem causing impaired daily function and loss of quality of life.<sup>9</sup> In Denmark, the prevalence is estimated to be 5% to 6% in people 60 years or older.<sup>10</sup> The authors of current international guidelines for the management of hip and knee OA recommend a combination of non-pharmacologic and pharmacologic treatment, and surgery is reserved for end-stage disease with severe pain and/or

functional disability.<sup>11-13</sup> Manual treatment is mentioned as a possible adjunct to these therapies, but research into the effectiveness and cost-effectiveness is needed.<sup>12,13</sup> Recently, a randomized clinical trial by Hoeksma et al<sup>14</sup> comparing manual therapy to exercise therapy in patients with hip OA showed that manual therapy was superior to exercise therapy in terms of improvement in patient-perceived assessment of treatment, pain reduction, walking speed, and range of hip joint motion. Manual therapy included passive stretching and joint traction manipulation, and exercise therapy included joint mobility exercises, muscular strengthening exercises, and walking exercises. This trial has generated an interest both inside and outside the chiropractic profession for initiating randomized clinical trials involving manual treatment for this patient group.<sup>15-19</sup> However, so far, diagnosis and management of patients with hip OA in chiropractic practice are documented only through case reports, case series, and pilot studies,<sup>17,20,21</sup> although textbooks describe specific manual chiropractic treatment methods for the hip joint.<sup>22,23</sup> Furthermore, it is not known just how common hip OA is in chiropractic practice or how often a doctor of chiropractic (DC) is the first health care person to diagnose a patient with hip OA.

Using cross-sectional retrospective and prospective data collection, we, therefore, aimed at determining the following:

- 1) The prevalence of clinical and radiographic hip OA in consecutive patients presenting in chiropractic practice
- 2) The occurrence of first-time diagnosis of hip OA in consecutive patients presenting in chiropractic practice
- 3) The components of the initial treatment rendered by the DC

## MATERIALS AND METHODS

The study was organized into 3 parts:

- (1) A retrospective investigation of clinical and radiographic diagnosis of hip OA in Danish chiropractic clinics based on review of consecutive patient records
- (2) A retrospective investigation of radiographic findings of hip OA in Danish chiropractic clinics based on review of consecutive radiographs
- (3) A prospective investigation of clinical and radiographic diagnosis and initial treatment of hip OA in consecutive patients in Danish chiropractic clinics based on a standardized survey form

A list of all chiropractic clinics in Denmark was obtained from the Danish Chiropractors' Association. The clinics are

listed sequentially by postal codes, which are distributed across the country. Therefore, to get an evenly distribution of participating clinics, every 10th clinic on the list was chosen and contacted based on the postal code. Each clinic was informed about the purpose of the study and asked to participate. In case of consent, a date was scheduled for the primary investigator to visit the clinic for collection of data. If the clinic declined to participate or if the clinic did not have in-house x-ray equipment, the clinic next on the list was contacted. This procedure was followed until a total of 20 clinics were enrolled representing approximately 10% of all chiropractic clinics in Denmark, which we estimated as an appropriate and representative sample.

*Part 1.* At each clinic, 100 consecutive patient records starting from August 31, 2007, and going backward were reviewed for the following items; age, sex, primary complaint, tentative diagnosis after the case history and physical examination in relation to clinical hip OA, findings indicating radiographic hip OA, treated by the DC for clinical hip OA, and referral to other health practitioners due to hip OA. *Hip OA* is defined by having clinical and radiographic signs of hip OA. *Clinical hip OA* is defined by findings from the case history and physical examination. *Radiographic hip OA* is defined by radiographic findings indicating hip OA.<sup>24</sup> The records were reviewed by the first author who had 18 years of clinical experience as a DC and 6 years of specific clinical and research interest in hip OA. If the case history contained the words "hip pain," "groin pain," or "buttock pain" and/or indicated aggravation of hip symptoms on initiation of movement or excessive hip flexion, the record was selected. If the physical examination described signs of limited or painful hip range of motion, the record was selected.

Patients were assigned a clinic and patient number, and thus, all information was anonymized in the subsequent database.

*Part 2.* At the same clinics, 50 sets of consecutive radiographs of patients 40 years or older, which included the hip joints, were reviewed retrospectively from August 31, 2007. Two projections including the hip joints could be included: (1) a standard anterior-posterior pelvis projection or (2) an anterior-posterior lumbopelvic projection commonly used in chiropractic practice.<sup>25</sup> The criteria for defining radiologic hip OA were based on (1) a minimal joint space width (JSW) of 2.00 mm or less,<sup>10</sup> or (2) a JSW difference of more than 1.00 mm when comparing right and left hips, or (3) a minimal JSW of 3.00 mm or less and a minimum of 1 of the 3 findings: subchondral cyst formation, osteophytosis, or acetabular sclerosis.<sup>26</sup> The methods used for measuring JSW are well described and reliable<sup>10</sup> and were performed with a ruler, increments of 1 mm or using digital software if the equipment in the clinic was digitalized.<sup>27</sup> Location for measurements was at the lateral end of the subchondral sclerotic line and at the medial end of the weight-bearing surface of the acetabulum

**Table 1.** Distribution of primary complaint in 2 consecutive patient populations from 20 Danish chiropractic clinics in 2007

Primary complaint	Retrospective			Prospective		
	n	%	95% CI	n	%	95% CI
Low back pain	705	35.1	33.2-37.4	148	38.2	32.9-42.8
Low back with referring leg pain	314	15.5	14.1-17.4	32	8.3	5.7-11.5 <sup>a</sup>
Leg pain	19	1.0	0.6-1.5	5	1.3	0.4-3.0
Neck pain	261	13.0	11.6-14.6	47	12.1	9.1-15.8
Neck with referring arm pain	66	3.3	2.6-4.2	11	2.8	1.4-5.0
Neck pain and headache	59	3.0	2.3-3.8	18	4.7	2.8-7.3
Thoracic/Chest pain	220	11.0	9.7-12.6	48	12.4	9.3-16.1
Thoracic/chest and arm pain	20	1.0	0.6-1.5	4	1.0	0.3-2.6
Extremity problem	102	5.1	4.2-6.2	28	7.2	4.6-10.0
Baby (0-1 y)	124	6.1	5.2-7.3	18	4.7	2.8-7.3
Other	119	6.0	5.0-7.1	28	7.2	4.6-10.0
Total	2009 <sup>b</sup>	100.1		387	99.9	

Populations are 2000 patient records reviewed retrospectively and 387 new patients registered prospectively.

<sup>a</sup> Statistically significant difference between the 2 groups.

<sup>b</sup> A total of 2009 primary complaints from 2000 records.

just before fossa acetabuli. The sampling of 50 radiographs was chosen for convenience.

*Part 3.* Then a prospective study was initiated at the same clinics where the DCs were asked to systematically record information on every new patient presenting to the clinic during a 2-week period in November 2007. Using a standardized form, the clinicians collected information on the following: age, sex, primary complaint, and (1) whether a tentative diagnosis of clinical hip OA was indicated after the case history and the physical examination; (2) whether the initial diagnosis of clinical hip OA was confirmed by radiographs; (3) whether this was a first-time diagnosis of hip OA for the patient; (4) whether the patient received treatment of hip OA at this first visit; (5) information on treatment rendered, that is, manipulation, mobilization, soft tissue therapy in the form of muscle energy technique, trigger point therapy, stretching, or massage; (6) whether advice was given regarding the use of glucosamine/chondroitin-sulfate, fish oil, and ginger, and/or over-the-counter pain medication; and, finally, (7) whether the patient was referred to his/her general practitioner or another health care practitioner for further evaluation or treatment.

### Ethical Considerations

In Denmark, central or regional ethic committees are governed by the Ministry of Health and are independent of universities and other institutions. According to Danish Law and the University of Southern Denmark, this study design is considered exempt.<sup>28</sup>

### Statistics

Data from patient files, radiographs, and questionnaires were all analyzed using Stata 10.0 (StataCorp, College Station, TX). Descriptive data in the form of proportions are

presented with 95% confidence intervals (CIs). Comparison is made between the 2 sets of clinical data referring to primary complaint and hip OA using overlapping CIs.

## RESULTS

The total number of clinics in Denmark at the time of data collection was 221. Thirty-four clinics were initially contacted, of which 7 did not have in-house x-ray equipment, 6 did not want to participate, and 1 was excluded because it did not routinely register primary complaint. No pattern was observed geographically in clinics not having x-ray equipment or not wanting to participate. Using the described sampling procedure, a total of 20 chiropractic clinics evenly distributed throughout the country of Denmark participated in the data collection.

### Part 1. Retrospective Study

A total of 2000 patient records were reviewed by the first author and included 1015 males and 985 females aged 0 to 88 years (mean  $\pm$  SD, 38.9  $\pm$  19.2 years). The distribution of primary complaints is presented in Table 1. In 3 records, 3 separate complaints were listed as primary, and in 2 records, 4 complaints were listed as primary. In 3 records, no primary complaint was indicated, so the total number of primary complaints was 2009 for the 2000 patient records. Based on the case history alone, the DCs rated 72 patients (3.6%) as having possible hip OA. In 21 of these 72 patient records, the DC had recorded clinical examination findings indicating a diagnosis of clinical hip OA. In an additional 6 records, the first author found clinical examination findings indicating clinical hip OA but no case history information indicating clinical hip OA. Hence, a total of 27 patients (1.4%) were rated as having clinical hip OA. Of these, 18 had a radiographic examination of the hips, and in 14, a

**Table 2.** Proportions of clinical and radiographic hip OA in 2 consecutive patient populations from 20 Danish chiropractic clinics in 2007

	Retrospective			Prospective		
	N	%	95% CI	n	%	95% CI
Suspected hip OA from case history alone	72	3.6	2.9-4.3	18	4.7	2.6-6.8
Clinical hip OA from case history and physical examination	27	1.4	0.9-2.0	13	3.4	1.8-5.7
Radiographic hip OA	16	0.8	0.5-1.3	7	1.8	0.7-3.7

Populations are 2000 patient records reviewed retrospectively and 387 new patients registered prospectively.

diagnosis of radiographic hip OA was recorded. Two patients were recorded as having radiographic hip OA, but the records did not indicate clinical hip OA from the case history or physical examination. According to the patient records, 9 patients had been treated in-house for clinical hip OA, 6 had been referred to their general practitioner, 1 had been referred to a physiotherapist for treatment, and 1 had been referred to a massage therapist for treatment in addition to being treated by the DC. For the total of 72 patients reviewed to have possible clinical hip OA based on the case history, 24 were categorized by the DC in the “low back pain” group, 44 in the “low back with referring leg pain” group, 3 in the group “leg pain,” and 1 in the category “extremity problem.”

Proportions of clinical and radiographic hip OA including 95% CI are presented in Table 2, and a flowchart of clinical and radiographic hip OA is presented in Figure 1.

### Part 2. Retrospective Radiographic Findings of Hip OA

A total of 1000 radiographs from the 20 clinics were evaluated. In 3 clinics, digital radiographic equipment was used, including digital viewing facilities, and 17 used conventional radiographic equipment and conventional viewing boxes.

One hundred twenty-four radiographs (12.4%) demonstrated findings of a JSW narrowing of 2.00 mm or less. Forty-three demonstrated a JSW narrowing of 1.00 mm or more (4.3%). In addition, 25 (2.5%) demonstrated a JSW narrowing of 3.00 mm or less and a minimum of subchondral cyst formation, or osteophytosis, or acetabular sclerosis, totalling 192 (19.2%) of all radiographs demonstrating signs of radiographic hip OA. A flowchart of the findings of radiographic hip OA is presented in Figure 2.

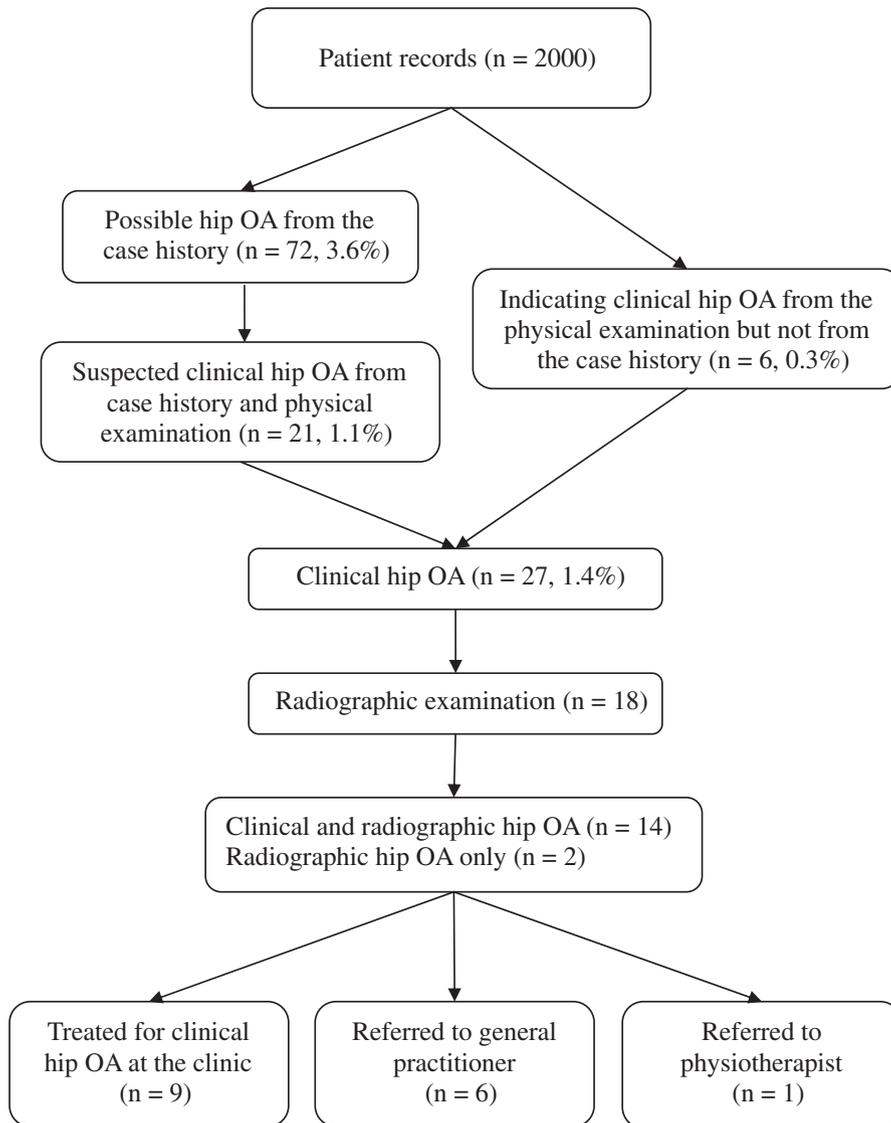
### Part 3. Prospective Study

A total of 387 new patients were registered at the selected 20 clinics during the 2-week period (range, 4-46/clinic) including 201 males and 186 females aged 0 to 93 years (mean ± SD, 38.6 ± 18.9 years). The distribution of primary complaints divided into anatomical regions is seen in Table 1. Based on the case history alone, the DCs rated 18 patients (4.7%) as having possible hip OA. Of these 18

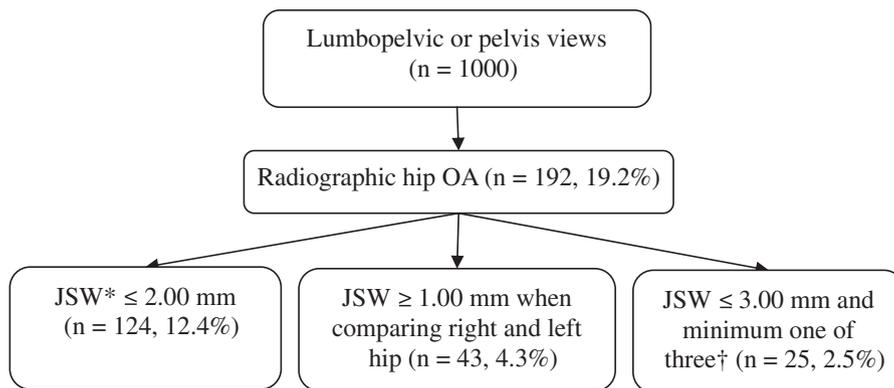
patients, 11 (2.8%) demonstrated physical examination findings indicative of clinical hip OA, whereas 2 patients (0.6%) had clinical examination findings indicating clinical hip OA but no case history information indicating clinical hip OA. Hence, a total of 13 patients (3.4%) were rated as having clinical hip OA. Of these, 7 had a radiographic examination, all of which demonstrating radiographic hip OA. Of these, 5 were diagnosed with hip OA for the first time. Five patients received treatment of the hip OA by the DC at the first visit, 1 of them based on the clinical diagnosis of hip OA alone without radiographic confirmation. According to the DCs, all 5 patients were treated with joint manipulation/mobilization and soft tissue techniques, 2 patients were given advice on glucosamine, and 2 patients were given advice on over-the-counter pain medication. Three patients with confirmed radiographic hip OA were referred to their general practitioner for further orthopedic evaluation without treatment by the DC. For the total of 18 patients reviewed to have possible clinical hip OA based on the case history, 4 patients were categorized in the “low back pain” group, 9 were categorized as having “low back with referring leg pain,” 4 were categorized in the group “leg pain,” and 1 patient was listed in the category “extremity problem.” Proportions of clinical and radiographic hip OA including 95% CI are presented in Table 2, and a flowchart of clinical and radiologic hip OA is presented in Figure 3.

## DISCUSSION

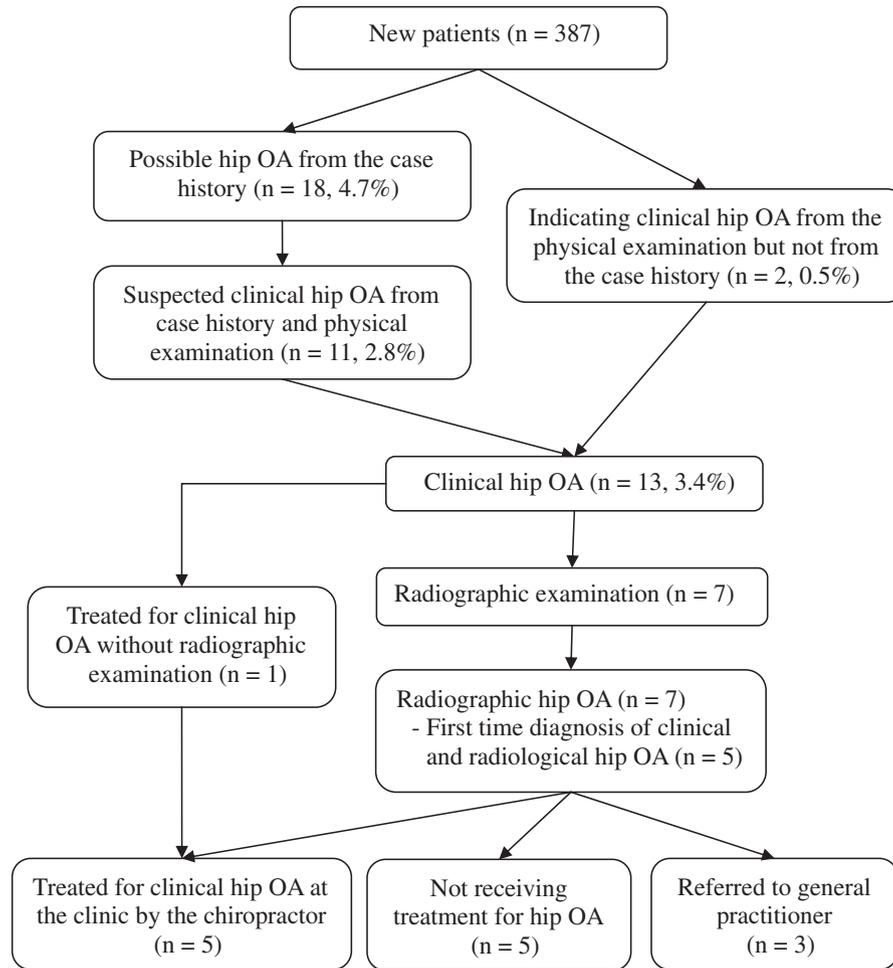
To our knowledge, the prevalence of patients with clinical and radiographic hip OA assessed retrospectively and prospectively in consecutive patients has not previously been described in chiropractic practice. This is important because textbooks and reviews recommend treatment of this condition by DCs.<sup>7,22</sup> Our findings indicate that clinical and radiographic hip OA is likely an under diagnosed condition among DCs in Denmark because we found a 2.5-fold increase in the number of patients diagnosed as having clinical hip OA when data were collected prospectively compared with retrospectively, likely reflecting an increased attention toward hip OA owing to the new patient questionnaire used in the prospective part of the study.



**Fig 1.** Flowchart of patient population with hip OA in 20 Danish chiropractic clinics. Records reviewed retrospectively.



**Fig 2.** Flowchart of radiographic hip OA in 50 consecutive radiographs of the lumbopelvic region in patients 40 years or older in 20 Danish chiropractic clinics. Radiographs reviewed retrospectively. \*JSW narrowing. †Subchondral cyst formation, osteophytosis, and acetabular subchondral sclerosis.



**Fig 3.** Flowchart of patient population with hip OA in 20 Danish chiropractic clinics from a prospective clinician questionnaire during a 2-week period.

Our study further demonstrates that first-time diagnosis of both clinical and radiographic hip OAs by the DC is common among new patients presenting to DCs with signs of hip OA.

In the retrospective review of radiographs where no correlation was made with clinical findings, we found a prevalence of 19.2% of radiographic hip OA in patients 40 years or older; however, this population does not reflect the overall chiropractic patient population because the ratio of patients examined by radiograph as well as the time frame during which the 50 radiographs were obtained are not known. Furthermore, the inclusion was limited to patients 40 years or older because the prevalence of radiographic hip OA in persons younger than 40 years is known to be small. The relationship between radiographic hip OA and hip pain is only supported in cases with severe radiographic hip OA<sup>29,30</sup>; however, the exception to this rule is in young adult men where Birrell et al<sup>30</sup> have documented the possibility of limited or no hip pain despite a diagnosis of severe radiographic hip OA. In our

prospective study, not all patients with recorded clinical hip OA had a radiographic examination. Consequently, the possibility that patient’s clinical signs are from other musculoskeletal disorders could not be eliminated, and the ratio of radiographic hip OA to clinical hip OA could not be estimated.

Prevalence rates of hip OA have been established in several countries, but because case definition varies between studies, estimates are difficult to compare.<sup>31,32</sup>

Data on the components of the initial treatment administered by the DC were available only from the prospective study. All patients with clinical hip OA were treated with joint manipulation, joint mobilization, and soft tissue therapy (trigger point therapy, muscle energy techniques, stretching, and/or massage). In addition, 40% were given advice on glucosamine/chondroitin products or over-the-counter pain medication.

The patients with clinical hip OA in both the retrospective and the prospective studies are not grouped solely in the category “extremity problem” by the treating

DC, but rather in 4 different categories, all related to the low back, pelvis, and lower extremities. This is to be expected because it is well documented that patients with symptoms related to hip OA demonstrate a heterogeneous distribution of pain.<sup>30,33-35</sup> Association between hip OA and low back pain has further been documented by Stupar et al.<sup>36</sup>

Comparing the data concerning “primary complaint” (Table 1) with previous studies comprising all chiropractic clinics in Denmark demonstrates a similar distribution indicating that these data are generalizable.<sup>3,37</sup> The distributions of primary complaint from the retrospective review of records and the prospective clinician questionnaire are also very similar. However, in 1 primary complaint category, “low back and leg pain,” a statistically significant difference was found between the 2 methods with a 2-fold increase in the prospective study. That the retrospective review revealed 2009 primary complaints for the 2000 records is not considered of relevance for this study.

Results from the prospective part of this study are almost identical to results from the 2002 study by Hartvigsen et al.<sup>3</sup> They examined prospectively the distribution of primary complaints among patients in Danish chiropractic clinics. Discrepancy between the prospective and retrospective part of the current study is likely caused by both a lack of standardization in file keeping routines and a lack of attention to hip OA in routine clinical practice.

The choice to use the radiographic criteria of a JSW narrowing of 2.00 mm or less or a JSW difference of 1.00 or more mm is based on a study by Jacobsen et al,<sup>10</sup> which demonstrated minimal JSW narrowing to have the highest association with hip pain, although correlation between JSW and pain remains controversial.<sup>30</sup> The combined criterion of a JSW narrowing of 3.00 mm or less and a minimum 1 of subchondral cyst formation, osteophytosis, or acetabular sclerosis is equivalent to grade 3 reported by Croft et al.<sup>26</sup> Older studies concerning the definition of radiographic hip OA have used classifications by Kellgren and Lawrence.<sup>38</sup> However, the reproducibility of their classification has not been convincing, and the categories use poorly defined terminology like “possible” and “gross” to describe JSW.

### Strength and Limitations

Previous studies dealing with patients in chiropractic clinics in North America and Europe have focused on a general description of the patient population.<sup>2,4</sup> This study focuses specifically on the prevalence of the diagnosis and initial management of one specific condition seen in chiropractic practice, namely, OA of the hip; at the same time, it uses both a retrospective and a prospective data collection resulting in more precise estimates.

Data were collected from approximately 10% of all Danish chiropractic clinics, and with the clinics being distributed

evenly throughout Denmark, the results are likely generalizable to the total number of clinics in Denmark.

In the retrospective review, the time frame of a new patient included was not recorded. Given the flow of new patients in Danish chiropractic clinics, it is unlikely that it would have exceeded 1 year. For the prospective survey, 2 weeks was decided to optimize the collection of data. Because the 2 time frames are not identical, this could have inflated the prevalence obtained in the prospective survey because clinicians had increased focus on the condition during the 2 weeks of data collection. Consequently, the comparison between the retrospective review and the prospective survey was based on the inclusion criteria of new patient information.

Information on case history and physical examination findings of clinical hip OA in the retrospective review was collected based on the clinical experience and opinion of the principal investigator, which potentially could have inflated the number of patients with possible hip OA judged from the case history.

Differentiation by sex was not possible in the retrospective study of radiologic findings because not all radiographs were coded for sex.

Components of the initial treatment were based on information from just 5 patients in the prospective study, so conclusions must be preliminary. To describe fully the components of chiropractic management of hip OA that likely includes patient education, reassurance, cardiovascular and strengthening exercises, possible weight control, information about treatment options, and prognosis, data must be collected over a longer period.

At the time of radiographic reviewing, 17 of the 20 clinics used x-ray equipment with conventional plain radiographs, whereas 3 clinics used digital processing and digital viewing with the possibility of enlarging radiographs and measuring to the nearest 0.01 mm. With the conventional plain films, measurements were made to the closest millimeter, introducing a larger degree of measurement error; however, for future studies, we expect that a much higher proportion of the chiropractic clinics in Denmark will have changed to digital processing and viewing because the Danish Health Insurance is now subsidizing DCs who change to this digital technology. Finally, focal film distance was probably not entirely uniform between participating clinics, making diagnosis by measurement of JSW narrowing somewhat less reliable. This needs to be accounted for in future studies.

Research evaluating the effectiveness of manual treatment and management for patients with hip OA is emerging, and it is of great interest to determine whether the promising results from pilot studies and initial randomized controlled trials will have an influence on the number of patients with hip OA consulting DCs or other practitioners of manual medicine. It appears, however, that there is a group of patients in chiropractic practice in

Denmark having symptoms from hip OA where this problem is not addressed. Future prospective studies should include questions pertaining to the broader management of hip OA according to international clinical guidelines. Specific questions should pertain to differentiation of interventions including patient education, exercises, and dosage and frequency.<sup>11</sup> Specific correlation between patient records with clinical hip OA and possible radiographic findings of hip OA is also recommended.

## CONCLUSIONS

Patients with hip OA are diagnosed and treated in Danish chiropractic practice, although the prevalence is low. First-time diagnosis of hip OA by a DC appears to be common among new presenters with clinical and radiographic signs of hip OA. Hip OA is likely under diagnosed in primary care chiropractic practice, but increased focus on this condition could change this.

### Practical Applications

- The prevalence of clinical hip OA is estimated to be 3.4% in chiropractic practice in Denmark.
- Among patients in chiropractic practice diagnosed as having hip OA, first-time diagnosis is common.
- Hip OA is likely underdiagnosed in chiropractic practice, but focus on the condition can change this.

## FUNDING SOURCES AND POTENTIAL CONFLICTS OF INTEREST

The study is funded by the Danish Foundation for Chiropractic Research and Postgraduate Education, Nordic Institute of Chiropractic and Clinical Biomechanics, and the University of Southern Denmark. The authors declare no competing interests.

## REFERENCES

1. Rubinstein S, Pfeifle CE, van Tulder MW, Assendelft WJ. Chiropractic patients in the Netherlands: a descriptive study. *J Manipulative Physiol Ther* 2000;23:557-63.
2. Coulter ID, Hurwitz EL, Adams AH, Genovese BJ, Hays R, Shekelle PG. Patients using chiropractors in North America: who are they, and why are they in chiropractic care? *Spine (Phila Pa 1976)* 2002;27:291-6.
3. Hartvigsen J, Sorensen LP, Graesborg K, Grunnet-Nilsson N. Chiropractic patients in Denmark: a short description of basic characteristics. *J Manipulative Physiol Ther* 2002;25:162-7.
4. Pedersen P. A survey of chiropractic practice in Europe. *Eur J Chiropr* 1994;42:3-28.
5. Leboeuf-Yde C, Hennius B, Rudberg E, Leufvenmark P, Thunman M. Chiropractic in Sweden: a short description of patients and treatment. *J Manipulative Physiol Ther* 1997; 20:507-10.
6. Humphreys BK, Peterson CK, Muehlemann D, Haueter P. Are swiss chiropractors different than other chiropractors? Results of the job analysis survey 2009. *J Manipulative Physiol Ther* 2010;33:519-35.
7. Brantingham JW, Globe G, Pollard H, Hicks M, Korporaal C, Hoskins W. Manipulative therapy for lower extremity conditions: expansion of literature review. *J Manipulative Physiol Ther* 2009;32:53-71.
8. International Chiropractic Accreditation Standards: Educational Objectives. The Councils On Chiropractic Educational Standards. 2009 [cited 2011 Oct 4]. Available from: [http://www.cceintl.org/Important\\_Documents.html](http://www.cceintl.org/Important_Documents.html).
9. Salaffi F, Carotti M, Stancati A, Grassi W. Health-related quality of life in older adults with symptomatic hip and knee osteoarthritis: a comparison with matched healthy controls. *Aging Clin Exp Res* 2005;17:255-63.
10. Jacobsen S, Sonne-Holm S, Soballe K, Gebuhr P, Lund B. Radiographic case definitions and prevalence of osteoarthritis of the hip: a survey of 4 151 subjects in the Osteoarthritis Substudy of the Copenhagen City Heart Study. *Acta Orthop Scand* 2004;75:713-20.
11. Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage* 2008;16: 137-62.
12. National Collaborating Centre for Chronic Conditions. Osteoarthritis: national clinical guidelines for care and management in adults. London: Royal College of Physicians; 2008.
13. Guideline for the non-surgical management of hip and knee osteoarthritis. The Royal Australian College of General Practitioners. 2009 [cited 2011 Oct 4]. Available from: [http://www.racgp.org.au/Content/NavigationMenu/ClinicalResources/RACGPGuidelines/Guidelineforthenonsurgicalmanagementofhipandkneeosteoarthritis/RACGP\\_OA\\_guideline.pdf](http://www.racgp.org.au/Content/NavigationMenu/ClinicalResources/RACGPGuidelines/Guidelineforthenonsurgicalmanagementofhipandkneeosteoarthritis/RACGP_OA_guideline.pdf).
14. Hoeksma HL, Dekker J, Ronday HK, Heering A, van der LN, Vel C, et al. Comparison of manual therapy and exercise therapy in osteoarthritis of the hip: a randomized clinical trial. *Arthritis Rheum* 2004;51:722-9.
15. Thorman P, Dixner A, Sundberg T. Effects of chiropractic care on pain and function in patients with hip osteoarthritis waiting for arthroplasty: a clinical pilot trial. *J Manipulative Physiol Ther* 2010;33:438-44.
16. Brantingham JW, Globe GA, Cassa TK, Globe D, de Luca K, Pollard H, et al. A single-group pretest posttest design using full kinetic chain manipulative therapy with rehabilitation in the treatment of 18 patients with hip osteoarthritis. *J Manipulative Physiol Ther* 2010;33:445-57.
17. de Luca K, Pollard H, Brantingham J, Globe G, Cassa T. Chiropractic management of the kinetic chain for the treatment of hip osteoarthritis: An Australian Case Series. *J Manipulative Physiol Ther* 2010;33:474-9.
18. French HP, Cusack T, Brennan A, White B, Gilsenan C, Fitzpatrick M, et al. Exercise and Manual Physiotherapy Arthritis Research Trial (EMPART): a multicentre randomised controlled trial. *BMC Musculoskelet Disord* 2009;10:9.
19. Poulsen E, Christensen HW, Roos EM, Vach W, Overgaard S, Hartvigsen J. Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: protocol for a three-armed randomized clinical trial. *BMC Musculoskelet Disord* 2011;12:88.

20. Vaux P. Hip osteoarthritis: a chiropractic approach. *Eur J Chiropr* 1998;46:17-22.
21. Brantingham JW, Williams AM, Parkin-Smith GF, Weston P, Wood T. A controlled, prospective pilot study of the possible effects of chiropractic manipulation in the treatment of osteo-arthritis of the hip. *Eur J Chiropr* 2003; 51:149-66.
22. Peterson DH, Bergmann TF. Chiropractic technique: principles and procedures. 2nd ed. St. Louis, Missouri: Mosby, Inc; 2002.
23. Broome RT. Chiropractic peripheral joint technique. Oxford: Butterworth-Heinemann; 2000.
24. Altman R, Alarcon G, Appelrouth D, Bloch D, Borenstein D, Brandt K, et al. The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hip. *Arthritis Rheum* 1991;34:505-14.
25. Rowe LJ, Yochum TR. Radiographic positioning and normal anatomy. *Essentials of skeletal radiology*, 2nd ed. Baltimore: Williams & Wilkins; 1996. p. 1-138.
26. Croft P, Cooper C, Wickham C, Coggon D. Defining osteoarthritis of the hip for epidemiologic studies. *Am J Epidemiol* 1990;132:514-22.
27. Pessis E, Chevrot A, Drape JL, Leveque C, Sarazin L, Minoui A, et al. Study of the joint space of the hip on supine and weight-bearing digital radiographs. *Clin Radiol* 1999;54: 528-32.
28. The Danish National Committee on Biomedical Research Ethics 2011 Aug 11 [cited 2011 Oct 4]. Available from: <http://www.cvk.sum.dk/English/guidelinesaboutnotification.aspx>.
29. Bierma-Zeinstra SM, Oster JD, Bernsen RM, Verhaar JA, Ginai AZ, Bohnen AM. Joint space narrowing and relationship with symptoms and signs in adults consulting for hip pain in primary care. *J Rheumatol* 2002;29:1713-8.
30. Birrell F, Lunt M, Macfarlane G, Silman A. Association between pain in the hip region and radiographic changes of osteoarthritis: results from a population-based study. *Rheumatology (Oxford)* 2005;44:337-41.
31. Busija L, Bridgett L, Williams SR, Osborne RH, Buchbinder R, March L, et al. Osteoarthritis. *Best Pract Res Clin Rheumatol* 2010;24:757-68.
32. Reijman M, Hazes JM, Koes BW, Verhagen AP, Bierma-Zeinstra SM. Validity, reliability, and applicability of seven definitions of hip osteoarthritis used in epidemiological studies: a systematic appraisal. *Ann Rheum Dis* 2004;63:226-32.
33. Leshner JM, Dreyfuss P, Hager N, Kaplan M, Furman M. Hip joint pain referral patterns: a descriptive study. *Pain Med* 2008;9:22-5.
34. Khan AM, McLoughlin E, Giannakas K, Hutchinson C, Andrew JG. Hip osteoarthritis: where is the pain? *Ann R Coll Surg Engl* 2004;86:119-21.
35. Khan NQ, Woolson ST. Referral patterns of hip pain in patients undergoing total hip replacement. *Orthopedics* 1998;21:123-6.
36. Stupar M, Cote P, French MR, Hawker GA. The association between low back pain and osteoarthritis of the hip and knee: a population-based cohort study. *J Manipulative Physiol Ther* 2010;33:349-54.
37. Sorensen LP, Stochkendahl MJ, Hartvigsen J, Nilsson NG. Chiropractic patients in Denmark 2002: an expanded description and comparison with 1999 survey. *J Manipulative Physiol Ther* 2006;29:419-24.
38. Kellgren JH, Lawrence JS. Radiological assessment of osteoarthrosis. *Ann Rheum Dis* 1957;16:494-502.

Hip OA: inter-rater reproducibility

## **Reproducibility of range of motion and muscle strength measurements in patients with hip osteoarthritis – an inter-rater study**

Erik Poulsen<sup>1,2\*</sup>, Henrik Wulff Christensen<sup>2</sup>, Jeannette Østergaard Penny<sup>3,4</sup>, Søren Overgaard<sup>3,4</sup>, Werner Vach<sup>2,5</sup>, Jan Hartvigsen<sup>1,2</sup>

<sup>1</sup>Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Denmark

<sup>2</sup>Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark

<sup>3</sup>Department of Orthopedic Surgery and Traumatology, Odense University Hospital, Denmark

<sup>4</sup>Institute of Clinical Research, University of Southern Denmark

<sup>5</sup> Institute of Medical Biometry and Medical Informatics, University of Freiburg, Germany

\*corresponding author

E-mail addresses:

EP: [e.poulsen@nikkb.dk](mailto:e.poulsen@nikkb.dk)

HWC: [h.wulff@nikkb.dk](mailto:h.wulff@nikkb.dk)

JØP: [jeannette.penny@yahoo.com](mailto:jeannette.penny@yahoo.com)

SO: [soeren.overgaard@ouh.regionsyddanmark.dk](mailto:soeren.overgaard@ouh.regionsyddanmark.dk)

WV: [wv@imbi.uni-freiburg.de](mailto:wv@imbi.uni-freiburg.de)

JH: [hartvigsen@health.sdu.dk](mailto:hartvigsen@health.sdu.dk)

## **Abstract**

**Objective:** To determine the inter-rater reproducibility of passive range of motion (ROM) and muscle strength measurements in patients with unilateral hip osteoarthritis (OA). In addition the reliability of clinical hip OA was assessed based on a combined evaluation of ROM and strength.

**Design:** Repeated measures.

**Setting:** University hospital.

**Participants:** Sixty-one patients with unilateral hip osteoarthritis (29 men, 32 women).

**Interventions:** Four blinded raters (two hospital orthopedists and two chiropractors) examined participants independently in random order. Range of motion was measured with a goniometer and muscle strength was measured using a hand-held dynamometer.

**Main outcome measures:** Reproducibility is reported as agreement and reliability between paired raters of the same profession (orthopedists and chiropractors). Agreement was reported as percent agreement and limits of agreement (LoA). Reliability was reported with intraclass correlation coefficients (ICC) including 95% confidence intervals (CI). Reliability of the assessment of clinical OA is reported as weighted kappa.

**Results:** Between orthopedists, agreement for ROM was highest for extension, percent agreement 79% and LoA (-8 – 13). Reliability ranged 0.53 – 0.73, highest for flexion (95% CI 0.38-0.87). Agreement for muscle strength was highest for flexion, LoA (-101 – 59). Reliability ranged 0.52 – 0.85, highest for abduction (95% CI 0.74-0.91). Between chiropractors, agreement for ROM was highest for flexion, percent agreement 83% and LoA (-13 – 21). Reliability ranged 0.14 – 0.79, highest for flexion (95% CI 0.63-0.88). Agreement for muscle

Hip OA: inter-rater reproducibility

strength was highest for abduction, LoA (-146 – 55). Reliability ranged between 0.38 – 0.81, highest for flexion (95% CI 0.69-0.88).

Reliability for the assessment of clinical hip OA was 0.52 between orthopedists and 0.65 between chiropractors.

**Conclusion:** Even among experienced clinicians of the same profession, reproducibility of hip ROM and strength measurements is poor when evaluating patients with hip OA. Reliability of clinical hip OA based on hip ROM and muscle strength is moderate between orthopedists and between chiropractors.

**Key words:** Hip; Examination; Inter-observer; Reliability; Osteoarthritis, Hip

**Abbreviations:**

OA – osteoarthritis

ROM – range of motion

RCT – randomised clinical trial

HHD – hand held dynamometer

ICC – intraclass correlation coefficient

CI – confidence interval

LoA – limits of agreement

## Background

In primary care, when patients over 40 years of age presents with hip pain the most common diagnosis is osteoarthritis (OA).<sup>1;2</sup> Although approximately half demonstrates definite radiological signs of OA<sup>1</sup>, radiographs are not recommended for solely confirming the diagnosis<sup>3</sup> thus making the clinical exam of key importance. Clinical practice guidelines recommend assessment of range of motion (ROM) and muscle strength when adult patients presents with hip pain<sup>4</sup> and the two clinical signs documented to correlate with hip OA are reduced ROM<sup>5-8</sup> and muscle strength<sup>5;8-11</sup>. Reduced ROM is further documented as a clinical predictor for hip OA<sup>2;12</sup> and in patients with mild symptomatic hip OA specific ranges of reduced ROM are correlated with radiographic signs<sup>13</sup>.

A number of studies have evaluated the reliability of ROM and muscle strength measurements in patients with hip OA and reported moderate to excellent reliability<sup>6;7;14-19</sup>. But methodological issue question the external validity. Equipment ill suited for clinical practice is used<sup>7;18</sup> or number of study subjects are small limiting the between-subject variation<sup>6;14;16;17</sup>. Inappropriate correlation coefficients are reported<sup>14;15</sup> or reliability coefficients are reported alone ignoring agreement parameters<sup>15;17;19</sup>. Reliability coefficients indicate the procedure's ability to discriminate between patients<sup>16;17</sup> whereas agreement parameters reflects error between repeated measurements. So when measurements are used to assess change over time agreement parameters should be reported<sup>20</sup>.

Intra-rater reproducibility is commonly found more reliable than inter-rater as between-rater variability is eliminated<sup>21-23</sup>. In the research setting intra-rater reproducibility is considered adequate when one rater consistently perform measurements whereas the inter-rater reproducibility is essential for clinicians when follow up consultations on the same patient are performed by different clinicians or when clinicians have to agree on a diagnosis. Three studies have examined inter-rater reliability of ROM measurements on hip OA patients but none reported agreement parameters<sup>16;17;24</sup>. One study reported inter-rater reliability of muscle strength measurements on hip OA patients but agreement parameters were not reported<sup>17</sup>. Only one study evaluating reproducibility among primary care clinicians has been identified<sup>16</sup>.

Therefore, the primary purpose of this study was to assess the inter-rater reproducibility of passive ROM and muscle strength measurements in participants with unilateral hip OA among clinicians in both primary care and secondary hospital care. The secondary purpose was to assess the inter-rater reliability of the degree of clinical hip OA among the same clinicians based on findings of ROM and strength measurements.

## **METHODS**

### **Participants**

Study participants are taking part in a randomised clinical trial (RCT) described elsewhere<sup>25</sup>. Recruitment of participants is illustrated in figure 1. Inclusion and exclusion criteria are presented in table 1. Prior to examination, each participant completed a questionnaire with details on age, gender, height, weight, side, duration of complaint and pain severity. The participant reported average pain experienced during the last week and worst pain experience during the last week.

Each participant had prior received verbal and written information about the study and signed a written consent form. The study was granted approval by the Regional Ethics Committee of Southern Denmark, approval number S-20080027 and registered and approved by the Danish Data Protection Agency, J.nr. 2008-41-1910.

### **Raters**

Four raters participated: Two medical doctors from hospital care; one male senior orthopedic surgeon specializing in hip surgery with clinical experience of > 20 years and one female first year resident in orthopedic surgery with four years experience. Two male chiropractors working in primary care both with clinical experience of > 20 years; one with 8 years of clinical interest in specific hip conditions and one with no specific interest or clinical experience with hip conditions. At the time of examination raters were aware of inclusion- and exclusion criteria.

### **Setting and Equipment**

All examinations took place at Odense University Hospital, Denmark. Passive hip ROM was measured using a standard two-arm plastic goniometer, 30 cm, 0-360 degrees with one degree increments<sup>a</sup>. Recordings were made to the nearest five degrees. Hip muscle strength was measured in Newton (N) using a hand-held dynamometer (HHD), model MicroFet II<sup>c</sup>. The

goniometer and HHD were chosen as they are inexpensive and easy to implement in both primary and outpatient hospital care. It was decided to test them on raters with minimal protocol standardisation and without rigorous training.

## **Procedures**

The protocol for the examination procedures is listed in appendix 1. The aim of the protocol was to resemble test procedures used in daily practice.

A day was scheduled to familiarise raters with use of equipment and rehearse individual examination procedures. Two university students acted as study subjects. Initially, measurements for ROM and strength were included for all six directions of movement, i.e. extension, flexion, abduction, adduction, internal and external rotation. Strength testing in adduction was excluded due to consensus on limited clinical value and strength testing in extension was subsequently excluded due to difficulties stabilising and standardising the placement of the HHD. For maximum strength measure a break test was decided<sup>26</sup>. The protocol was revised and a training day was scheduled with eight patients with hip pain and radiographic hip OA. Following the training session corrections were made regarding positioning of participants. The final protocol was approved by all raters. Measurements were performed on both hips.

At the days of data collection, four separate cubicles were created by room dividers with identical examination tables. Four participants were asked to each enter a cubicle, undress to their underwear and wait for a rater. Each participant was then examined by the four raters in row, randomly permuting the raters among the remaining participants after each examination. This was to minimize an impact of any possible learning effect. Raters were free to determine which hip to examine first. Communication between rater and participants regarding examination procedures was allowed but not regarding information pertaining to the case history. No communication between raters was allowed in between sessions. An assistant was assigned to each rater to record the result of the examination findings on a standardized form and to assist holding the goniometer during ROM in extension. ROM was measured once and muscle strength measured twice.

Following completion of all measurements each rater independently assessed each hip to the degree of clinical hip OA into one of three categories; no hip OA, mild hip OA and severe hip OA.

For generalizability and to obtain a representative study sample it was decided to include a minimum of 60 participants.

## Statistical analysis

Double data entry was performed by a person not involved in the study. Descriptive statistics are presented for participant characteristics. For the continuous variables of hip ROM and strength, means and standard deviations (SD) for each rater are reported and since we are interested in the reproducibility between raters of the same profession, i.e. orthopedists and chiropractors, pair-wise mean differences and SD between raters of the same profession are reported. The value reported for strength is an average of two measurements. Bland and Altman plots were inspected visually for indication of heteroscedasticity. Measurement error is reported as standard error of the measurement ( $SEM_{\text{agreement}}$ ) described by de Vet et al.<sup>20</sup> and is reported for the purpose of comparison to other studies.  $SEM_{\text{agreement}}$  incorporates measurement error between raters and error from interaction between raters and participants.

Agreement between raters is reported as 95% limits of agreement (LoA) as described by Bland and Altman<sup>27</sup> where the clinical interpretation is based on the 95% range. So if the systematic rater error is zero half the range can be considered the smallest detectable change which within 95% confidence can be distinguished from fluctuations due to measurement error, if two different raters are assessed. Percent agreements between raters are reported for ROM as agreement within 10 degrees for flexion and 5 degrees for all other ROMs. 10 degrees for flexion was chosen since the range in flexion is considerably larger. Clinical acceptable percent agreement between clinicians was set a priori to 75%. Reliability is reported with the intraclass correlation coefficient ( $ICC_{2,1}$ ) including 95% confidence intervals and is reported within raters of the same profession. Interpretation of ICC is according to the classification < 0.69, poor; 0.70-0.79, fair; 0.80-0.89, good; 0.90-1.00, excellent<sup>28</sup>. Acceptable reliability was set *a priori* at  $\geq 0.70$ <sup>29</sup>. The use of  $ICC_{2,1}$  was decided in order to generalize raters to a wider population of raters<sup>30</sup>. The reliability of the overall assessment of clinical hip OA is reported with Cohen's weighted kappa. The interpretation of Cohen's weighted kappa is according to the classification by Landis and Koch<sup>31</sup>: < 0.00, poor; 0.00-0.20, slight; 0.21-0.40, fair; 0.41-0.60, moderate; 0.61-0.80, substantial, 0.81-1.00, almost perfect. Kappa is weighted as 1.0 / 0.5 / 0.0. Acceptable kappa values were set a priori at  $\geq 0.60$ . Analysis was performed using Stata 10<sup>c</sup>.

## RESULTS

Sixty-seven participants were invited to take part in the study. Three were excluded due to bilateral hip pain, one due to neuropathy, one for having no radiographic signs of hip OA and one failed to attend resulting in 61 participants. Inclusion of participants took place from January 2009 – September 2009 and a total of five days evenly distributed throughout the period were used for examinations. The senior orthopedic surgeon was not available for one day of examination so a total of 48 participants were assessed for comparison between the two orthopedists. Results are only presented for the hip with clinical and radiographic OA. Descriptive participant characteristics are listed in table 2. Means and SD for ROM and strength measurements for all four raters are listed in table 3 as well as pair-wise mean differences and SDs between orthopedists and between chiropractors.  $SEM_{\text{agreement}}$ , percent agreement for ROM, LoA and ICC for the pair-wise comparison is also listed in table 3.

Statistically significant differences ( $p < 0.05$ ) were found in general between all pair-wise measurements. But specific patterns for ROM measurements were not noted for the pair-wise comparisons. One chiropractor demonstrated systematic higher values for all hip muscle strength measurements. The systematic difference for the individual measurements is further reflected in the LoA with the upper and lower limits deviating non-symmetrically from zero. Visual inspection of the Bland and Altman plots did not indicate heteroscedasticity.

Percent agreement for ROM between orthopedists ranged between 42 – 79%. Between chiropractors the range was 31 – 83%. LoA between orthopedists for ROM ranged from -8-13 for extension to -28-11 for internal rotation and between chiropractors it ranged from -13-21 for flexion to -25-30 for internal rotation. Reliability for ROM between orthopedists ranged from 0.53 for external rotation [95% CI 0.26-0.72] to 0.73 for flexion [95% CI 0.38-0.87]. Between chiropractors the range was 0.14 for internal rotation [95% CI -0.09-0.36] to 0.79 for flexion [95% CI 0.63-0.88].

LoA for muscle strength between orthopedists ranged from -65-47 for external rotation to -101-59 for flexion and between chiropractors the range was from -80-20 for external rotation to -146-55 for abduction. ICC for orthopedists ranged from 0.52 for internal rotation [95% CI 0.29-0.70] to 0.85 for abduction [95% CI 0.29-0.70]. For chiropractors the ICC ranged from 0.38 for abduction [95% CI 0.00-0.64] to 0.81 for flexion [95% CI 0.69-0.88].

Reliability for clinical hip OA is presented in table 4. Between orthopedists weighted kappa was 0.52 and between chiropractors 0.65.

## DISCUSSION

To our knowledge this is the first study involving clinicians from both primary care (chiropractors) and secondary hospital care (orthopedists). We found generally poor to moderate inter-rater reproducibility for all ROM and muscle strength measurements both between orthopedists and between chiropractors. Acceptable reproducibility was found only for hip ROM in flexion both between orthopedists and between chiropractors. Reliability for the assessment of clinical hip OA is moderate both between orthopedists and between chiropractors.

When incorporating the measurement error into a clinical context, the wide limits of all LoAs for ROM for both orthopedists and chiropractors indicate that an effect following intervention should be a minimum of 17 degrees for flexion, 10 for extension, 15 for abduction, 12 for adduction and 20 and 17 for internal and external rotation before it with 95% confidence can be distinguished from random fluctuations due to measurement error, if two different raters are involved. Considering the normal range for flexion and abduction this is possible but unlikely for extension, adduction and internal and external rotation. Interpretation of the results for flexion and abduction must though be done with care as Müller and Büttner argue the ICC being “dependent on the range of the measuring scale”<sup>32</sup>. So the larger the scale, the higher the coefficient and the range for flexion and abduction is considerably larger than the other ROMs of the hip. The clinical interpretation of reliability must involve the lower 95% CIs<sup>33</sup> which further reflect the poor to moderate findings. Only muscle strength between orthopedists for abduction demonstrated acceptable lower 95% CI of 0.74 and between chiropractors for flexion with lower 95% CI of 0.69.

For hip muscle strength the same interpretation of LoA is not possible as muscle strength diminishes with each decade and is up to 50% higher in males<sup>26</sup>. Further, variation in force applied between raters can be significantly different<sup>34</sup> and between raters of opposite sex<sup>35</sup>. The latter was not apparent between the orthopedist as mean flexion and external rotation was significant higher for the female orthopedist.

Observing results between the two orthopedists and the two chiropractors did not give indication of one group of professionals producing more reliable measurements than the other. However, the reliability measures between chiropractors were lower when assessing both ROM and muscle strength and could reflect that clinical practice for chiropractors is not solely hip pain patients. The variation between the orthopedic surgeon and the first year intern probably reflects the difference in experience.

The level of standardisation and minimal training likely influenced the systematic differences seen in almost all individual measurements and as differences were random between raters across individual ROMs individual habits like placement of instrument and raters force are likely the cause. The poor results of ROM in internal and external rotation could reflect participants being positioned supine and not sitting as position is known to influence the precision of individual measurements<sup>17</sup>. One chiropractor had higher measurements for all strength tests which are likely attributed to the force generated accomplishing the break test and in interpreting when the break test is accomplished. The results are also likely influenced by the orthopedists or chiropractors having limited experience with the HHD. The procedures were tested in a validation study as part of the before mentioned RCT (data not published). The rater tested had levels of similar experience with the HHD and demonstrated similar levels of intra-rater reliability but with much narrower LOA intervals. For ROM measurements the rater demonstrated clinical acceptable intra-rater reproducibility without routinely use of a goniometer in practice.

Several studies have documented from poor to excellent inter-rater reliability of ROM on patients with hip OA using a goniometer. Sutlive et al. found fair to good reliability but agreement parameters were not reported<sup>19</sup>. Holm et al. studied teams of raters but results for mean measurements of each ROM were combined from all raters<sup>14</sup>. Cibere et al. found clinical acceptable reliability both before and after standardisation of ROM and muscle strength measurements but they did not incorporate variance components from the patients and agreement parameters were not reported<sup>17</sup>. Theiler et al. reported reliability coefficients similar to our study but used Pearson's correlation coefficient which does not incorporate systematic differences between raters<sup>15</sup>. For hip muscle strength Arnold et al. found excellent inter-rater reliability using a different HHD model but subjects were a mix of patients with both hip and knee OA<sup>36</sup>. Studies have documented good to excellent intra- and inter-rater reliability on healthy subjects using goniometer and HHD but they are not comparable as age and disease characteristics influence the variation between subjects<sup>21-23;35;37;38</sup>.

### **Study Limitations**

First, raters were aware of participant's inclusion criteria of unilateral clinical and radiographic hip OA so in the context of the clinical setting no other hip conditions had to be considered. Second, the study did not involve rigorous training between the raters but we were interested in results reflecting current clinical practice. Several studies have reported on the added effect of protocol standardisation and rigorous training in musculoskeletal medicine<sup>17;39;40</sup> and such

training could potentially result in better agreement. Third, the orthopedic surgeon was not available for one of the examination sessions, so only 48 participants were included in the analysis between orthopedists. Forth, the assessment of clinical hip OA was based solely on ROM and strength evaluation. In clinical practice a more extensive lists of individual tests are used as well as information from the case history. Last, differentiation between levels of clinical hip OA following the overall assessment was only made from mild to severe hip OA. In the assessment of radiographic hip OA it is common to categorise into none, mild, moderate and severe.

The literature on reproducibility of the clinical hip examination in patients with hip OA is limited and heterogeneous but recently the first set of guidelines on the reporting of reliability and agreement studies was published<sup>33</sup>. As patient characteristics differs in symptom and disease severity in primary and hospital care, future studies should take place in the setting where patient populations are examined and managed and involve clinicians from the same setting. To improve external validity, more than two clinicians should be included and selected randomly among an appropriate population of clinicians.

## **CONCLUSIONS**

When using goniometry for the assessment of hip ROM and hand-held dynamometry for hip muscle strength in patients with hip OA, reproducibility of individual measurements is in general poor between pairs of orthopedists and pairs of chiropractors indicating standardisation and rigorous training is essential. Both orthopedists and chiropractors are able to differentiate between hips without clinical OA and hips assessed as having either mild or severe clinical OA.

## **Competing interests**

All authors declare that they have no competing interests.

### Author contributions

EP, HWC, SO and JH contributed to conception and design of the study. EP, HWC, JØP and SO participated in data collection. EP drafted the manuscript and performed the statistical analysis. EP, HWC, SO, WV and JH participated in the interpretation of data. All authors participated in the critical revision of the article and made important contributions to the content. All authors read and approved the final manuscript.

### Acknowledgements

We would like to thank research secretary Jytte Johannesen for designing the recording forms and project nurse Annie Gam-Pedersen for keeping order of participants and clinicians on the days of examination.

### Reference List

- (1) Birrell F, Croft P, Cooper C, Hosie G, Macfarlane GJ, Silman A. Radiographic change is common in new presenters in primary care with hip pain. PCR Hip Study Group. *Rheumatology (Oxford)* 2000;39:772-775.
- (2) Bierma-Zeinstra SM, Oster JD, Bernsen RM, Verhaar JA, Ginai AZ, Bohnen AM. Joint space narrowing and relationship with symptoms and signs in adults consulting for hip pain in primary care. *J Rheumatol* 2002;29:1713-1718.
- (3) Cibere J. Do we need radiographs to diagnose osteoarthritis? *Best Pract Res Clin Rheumatol* 2006;20:27-38.
- (4) Cibulka MT, White DM, Woehrle J et al. Hip pain and mobility deficits--hip osteoarthritis: clinical practice guidelines linked to the international classification of functioning, disability, and health from the orthopaedic section of the American Physical Therapy Association. *J Orthop Sports Phys Ther* 2009;39:A1-25.
- (5) Arokoski MH, Haara M, Helminen HJ, Arokoski JP. Physical function in men with and without hip osteoarthritis. *Arch Phys Med Rehabil* 2004;85:574-581.
- (6) Klassbo M, Harms-Ringdahl K, Larsson G. Examination of passive ROM and capsular patterns in the hip. *Physiother Res Int* 2003;8:1-12.

## Hip OA: inter-rater reproducibility

- (7) Pua YH, Wrigley TV, Cowan SM, Bennell KL. Intrarater test-retest reliability of hip range of motion and hip muscle strength measurements in persons with hip osteoarthritis. *Arch Phys Med Rehabil* 2008;89:1146-1154.
- (8) Rydevik K, Fernandes L, Nordsletten L, Risberg MA. Functioning and disability in patients with hip osteoarthritis with mild to moderate pain. *J Orthop Sports Phys Ther* 2010;40:616-624.
- (9) Rasch A, Bystrom AH, Dalen N, Berg HE. Reduced muscle radiological density, cross-sectional area, and strength of major hip and knee muscles in 22 patients with hip osteoarthritis. *Acta Orthop* 2007;78:505-510.
- (10) Pua YH, Wrigley TV, Collins M, Cowan SM, Bennell KL. Association of physical performance with muscle strength and hip range of motion in hip osteoarthritis. *Arthritis Rheum* 2009;61:442-450.
- (11) Suetta C, Aagaard P, Magnusson SP et al. Muscle size, neuromuscular activation, and rapid force characteristics in elderly men and women: effects of unilateral long-term disuse due to hip-osteoarthritis. *J Appl Physiol* 2007;102:942-948.
- (12) Birrell F, Croft P, Cooper C, Hosie G, Macfarlane G, Silman A. Predicting radiographic hip osteoarthritis from range of movement. *Rheumatology (Oxford)* 2001;40:506-512.
- (13) Holla JF, Steultjens MP, van der Leeden M et al. Determinants of range of joint motion in patients with early symptomatic osteoarthritis of the hip and/or knee: an exploratory study in the CHECK cohort. *Osteoarthritis Cartilage* 2011;19:411-419.
- (14) Holm I, Bolstad B, Lutken T, Ervik A, Rokkum M, Steen H. Reliability of goniometric measurements and visual estimates of hip ROM in patients with osteoarthrosis. *Physiother Res Int* 2000;5:241-248.
- (15) Theiler R, Stucki G, Schutz R et al. Parametric and non-parametric measures in the assessment of knee and hip osteoarthritis: interobserver reliability and correlation with radiology. *Osteoarthritis Cartilage* 1996;4:35-42.
- (16) Croft PR, Nahit ES, Macfarlane GJ, Silman AJ. Interobserver reliability in measuring flexion, internal rotation, and external rotation of the hip using a plurimeter. *Ann Rheum Dis* 1996;55:320-323.
- (17) Cibere J, Thorne A, Bellamy N et al. Reliability of the hip examination in osteoarthritis: effect of standardization. *Arthritis Rheum* 2008;59:373-381.
- (18) Rasch A, Dalen N, Berg HE. Test methods to detect hip and knee muscle weakness and gait disturbance in patients with hip osteoarthritis. *Arch Phys Med Rehabil* 2005;86:2371-2376.

## Hip OA: inter-rater reproducibility

- (19) Sutlive TG, Lopez HP, Schnitker DE et al. Development of a clinical prediction rule for diagnosing hip osteoarthritis in individuals with unilateral hip pain. *J Orthop Sports Phys Ther* 2008;38:542-550.
- (20) de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. *J Clin Epidemiol* 2006;59:1033-1039.
- (21) Aalto TJ, Airaksinen O, Harkonen TM, Arokoski JP. Effect of passive stretch on reproducibility of hip range of motion measurements. *Arch Phys Med Rehabil* 2005;86:549-557.
- (22) Prather H, Harris-Hayes M, Hunt DM, Steger-May K, Mathew V, Clohisy JC. Reliability and agreement of hip range of motion and provocative physical examination tests in asymptomatic volunteers. *PM R* 2010;2:888-895.
- (23) Bierma-Zeinstra SM, Bohnen AM, Ramlal R, Ridderikhoff J, Verhaar JA, Prins A. Comparison between two devices for measuring hip joint motions. *Clin Rehabil* 1998;12:497-505.
- (24) Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA* 2002;288:2469-2475.
- (25) Poulsen E, Christensen HW, Roos EM, Vach W, Overgaard S, Hartvigsen J. Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: Protocol for a three-armed randomized clinical trial. *BMC Musculoskelet Disord* 2011;12:88.
- (26) Andrews AW, Thomas MW, Bohannon RW. Normative values for isometric muscle force measurements obtained with hand-held dynamometers. *Phys Ther* 1996;76:248-259.
- (27) Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986;1:307-310.
- (28) Currier DP. *Elements of Research in Physical Therapy*. 3rd ed. Baltimore: Williams & Wilkins, 1990.
- (29) Assessing health status and quality-of-life instruments: attributes and review criteria. *Qual Life Res* 2002;11:193-205.
- (30) Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. *J Strength Cond Res* 2005;19:231-240.
- (31) Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33:159-174.

## Hip OA: inter-rater reproducibility

- (32) Muller R, Buttner P. A critical discussion of intraclass correlation coefficients. *Stat Med* 1994;13:2465-2476.
- (33) Kottner J, Audige L, Brorson S et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *J Clin Epidemiol* 2011;64:96-106.
- (34) Wikholm JB, Bohannon RW. Hand-held Dynamometer Measurements: Tester Strength Makes a Difference. *J Orthop Sports Phys Ther* 1991;13:191-198.
- (35) Thorborg K, Bandholm T, Schick M, Jensen J, Holmich P. Hip strength assessment using handheld dynamometry is subject to intertester bias when testers are of different sex and strength. *Scand J Med Sci Sports* 2011.
- (36) Arnold CM, Warkentin KD, Chilibeck PD, Magnus CR. The reliability and validity of handheld dynamometry for the measurement of lower-extremity muscle strength in older adults. *J Strength Cond Res* 2010;24:815-824.
- (37) Lu YM, Lin JH, Hsiao SF, Liu MF, Chen SM, Lue YJ. The relative and absolute reliability of leg muscle strength testing by a handheld dynamometer. *J Strength Cond Res* 2011;25:1065-1071.
- (38) Fulcher ML, Hanna CM, Raina EC. Reliability of handheld dynamometry in assessment of hip strength in adult male football players. *J Sci Med Sport* 2010;13:80-84.
- (39) Cibere J, Bellamy N, Thorne A et al. Reliability of the knee examination in osteoarthritis: effect of standardization. *Arthritis Rheum* 2004;50:458-468.
- (40) Brunse MH, Stochkendahl MJ, Vach W et al. Examination of musculoskeletal chest pain - an inter-observer reliability study. *Man Ther* 2010;15:167-172.

## Suppliers' list:

- a. MSD Europe bvba, Neringstraat 7, B 1840 Londerzeel, Belgium.
- b. Hoggan Health Industries Inc., 8020 South 1300 West, West Jordan, UT 84088, USA.
- c. Stata Corp LP. 4905 Lakeway Drive, College Station, TX 77845, USA.

## **APPENDIX 1: Examination protocol**

### **Protocol for examination of passive hip range of motion**

#### Hip flexion – supine

Participant is supine with arms along the side (alternatively crossed across the chest if the rater considers the arms interfering with placement of goniometer). Rater is standing on same side as the examined hip. The rater flexes the examined hip to the point of maximal passive flexion; either by observing raising of the opposite thigh or by felt restriction of the thigh. The goniometer is centred at the greater trochanter with the stabilizing arm horizontal and parallel to the trunk of the patient and the moveable arm parallel to the femur. The degree of flexion is relayed to the assistant.

#### Hip abduction - supine

Participant is supine. Rater is standing on same side as the examined hip. The goniometer is centred at a point midway between the anterior superior iliac spine (ASIS) and the symfysis pubis. The stabilizing arm is parallel to the midline of the participant and the participant is asked to hold the stabilizing arm against his/her lower abdomen with instruction not to move it. The moving arm is placed parallel to the thigh. With one hand the rater stabilizes the pelvis by

## Hip OA: inter-rater reproducibility

holding one hand around the opposite ASIS. With the other hand the examined leg is moved into abduction until resistance is felt. Attention is made not to externally rotating the hip when it is moved into abduction. The movable arm on the goniometer is replaced aligning the examined thigh and the degree of abduction is relayed to the assistant.

## Hip adduction - supine

Participant, rater and placement of goniometer as in hip abduction. The rater moves the examined leg into adduction across the non-examined leg until resistance is felt. Attention is made not to externally rotating the hip when it is moved into adduction and attempt is made to avoid the non-involved thigh resisting the movement of the examined leg. The movable arm on the goniometer is replaced aligning the examined thigh and the degrees of adduction are relayed to the assistant.

## Hip Internal rotation - supine

Participant is supine. Rater is standing on same side as the examined hip. The rater flexes the examined leg to 90 degrees hip and knee flexion. The goniometer is placed with the center at the tip of the patella and both arms facing distal along the shaft of the tibia. The longitudinal plane is defined to be that parallel to the body. The rater moves the hip into full internal rotation until resistance is felt. The moveable arm of the goniometer is re-placed to the starting position of the tibia and the degrees of internal rotation are relayed to the assistant.

Hip OA: inter-rater reproducibility

### Hip external rotation - supine

Participant, rater and placement of goniometer as in internal rotation. The rater moves the hip into full external rotation until resistance is felt. The degrees of external rotation are relayed to the assistant.

### Hip extension - prone

Participant is prone. Rater is standing opposite of the examined hip. The rater stabilizes the pelvis on the side of examination by placing one hand distal to the iliac crest with the heel of the hand on the posterior superior iliac spine. The assistant is asked to place the goniometer on the side of the thigh with the center at the trochanter major and the arms parallel to the thigh. The rater lifts the thigh into extension until resistance is felt. The assistant re-positions the movable arm so it is parallel to the thigh and records the degrees of extension.

### **Protocol for examination of hip muscle strength**

During all procedures of muscle testing a break test is applied. The participant is asked to increase the resistance of the force applied as the rater increases the opposite force until resistance of the force by the participant is “broken”.

### Hip abduction – side lying

The participant is lying on the side with the examined side up. The opposite leg is flexed 45 degrees at the hip and knee for stability. The rater is placed behind the participant with one hand stabilizing the pelvis. The participant is asked to lift the leg 5 centimeters into abduction with 5 degrees of hip extension in order to avoid the use of hip flexors during abduction. The rater places the dynamometer 10 centimeters proximal to the knee joint. The participant is instructed to hold the leg in the placed position while the rater gradually increases the opposite force until “give” of the leg.

The recorded degree of maximal force is relayed to the assistant.

### Hip flexion - sitting

The participant is seated on the examination table with legs hanging over the side of the table avoiding contact of the back of knees with the table. In order to minimize co-contraction of the arm and torso musculature during test procedure the arms of the participants are placed behind the back and the participant is asked to avoid co-contraction. The rater is standing to the side of hip being tested. The participant is asked to lift the examined leg 10 degrees from the table and the dynamometer is placed 10 cm proximal to the patella. The participant is instructed to hold the leg in the placed position while the rater gradually increases the opposite force until “give” of the thigh.

Hip OA: inter-rater reproducibility

The recorded degree of maximal force is relayed to the assistant.

#### Hip internal rotation - sitting

Participant placement and instruction as in flexion. The rater is kneeling in front of the participant next to the leg being tested. One hand is stabilizing the knee to minimise lateral knee movement. The dynamometer is placed on the lateral side of lower leg approximately 5 cm proximal to the lateral malleoli. The participant is instructed to hold the leg in the placed position while the rater gradually increases the force into external rotation until “give” of the lower leg.

The recorded degree of maximal force is relayed to the assistant.

#### Hip external rotation - sitting

Participant placement and instruction as in flexion. The rater is kneeling in front of the participant next to the leg opposite the one being tested. One hand is stabilizing the knee to minimise lateral knee movement. The dynamometer is placed on the medial side of lower leg approximately 5 cm proximal to the medial malleoli. The participant is instructed to hold the leg in the placed position while the rater gradually increases the force into internal rotation until “give” of the lower leg.

The recorded degree of maximal force is relayed to the assistant.

Hip OA: inter-rater reproducibility

### **Protocol for rating of clinical hip osteoarthritis**

Based on findings on the clinical examination of passive hip range of motion and hip muscle strength the rater categorizes the hip in one of three: No hip OA, mild hip OA or severe hip OA.

## **Figure legends**

Figure 1. Flow chart of participants included in the study.

## **Tables and legends**

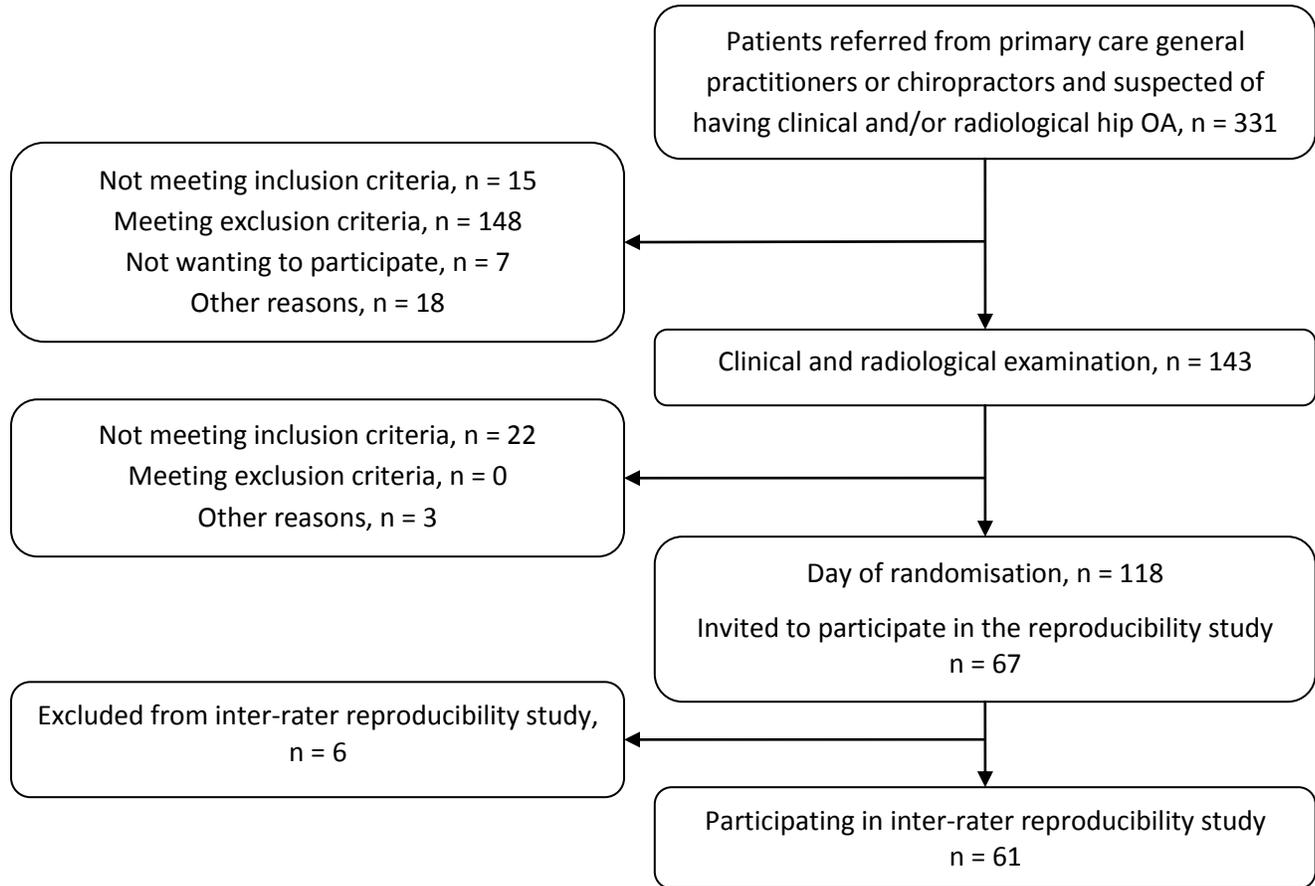
**Table 1. Inclusion and exclusion criteria for participants**

**Table 2. Characteristics of participants, listed as numbers, means and standard deviations**

**Table 3. Inter-rater reproducibility of hip range of motion (degrees) and muscle strength (N) for 2 orthopaedists and 2 chiropractors**

**Table 4. Reliability of the degree of clinical hip osteoarthritis assessed by range of motion and muscle strength assessment reported as weighted kappa between pair-wise 2 orthopaedists and 2 chiropractors**

Figure 1. Flow chart of participants included in the study.



**Table 1. Inclusion and exclusion criteria for participants**

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>- 40-80 years of age</li> <li>- Unilateral hip pain &gt; 3 months</li> <li>- Radiographic measurement of joint space width &lt; 2.00 mm or side difference &gt; 10%</li> <li>- Able to speak and read Danish</li> </ul>	<ul style="list-style-type: none"> <li>- Bilateral hip pain</li> <li>- Hip OA due to hip fracture or infection</li> <li>- Previous hip or knee joint replacement surgery</li> <li>- Indication for hip joint replacement surgery within the next 6 months</li> <li>- Rating of worst hip pain during the last week as <math>\leq 2</math> on 11-box rating scale</li> <li>- Manual therapy for the hip within the last 12 months</li> <li>- Hip dysplasia, Center Edge angle &lt; 25 and Acetabular index Angle &gt; 10</li> <li>- Local knee pain originating from the knee on the same side as the hip OA</li> <li>- Low back pain dominating over the hip symptoms</li> <li>- Inflammatory joint disease</li> <li>- Polyarthritis defined as &gt; 3 regional sites</li> <li>- Cerebrovascular disease</li> <li>- Polyneuropathy or neuromuscular disease</li> <li>- Malignant disease</li> <li>- Other conditions than hip osteoarthritis (OA) appearing to be the cause of the patient's symptoms</li> <li>- Refusal to participate</li> </ul>

**Table 2. Characteristics of participants, listed as numbers, means and standard deviations**

Involved side, right / left (n)	36 / 25
Gender, men / women (n)	29 / 32
Mean age in years (SD)	65.6 (8.0)
Mean BMI in kg/m <sup>2</sup> (SD)	26.8 (3.4)
Mean duration of symptoms in months (SD)	37 (32)
Mean average level of pain during the last week* (SD)	4.7 (1.8)
Mean worst level of experienced pain during the last week* (SD)	5.7 (2.0)

\* Scores rated on a 0-10 Likert scale, 0 = no pain, 10=worst possible pain

**Table 3. Inter-rater reproducibility of hip range of motion (degrees) and muscle strength (N) for 2 orthopaedists and 2 chiropractors**

<b>Hip range of motion measured with a goniometer to the nearest 5 degree</b>	<b>Ortho 1 (degrees) Mean (SD)</b>	<b>Ortho 2 (degrees) Mean (SD)</b>	<b>Mean difference (SD)</b>	<b>Percent agreement (%)*</b>	<b>LOA</b>	<b>SEM†</b>	<b>ICC (95% CI)</b>
Flexion (n= 48)	112.5 (16.7)	105.5 (14.1)	7.0 (9.7)‡	71	-12.0 – 25.9	8.4	0.73 (0.38 – 0.87)
Extension (n= 48)	6.1 (6.1)	3.9 (7.7)	2.3 (5.3)‡	79	-8.0 – 12.6	4.0	0.68 (0.46 – 0.81)
Abduction (n= 48)	28.7 (9.7)	26.0 (7.9)	2.7 (7.4)‡	67	-11.7 – 17.1	5.5	0.63 (0.41 – 0.76)
Adduction (n= 48)	17.1 (7.2)	16.9 (7.0)	0.3 (6.0)	77	-11.4 – 12.0	4.2	0.65 (0.45 – 0.79)
Internal rotation (n= 48)	3.5 (13.6)	11.8 (14.2)	-8.3 (10.1)‡	42	-28.2 – 11.5	9.2	0.63 (0.17 – 0.82)
External rotation (n= 48)	28.3 (11.1)	32.8 (7.4)	-4.4 (8.6)‡	69	-21.2 – 12.5	6.3	0.53 (0.26 – 0.72)
<b>Hip muscle strength measured with a dynamometer in Newton (N)</b>	<b>Strength (N)</b>	<b>Strength (N)</b>					
Abduction (n= 48)	213 (65)	212 (67)	0.0 (37)		-72 – 72	26	0.85 (0.74 – 0.91)
Flexion (n= 48)	167 (42)	185 (50)	-20.8 (41)‡		-101 – 59	32	0.55 (0.28 – 0.73)
Internal rotation (n= 48)	151 (38)	146 (36)	4.8 (36)		-66 – 76	26	0.52 (0.29 – 0.70)
External rotation (n= 48)	123 (34)	132 (39)	-8.9 (28)‡		-65 – 47	21	0.68 (0.49 – 0.81)
<b>Hip range of motion measured with a goniometer to the nearest 5 degree</b>	<b>Chiro 1 (degrees) Mean (SD)</b>	<b>Chiro 2 (degrees) Mean (SD)</b>	<b>Mean difference (SD)</b>	<b>Percent agreement (%)*</b>	<b>LOA</b>	<b>SEM†</b>	<b>ICC (95% CI)</b>
Flexion (n= 61)	111.8 (13.3)	108.0 (15.4)	3.8 (8.8)‡	83	-13.4 – 21.0	6.7	0.79 (0.63 – 0.88)
Extension (n= 61)	8.5 (5.4)	14.0 (5.2)	-5.5 (5.3)‡	66	-15.9 – 4.9	5.4	0.33 (0.06 – 0.61)
Abduction (n= 61)	28.9 (8.9)	21.6 (8.6)	7.3 (7.8)‡	46	-7.9 – 22.5	7.5	0.45 (0.01 – 0.71)
Adduction (n= 61)	17.0 (7.3)	14.1 (4.5)	2.9 (7.9)‡	61	-12.7 – 18.4	5.9	0.14 (0.09 – 0.36)
Internal rotation (n= 61)	13.0 (9.8)	10.9 (16.0)	2.1 (14.1)	31	-25.4 – 29.7	10.0	0.44 (0.21 – 0.62)
External rotation (n= 61)	31.9 (8.9)	30.0 (12.0)	1.9 (10.7)	59	-19.1 – 22.8	7.6	0.48 (0.27 – 0.65)
<b>Hip muscle strength measured with a dynamometer in Newton (N)</b>	<b>Strength (N)</b>	<b>Strength (N)</b>					
Abduction (n= 61)	141 (42)	186 (61)	-45 (51)‡		-146 – 55	48	0.38 (0.00 – 0.64)
Flexion (n= 61)	165 (50)	178 (65)	-11 (35)‡		-79 – 56	26	0.81 (0.69 – 0.88)
Internal rotation (n= 61)	142 (43)	190 (49)	-48 (34)‡		-115 – 19	42	0.48 (0.09 – 0.77)
External rotation (n= 61)	120 (34)	150 (48)	-30 (26)‡		-80 – 20	28	0.65 (0.00 – 0.82)

N, newton; SD, standard deviation; LOA, limits of agreement; SEM, standard error of the measurement; ICC, intraclass correlation coefficient; CI, confidence interval

## Hip OA: inter-rater reproducibility

\*Percent agreement. Difference  $\leq 5^\circ$  between examiners except for flexion  $\leq 10^\circ$

†SEM<sub>agreement</sub>

‡Statistical significant differences between means,  $p < 0.05$

Hip OA: inter-rater reproducibility

**Table 4. Reliability of the degree of clinical hip osteoarthritis reported as weighted kappa between pair wise 2 orthopaedists and 2 chiropractors. Clinical hip OA is assessed by range of motion and muscle strength.**

<b>Pair-wise comparison</b>	<b>Kappa – weighted*</b>
Orthopedist 1 – Orthopedist 2	0.52
Chiropractor 1 – Chiropractor 2	0.65

\*weighted 1.0 ; 0.5 ; 0.0

**Effectiveness of patient education and manual therapy compared to a minimal control intervention in patients with osteoarthritis of the hip – a proof of principle randomized clinical trial**

Erik Poulsen<sup>1,2\*</sup>, Henrik W. Christensen<sup>2</sup>, Ewa M. Roos<sup>1</sup>, Jan Hartvigsen<sup>1,2</sup>, Werner Vach<sup>2,5</sup>, Søren Overgaard<sup>3,4</sup>

<sup>1</sup>Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Denmark

<sup>2</sup>Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark

<sup>3</sup>Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Denmark

<sup>4</sup>Institute of Clinical Research, University of Southern Denmark

<sup>5</sup>Institute of Medical Biometry and Medical Informatics, University of Freiburg, Germany

\* Corresponding author

EP: [e.poulsen@nikkb.dk](mailto:e.poulsen@nikkb.dk)

HWC: [h.wulff@nikkb.dk](mailto:h.wulff@nikkb.dk)

ER: [eroos@health.sdu.dk](mailto:eroos@health.sdu.dk)

JH: [jhartvigsen@health.sdu.dk](mailto:jhartvigsen@health.sdu.dk)

WV: [wv@imbi.uni-freiburg.de](mailto:wv@imbi.uni-freiburg.de)

SO: [soeren.overgaard@ouh.regionsyddanmark.dk](mailto:soeren.overgaard@ouh.regionsyddanmark.dk)

## **Abstract**

### *Objective*

To examine the feasibility of a three-arm randomized clinical trial for primary care patients with hip osteoarthritis (OA) in a Danish setting and investigate the effectiveness of a patient education (PE) program with or without the added effect of manual therapy (MT) compared to a minimal control intervention (MCI). A secondary aim was to explore any benefit from the added effect of MT compared to the PE program alone.

### *Design*

Proof of principle three-arm parallel group randomized clinical trial.

### *Setting*

Single-centre university hospital, Odense, Denmark.

### *Participants*

A total of 118 patients with clinical and radiographic unilateral hip OA referred from general practitioners and chiropractors in primary care.

### *Primary outcome:*

Pain severity on an eleven-box numeric rating scale (NRS).

### *Methods*

The 118 patients were randomized into one of three groups: PE, PE and MT and MCI. The PE was taught by a physiotherapist and involved two individual sessions and three group sessions. The MT was a combination

of trigger point release therapy, muscular stretching and joint manipulation delivered by a chiropractor. The MCI included exercises from the PE program with a short introduction and a message to “live as usual”. Patients and care providers were not blind to group allocation. Pair-wise comparisons between groups of PE and MCI and PE/MT and MCI were analyzed using Dunnett’s test at the primary end point immediately following a 6 weeks intervention period. Outcome assessment was analyzed by an independent statistician.

### *Results*

A total of 111 patients were analyzed at the primary end point. For pain severity at 6 weeks no difference was found on the NRS between the PE group and MCI, mean difference 0.0 (95% CI -1.0 – 1.0). The combined group with PE/MT was able to reduce pain severity on the NRS in comparison to the MCI with -1.90 points (95% CI -2.9 – -0.9),  $p=0.001$ . In the exploratory post-hoc analysis the PE/MT group reduced pain severity -1.9 points on the NRS compared to the PE group (95% CI -3.0 – -0.7),  $p<0.05$ .

### *Conclusions*

This proof of principle trial provides foundation for further trials in a Danish setting investigating the effectiveness of manual therapy combined with or in comparison with patient education. A combined intervention of manual therapy and patient education was able to reduce pain severity with a statistically significant difference in comparison to a minimal control intervention. Comparison of patient education alone with the combination of patient education and manual therapy indicates manual therapy being the active intervention.

**Trial registration:** [clinicaltrials.gov - NCT01039337](https://clinicaltrials.gov/ct2/show/study/NCT01039337)

## Introduction

Hip osteoarthritis (OA) is a common joint disease with a lifetime risk at 25% (1). When symptomatic the disease has a negative impact on activities of daily living (ADL) and quality of life (QoL) (2;3) and has recently been linked to higher mortality rates (4). If hip OA progresses to end stage of degeneration joint disease, joint replacement surgery might be an appropriate and cost-effective treatment (5;6). But long term follow-up has documented that only 20% of patients have surgery 11-28 years after the initial radiographic diagnosis (7). Therefore, interventions with documented effectiveness become essential for the majority of patients who do not need surgery.

Patient education (PE) programs have been developed for OA patients to improve self-management through disease understanding and change of health behaviour (8). But although guidelines recommend PE programs as a core intervention (9) systematic reviews are contradictory in conclusions regarding effectiveness (10;11). Manual therapy (MT) has been proposed as an adjunct intervention for patients with hip OA (9;12) and authors of a recent systematic review of randomized clinical trials (RCT) (13) concluded that MT can currently not be implemented as an individual therapy for hip OA due to limited evidence (14). In Denmark, PE programs for hip OA patients are currently not standard care and effectiveness have to our knowledge not been tested in a research setting. Manual therapy in Denmark is offered infrequently and is dependent on clinician or therapist preference and skill. With the limited number of trials on PE and MT for hip OA, the primary aim was to examine the feasibility of a trial set-up and investigate if the chosen outcome measures were responsive in patients with hip OA from primary care in Denmark. The long term interest is in the effectiveness of PE and MT. Therefore, the current trial was designed as proof of principle to inform design of future RCTs involving PE and MT by investigating the effectiveness, in terms of pain reduction, of a PE program with or without the added effect of MT compared to a minimal control intervention (MCI). The secondary aim was to explore any benefit from the added effect of MT.

## **Methods**

### *Design*

Single-centre proof of principle three-arm parallel group randomized clinical trial.

### *Participants and setting*

Patients, recruitment procedures and exclusion criteria are published in the study protocol (15). Inclusion criteria were 1) Unilateral hip pain of more than three months duration 2) Age between 40 – 80 years 3) Radiographic hip OA defined by minimal joint space width (JSW) measurement < 2.00 mm (16) or a side difference in minimal JSW > 10% 4) Able to speak and read Danish. To include patients with onset of or mild hip OA, patients were referred from primary care to the Department of Orthopaedic Surgery and Traumatology at Odense University Hospital, Denmark either with a working diagnosis of clinical hip OA or with a confirmed diagnosis of radiographic hip OA. Recruitment was from general medical practitioners (GP) and chiropractors on the island of Funen, Denmark. A small proportion of patients were referred from outpatient clinics at Department of Orthopaedic Surgery and Traumatology on Funen following initiation of the study. Radiographs were assessed by the principle investigator and in cases with diagnostic uncertainty the professor of orthopaedic surgery was consulted. The study was approved by the regional ethics committee of Southern Denmark, approval number S-20080027 and the Danish Data Protection Agency, J.nr.2008-41-1910. Patients received written and oral information and signed an informed consent form.

During the first two months of recruitment three exclusion criteria were added to the original criteria. 1) Referred patients were already receiving manual therapy so exclusion was implemented for patients who had had manual therapy within the last twelve months. 2) On the primary outcome scale patients were rating pain severity as 1 or 2 on an eleven-box numerical rating scale (NRS) so in order to avoid a large floor effect exclusion was implemented when pain intensity was rated < three. 3) Patients were referred with

pain complaints from multiple anatomic sites: knees, ankles, hands, shoulders, low back and neck so exclusion was implemented for patients with a definition of polyarthritis defined as having osteoarthritis like symptoms from more than three anatomic areas.

### *Randomization*

Patients were randomized to one of three groups. One receiving a PE program, another receiving the PE program and MT. The third group received the MCI. The randomization sequence with block sizes of three, six or nine was computer generated by a person not otherwise involved in the study and contained three letters referring to each intervention group. To ensure sufficient patients in each PE program for group interaction, intervention was initiated when enough eligible patients were referred from primary care. The requirement was a minimum of three patients for each of the two PE groups. This would correspond with the period of 6 weeks intervention when a new cohort of patients would initiate treatment. On day of randomization sealed opaque envelopes were generated for the corresponding number of patients meeting for completion of patient reported outcomes and randomization. Envelopes were generated by another person not otherwise involved in the study. The person was contacted by the principle investigator (PI) by phone with number of patients meeting inclusion criteria and envelopes were created from the randomization sequence. The envelopes were handed to the project nurse who brought them to the physical location for completion of patient reported outcomes. On the day following completion of patient reported outcome measures, patients would select an envelope from the stack of envelopes. The envelope was opened in front of the project nurse and appointments were made to the appropriate groups. If patients were allocated to the MCI group the project nurse handed patients the sheet with exercises from the PE program followed by 5-10 minutes instruction. The project nurse was not involved in assessment of patients.

### *Follow-up time points and blinding*

Assessment of patients was performed at baseline, 6-weeks (immediately after intervention period) and at 3- and 12- months. Assessments at all time points were in the form of self-reported patient questionnaires and a physical examination identical to the baseline examination. Baseline questionnaires were completed at the university hospital on day of randomization. At subsequent time points questionnaires were mailed to patients prior to appointments for the physical examination. They were brought in a sealed envelope to the physical examination assessor, a trained physiotherapist who performed all examinations at all time points. Patients were instructed not to reveal group allocation to the physiotherapist at any time but this proved difficult and group allocation was revealed for the majority of patients. Due to the nature of interventions patients and care providers were not blinded to allocation.

### *Interventions*

Protocols for the PE program, MT and MCI are attached in appendix 1. The PE program, originally termed “hip school” was taught by a physiotherapist with eleven years experience in orthopaedic hospital departments involving aspects of patient education and rehabilitation. The person was selected by administrative staff at the hospital’s Rehabilitation Unit and was not identical to the physiotherapist performing the clinical examination. Specific training in teaching the program was obtained prior to study initiation. The hip school included two individual sessions and three group sessions (17). The MT was administered by the PI, a chiropractor with 20 years of clinical experience in primary care and 8 years of special clinical and research interest in patients with hip OA. Selection was for allowing optimal effectiveness of the manual therapy. MT was planned twice a week for the 6 weeks intervention period. Treatment was individualized to each patient dependant on physical examination findings. Instructions for the MCI were administered by the project nurse. She was selected due to prior experience with research projects.

### *Outcome measures*

The primary outcome was pain severity rated on an eleven-box NRS measured after 6-weeks of intervention. Patients were asked to rate their worst pain experience during the last week. The primary end point for the maximum effectiveness of PE and MT was determined as a 17 percentage point reduction in pain reported by the patient immediately following the six weeks intervention period. The scale is recommended and documented as valid and responsive in chronic pain patients (18;19).

The original protocol registered with [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01039337) (NCT01039337) listed two primary outcomes; pain severity and physical function. Due to CONSORT recommendations and to avoid multiplicity of analysis pain severity was selected as the sole primary outcome as published in the study protocol (15).

Secondary outcome measures were the Hip disability and Osteoarthritis Outcome Score (HOOS), patients' perceived global effect of interventions (PGE), passive hip range of motion (ROM), use of pain medication at 12 months and hip replacement surgery within the 12 month follow-up period. The HOOS includes five subscales 1) pain 2) other symptoms 3) function in daily living (ADL) 4) function in sport and recreation (Sport/rec.) and 5) hip related quality of life (QoL) (20). Scoring of HOOS is on a five-point Likert scale and converted into a 0-100 worst to best scale. HOOS is considered valid and responsive in hip patients receiving PE and total hip replacement (21). Patients' perceived global effect of interventions is rated on a seven-point Likert scale ranging from "much worse" to "much better" with "no change" being the neutral response. It is tested reliable in patients with musculoskeletal conditions (22). Hip ROM was measured with a standard hand-held two arm goniometer to the nearest five degrees. The outcome assessor was a physiotherapist not otherwise involved in assessment of patients. This person also made patient appointments for the initial clinical and radiographic examinations. The ranges of flexion, abduction, adduction, internal and external rotation were measured following a standardized protocol. A reproducibility study of the ROM measurements was conducted involving 51 patients at either 6-weeks or 12-months follow-up. The intraclass correlation coefficient ( $ICC_{1,0}$ )(23) ranged from 0.73 – 0.93 with narrow

95% confidence intervals and standard error of the measurements ( $SEM_{\text{agreement}}$ )(24) ranging between 1.1 – 6.1. Use of pain medication was dichotomized into yes/no as half the patients did not record usage of pain medication. Hip surgery at 12-month follow-up was dichotomized into yes/no. The original protocol listed a patient specific functional scale as a secondary outcome and required patients to prioritize and rank up to three activities. The outcome was excluded from the analysis as patients had difficulties prioritising one individual activity from another.

#### *Adverse events*

A standardized questionnaire was used to assess adverse reaction or unintended effect to interventions in any of the three groups. Questions included: 1) Location 2) Severity 3) Onset 4) Duration 5) Influence on ADL. In the PE group the physiotherapist would ask patients at the last individual session. In the PE/MT group the PI would ask patients at their last MT session and in the MCI group a research secretary would call patients the week following the 6-weeks intervention. Adverse events were collected for 50% of patients as the benefit of including this information was recognized half way into the trial.

#### *Sample size*

In patients with hip OA the MCI for pain is estimated to -15.3 on a 0-100 scale (25). So with a conservative estimate, we aimed at demonstrating a statistically significant difference of 17 percentage points on the primary outcome after treatment with a 5% significance level and 80% power between the group of PE vs. MCI and PE/MT vs. MCI, 30 patients needed to be included in each group assuming a joint normal distribution for baseline and 6-weeks follow-up with a correlation of 0.3 and equal variances. Allowing for a 15% drop out per group it was decided to include a minimum of 106 patients.

### *Statistical analyses*

Double data entry was done by a person not otherwise participating in the study. The primary statistical analysis was performed with respect to the change over the 6-week intervention period as the largest treatment effect was expected at this time point. The group differences in pain severity were analyzed using ANCOVA with adjustment for baseline values with a significant level of 0.05. The pre-specified pair-wise comparisons between the two active treatments and the MCI were analyzed using the Dunnett's test which does not require the ANCOVA omnibus test to be significant. A post-hoc secondary exploratory analysis of the difference between the PE group and PE/MT was performed using Bonferroni corrected ANCOVA. The secondary statistical analysis included the same approach as described above for all the secondary outcomes involving continuous data.

In addition, a longitudinal analysis of the primary and secondary outcomes, incorporating data from baseline, 6-weeks, 3-months and 12-months, was conducted using a linear mixed model approach. The p-values of the two comparisons with the MCI group were again based on the Dunnett's test. Binary outcomes, use of pain medication and hip surgery at 12 months, were analysed by pair-wise application of Fisher's exact. Effect sizes reporting Cohen's d including 95% CIs are displayed for the comparisons: PE and MCI, PE/MT and MCI, PE and PE/MT. Due to few numbers of drop outs, decision was made not to use multiple imputation model for missing data as described in the protocol.

PGE was categorized into 1) better and 2) no change. Statistical software used for analyses was Stata 12 software (StataCorp, Texas, USA).

### **Results**

Three-hundred and thirty-one patients were referred from December 2008 to May 2010. Inclusion ended when the target sample of 106 was surpassed in mid May 2010. Patient flow through the study is illustrated in figure 1. Two-hundred and eighty-eight were referred from GPs, 22 from chiropractors, 15 by orthopaedic

surgeons and six patients contacted the project directly. Two-hundred and thirteen were excluded. Reason and numbers for exclusion are listed in appendix 2. One-hundred and eighteen were randomized into the three groups. On the day of randomization, four patients were excluded; three presented with bilateral hip pain and one with lower leg neuropathy. Patients were contacted by phone and informed of exclusion. On the day of first appointment for the MT, three patients were further excluded; one did not have clinical signs of hip OA and two had polyarthrititis. In order not to disrupt the sequence of randomization, each letter from the seven excluded was re-entered into the sequence and thus, a total of 111 patients were included in the analyses at the primary end point at six weeks. Patient characteristics at baseline for all participants are presented in table 1. Of the 71 patients initiating the two PE programs, 10 missed one group session, one missed two sessions and four missed the second personal interview. Thirty-five patients initiated the MT intervention, 33 received all 12 sessions, one received 11 sessions and one withdrew feeling worse from the treatment after 7 sessions.

At 6-weeks follow-up nine patients (8.1%) had withdrawn. Number of patients per group, mean age and duration of symptoms are presented in table 2. One in the PE group due to lack of commitment, four in the PE/MT group: one felt the group was too time-consuming, one wanted hip surgery, one had surgery for another unrelated health reason and one got worse from the MT. Mean age of patients withdrawing were 71.8 (SD 3.3) and pain severity on the NRS score 5.8 (SD 2.2). In the MCI group, three were discontent with group allocation and one wanted hip surgery. Mean age of patients withdrawing were 63.2 (SD 11.0) and pain severity on the NRS score 6.5 (SD 1.7). Overall, no statistically significant differences were found between patients withdrawing and patients completing the trial for age, duration of symptoms or for pain severity. At three months one patient from the PE group (0.9%) had withdrawn due to hip surgery. and between three and twelve months 20 (18%) had withdrawn for hip surgery. Final one year follow-up for patient reported and clinical outcome measures ended June 2011.

Patients who dropped out were significantly worse at the 12-month follow-up for pain severity ( $p=0.005$ ), duration of symptoms ( $p=0.04$ ) and use of medication ( $p=0.002$ ). All drop-outs between the 6 weeks and 12 months follow-ups were due to hip surgery (PE=12, PE/MT=4 and MCI=7).

### *Primary outcome*

At the primary end point (6 weeks) no overall statistically significant differences were found between all three groups for pain severity ( $p=0.058$ , ANCOVA). However, the PE/MT group was able to reduce pain severity with -1.9 points on the 11-point NRS in comparison to the MCI (95% CI -2.9 – -0.9),  $p<0.05$ . No difference was found between the PE and MCI group (95% CI -1.0 – 1.0),  $p>0.05$ . Effect size (Cohen's  $d$ ) between PE/MT and MCI was 0.92 (95% CI 0.41 – 1.42) and 0.02 (-0.49 – 0.46) between PE and MCI. Group means with SDs are presented in table 3. Mean change scores from baseline to each follow-up point including SDs, mean differences with 95% CIs and significance levels and effect sizes including 95% CIs are listed in table 4.

### *Secondary outcomes at 6-weeks*

Differences between all three groups were significant for the HOOS subscales Pain ( $p=0.02$ ), Sport/rec. ( $p=0.02$ ) and Hip-QoL ( $p=0.04$ ) but not for the subscales of Symptoms ( $p=0.09$ ) and ADL ( $p=0.06$ ). All HOOS subscales demonstrated statistically significant improvement for the PE/MT group when compared to the MCI group: 17 points (11-23),  $p<0.05$  for Pain; 13 points (5-20),  $p<0.05$  for Symptoms; 14 points (7-22),  $p<0.05$  for ADL; 17 points (8-25),  $p<0.05$  for Sport/rec. and 13 points (6-20),  $p=0.05$  for Hip-QoL. Mean differences between PE and MCI were small (range -4 – 1) and not significant,  $p>0.05$ . Effect sizes for HOOS subscales between PE/MT and MCI ranged between 0.75 – 1.08 with wide CIs. For ROM measurements group differences were not significant and there were no change when comparing pair-wise between PE/MT and MCI or PE and MCI,  $p>0.05$ . Group means with SDs are presented in table 3. Mean change scores

from baseline to each follow-up point including SDs, mean differences with 95% CIs and significance levels and effect sizes including 95% CIs are listed in table 4.

*Post-hoc secondary exploratory analysis of difference between PE and PE/MT groups at 6 weeks*

The combined PE/MT was able to reduce pain severity with -1.9 points on the NRS compared to PE alone 95% CI (-2.9 – -0.8),  $p < 0.05$ . The same pattern was demonstrated for all HOOS subscales. No difference between groups was found for ROM measurements. Mean differences between groups including 95% CIs and effect sizes including 95% CIs are listed in table 5.

*Pair-wise comparison between PE and MCI and PE/MT and MCI incorporating baseline, 6-weeks and 3- and 12-months*

Applying Dunnett's test to the linear mixed model the combined PE/MT group reduced pain severity on the NRS with 1.1 percentage points (-2.1 – -0.1),  $p = 0.03$  compared to the MCI group and all HOOS subscales improved in the PE/MT group in comparison with the MCI demonstrating statistically significant changes. Conversely, no differences were demonstrated for any of the ROM measurements or between PE and MCI for NRS pain, HOOS subscales or ROM measurements. Group means with SDs for 3 and 12 months are presented in table 2. Mean change scores and SDs for 3 and 12 months are presented in table 3 as well as mean differences with 95% CIs and significance levels incorporating all time points.

*Post-hoc secondary exploratory comparison between PE and PE/MT incorporating baseline, 6-weeks and 3- and 12-months*

Applying Bonferroni corrected linear mixed model for pain severity on the NRS, the reduction for the PE/MT group compared to PE alone -1.0 points but not statistically significant (-0.0 – 2.1),  $p = 0.07$ .

### *Patients' perceived global effect of intervention*

At six weeks, 76.5% of patients in the PE/MT group had classified themselves as improved compared to 22.2% in the PE group and 12.5% in the MCI group (figure 3). Statistical significance between PE/MT vs. PE and PE/MT vs. MCI were  $p < 0.0001$ .

Use of pain medication at 12 months was statistically significantly lower in the PE/MT group ( $n=10$ ) than the PE group ( $n=23$ ),  $p = 0.015$  but there was no difference between all three groups with respect to hip surgery (PE=12, PE/MT=4, MCI=7).

### *Adverse reactions or unintended effects*

Data were collected for 63 patients from September 2009 – June 2010. Questions included location of pain/discomfort, time of appearance, severity, frequency, duration and effect on ADL. The PE group reported no reaction to exercises. In the PE/MT group seven patients reported discomfort, muscle soreness or mild pain appearing up to 24 hours after MT, lasting for no more than 24 hours not effecting ADL. One reported moderate pain appearing after four weeks of therapy lasting for two weeks having some effect on ADL. One patient withdrew after four weeks of therapy reporting the therapy worsened the hip pain. In the MCI group one patient reported severe groin following two exercises in the sitting position. The pain lasted for more than two days and had a moderate effect on ADL. One reported severe pain in the low back following two standing exercises. Pain lasted for more than two days and had a moderate effect on ADL. Both patients stopped the specific exercises.

## **Discussion**

This current RCT set-up was able to demonstrate clinically relevant differences between a combined PE program and MT when compared to a simple program of exercises in hip OA patients and provides a useful framework for further studies. Results of the study corroborate a large effect of PE plus MT in comparison

to minimal intervention as suggested by the existing literature, whereas PE alone in comparison with the minimal intervention was only associated with a rather minimal effect. The framework will allow investigations of the effectiveness of PE and MT in future RCTs. With small group sizes the trial was able to demonstrate statistically significant pain reduction and improvement in self-assessed ADL and hip related QoL after receiving the combined PE program and MT. By comparing PE alone to the MCI and to the PE/MT, results point to MT being the active intervention.

The finding of pain reduction and improvement in activities of daily living and QoL in the group receiving PE/MT may have several explanations. First, the physical components of the MT are aimed at affecting soft tissue joint structures including musculature, tendons, ligaments and joint capsule (26). Since the protocol includes three different manual techniques; trigger point therapy, muscle energy technique and joint manipulation individual effects are unknown. But in trials including MT with documented effectiveness the consistent component is joint manipulation. Second, among practitioners of manual therapy manipulation or manipulative treatment is by definition different from mobilization. Manipulation involves high volume low amplitude (HVLA) thrusts or forceful distraction whereas mobilization passively moves the joint through its active and passive ranges of motion (27). The difference between the two is the force generated. Studies on patients with hip OA using mobilization techniques have not demonstrated effectiveness (28;29).

Vaarbakken & Ljunggren argue that the effectiveness of hip joint distraction is dependent on this force (30) and Arvidsson has demonstrated the minimum force required to affect the capsule to be minimum 400-600 Newton (31). The mechanisms of pain reduction and improvement in ADL and hip QoL are to our knowledge not investigated specifically for hip conditions. Effects of joint manipulation have been studied in the spine and alteration of pain thresholds has been documented (32) and in healthy subjects changes in inflammatory cytokines and beta-endorphins have been observed (33;34). Third, no difference was found between or within PE and MCI groups at follow-ups and since this PE program has not previously been compared to a MCI group sizes might be too small to detect a difference. Fourth, as PE programs have

documented effectiveness compared to exercise therapy in trials with less extensive exclusion criteria, this PE program could be effective in other groups of hip OA patients (11). Fifth, placebo is a possible explanation for effects in any trial but masking interventions like PE and MT is challenging. Zhang et al. in a meta-analysis have reported effect sizes of 0.37 (95% CI 0.21-0.53) for pain reduction in hip OA. Sixth, the non significant reduction in pain severity registered at 12 months for all three groups is biased as patients withdrawing for hip surgery are not included. Drop-out analysis demonstrated significantly higher levels of pain severity in this group as could be expected.

Few studies are published on MT in hip OA patients. Authors of a recent systematic review report that MT as an individual intervention should not currently be offered in practice as evidence is inconclusive due to limited number of trials (13). The recommendation is based on the one trial by Hoeksma et al. comparing MT to exercise therapy (35). They document significant improvement in pain and physical function for the group receiving MT with nine treatment sessions during a five week period. In a small study including 19 subjects with hip disability (75% diagnosed with hip OA), Vaarbakken and Ljunggren compared a forceful hip traction technique to joint mobilization and reported statistically significant improvement in the HOOS subscales Symptoms, ADL and Sport/rec. in the group receiving hip traction (30).

Several studies have examined the effect of PE programs on hip and knee OA patients. A meta-analysis by Chodosh et al. (2005) found little or no effect on pain and function of self-management programs (10). A recent RCT by Hansson et al. examined the effect of an education program on patients with hand, knee or hip OA with program content and duration similar to this one (36). At 6-months follow-up no change was reported for pain measures or functional outcomes. Allen et al. recorded no difference in pain reduction between an extensive telephoned-based self-management program including written and video material versus usual care in hip and knee OA (37). Patel et al. did not find cost effectiveness for a self management program vs. an education booklet alone in patients with hip and knee OA (38). The only study to include just hip OA patients was by Fernandes et al. (39). They compared a PE program identical to this one with a

combination of PE and exercise therapy and found no difference in pain severity between groups at 10- and 16-months follow-ups. So overall, the majority of comparable studies demonstrate similar results with limited effectiveness of PE programs in terms of pain improvement.

Strengths of this study include patients from primary care, block randomization, allocation, comparison to a minimal intervention, patient reported outcomes, the clinical setting, patient compliance and sufficient power.

The following limitations have been identified. First, the inclusion criteria of minimal JSW difference > 10% could include patients without hip OA as measuring error could contribute for the 10% difference. Included patients with minimal JSW difference > 10% and < 25% were few (n=7) and distribution was to all three groups. Influence on results are likely minimal. Second, the choice of pain severity on an NRS as the primary outcome has only been validated in patients with chronic pain and not specifically in trials with hip OA patients (18). But the scale demonstrated comparable results to the subscale HOOS-pain. Third, due to practicality and logistic issues objective measures of physical function were not incorporated, e.g. timed up and go test or timed 6 min. walk test. They are recommended as complimentary outcomes in hip and knee OA research (40;41). Fourth, the inclusion process was not optimal and resulted in excluding seven patients post-randomization interfering with the intention-to-treat principle (42). Fifth, performance bias is common in trials where physical and verbal contact are components of the interventions (43) and could contribute to the large treatment effect observed in the PE/MT group as they receive additional 12 sessions with a chiropractor. Sixth, differentiated expertise bias could account for differences between the PE and PE/MT group as the physiotherapist did not have any prior experience with the PE program or this patient group. Seventh, two randomized patients deteriorated from the time of referral to day of randomization and withdrew for surgery before initiating interventions and no follow-up data were available for the patient withdrawing due to worsening of symptoms from MT. Eighth, since adding the exclusion criteria of polyarthritis and MT within the last 12 months following study initiation, patients with the criteria could

potentially have been included prior to implementation, particularly in the MCI group. Last, the MT was administered by only one chiropractor limiting the external validity.

As proof of principle trial clinical implementations are not recommended. In future trials the following should be considered: 1) Larger trials should compare MT to PE alone and this particular PE program should be evaluated against a similar MCI. 2) Frequency and dose response of MT are appropriate to investigate as it varies in current trials. 3) Predictors for responders and not responders of MT should be included. 4) Inclusion of patients with co-morbidities and multiple sites of symptomatic OA as current trials have excluded these patients. 5) Incorporation of a number of chiropractors to deliver the MT to strengthen the external validity. 6) Incorporation of a multidisciplinary case review process when evaluating eligible patients for inclusion. 7) If interventions cannot be initiated immediately following inclusion two baseline evaluations should be implemented; one at time of initial examination and one just prior to randomization. 8) Inclusion and adherence strictly to protocols regarding blinding of patients and assessors to group allocation throughout the trial and consideration of specific education for both participants and staff involved. 9) If the patient specific functional scale is incorporated as outcome measure, patients should obtain better instructions in selecting items to get closer to individualized outcomes.

Experience and results from this trial suggest that patients currently receiving MT for the hip in primary care should be informed about possible short term discomfort, muscle soreness or mild pain following MT lasting up to 48 hours.

## **Conclusions**

The current trial set-up for patients with hip OA was able to reduce pain as primary outcome when comparing a combined intervention of two non-pharmacological treatments (patient education and manual therapy) to a minimal control intervention and improve self-reported activities of daily living and hip related

quality of life as secondary outcomes. The experience from this trial provides a strong foundation for future studies including the two interventions in different combinations.

### **Conflict of interest**

All authors declare that they have no competing interests.

### **Author contributions**

EP, HWC, ER, JH and SO participated in conception and design of the study. None of the authors participated in data collection except EP who interviewed patients receiving MT for adverse events. EP drafted the manuscript. All authors participated in interpretation of data, in critical revision of the manuscript and made important contributions to the content. All authors read and approved the final manuscript.

### **Acknowledgements**

We acknowledge physiotherapist Lisa Hargreaves for teaching the PE program, physiotherapist Bodil L. Pedersen for performing all clinical outcome assessments and project nurse Annie Gam-Pedersen for appointment-making and giving instructions to patients in the MCI group. We further thank research secretary Jytte Johannesen for graphic design of patient information and questionnaires, Eleanor Boyle for performing the statistical analyses and Gert Brønfort for valuable assistance with the final manuscript. The Danish Rheumatism Association for providing graphic illustrations of the exercise sheet used in the PE program and a special thank you to all participating patients for making the study possible.

## Funding

The study was funded by the Danish Foundation for Chiropractic Research and Postgraduate Education, Region of Southern Denmark, The Danish Rheumatism Association, University of Southern Denmark, Odense University Hospital and Nordic Institute of Chiropractic and Clinical Biomechanics.

## Reference List

1. Murphy LB, Helmick CG, Schwartz TA, Renner JB, Tudor G, Koch GG, Dragomir AD, Kalsbeek WD, Luta G, Jordan JM. One in four people may develop symptomatic hip osteoarthritis in his or her lifetime. *Osteoarthritis.Cartilage*. 2010 Nov;18(11):1372-9.
2. Guccione AA, Felson DT, Anderson JJ, Anthony JM, Zhang Y, Wilson PW, Kelly-Hayes M, Wolf PA, Kreger BE, Kannel WB. The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *Am.J Public Health* 1994 Mar;84(3):351-8.
3. Dominick KL, Ahern FM, Gold CH, Heller DA. Health-related quality of life and health service use among older adults with osteoarthritis. *Arthritis Rheum*. 2004 Jun 15;51(3):326-31.
4. Nuesch E, Dieppe P, Reichenbach S, Williams S, Iff S, Juni P. All cause and disease specific mortality in patients with knee or hip osteoarthritis: population based cohort study. *BMJ* 2011;342:d1165.
5. Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis.Cartilage*. 2008 Feb;16(2):137-62.
6. Rasanen P, Paavolainen P, Sintonen H, Koivisto AM, Blom M, Ryyanen OP, Roine RP. Effectiveness of hip or knee replacement surgery in terms of quality-adjusted life years and costs. *Acta Orthop*. 2007 Feb;78(1):108-15.
7. Franklin J, Ingvarsson T, Englund M, Ingimarsson O, Robertsson O, Lohmander LS. Natural history of radiographic hip osteoarthritis. A retrospective cohort study with 11-28 years follow-up. *Arthritis Care Res.(Hoboken.)* 2011;63(5):689-95.
8. Koehn CL, Esdaile JM. Patient education and self-management of musculoskeletal diseases. *Best.Pract.Res.Clin.Rheumatol*. 2008 Jun;22(3):395-405.
9. National Collaborating Centre for Chronic Conditions. Osteoarthritis: national clinical guidelines for care and management in adults. London: Royal College of Physicians; 2008.

10. Chodosh J, Morton SC, Mojica W, Maglione M, Suttorp MJ, Hilton L, Rhodes S, Shekelle P. Meta-analysis: chronic disease self-management programs for older adults. *Ann.Intern.Med.* 2005 Sep 20;143(6):427-38.
11. Walsh NE, Mitchell HL, Reeves BC, Hurley MV. Integrated exercise and self-management programmes in osteoarthritis of the hip and knee: a systematic review of effectiveness. *Phys Ther Rev* 2006;11:289-97.
12. Guideline for the non-surgical management of hip and knee osteoarthritis. The Royal Australian College of General Practitioners. 2009 [cited 2011 Oct 4] Available from [http://www.racgp.org.au/Content/NavigationMenu/ClinicalResources/RACGPGuidelines/Guidelineforthenonsurgicalmanagementofhipandkneeosteoarthritis/RACGP\\_OA\\_guideline.pdf](http://www.racgp.org.au/Content/NavigationMenu/ClinicalResources/RACGPGuidelines/Guidelineforthenonsurgicalmanagementofhipandkneeosteoarthritis/RACGP_OA_guideline.pdf).
13. French HP, Brennan A, White B, Cusack T. Manual therapy for osteoarthritis of the hip or knee - A systematic review. *Man.Ther* 2011 Apr;16(2):109-17.
14. OCEBM Levels of Evidence Working Group\*. "The Oxford 2011 Levels of Evidence". Oxford Center for Evidence-Based Medicine. 2011 [cited 2011 Nov 18] Available from <http://www.cebm.net/index.aspx?o=5653>.
15. Poulsen E, Christensen HW, Roos EM, Vach W, Overgaard S, Hartvigsen J. Non-surgical treatment of hip osteoarthritis. Hip school, with or without the addition of manual therapy, in comparison to a minimal control intervention: Protocol for a three-armed randomized clinical trial. *BMC.Musculoskelet.Disord.* 2011;12:88.
16. Jacobsen S, Sonne-Holm S, Soballe K, Gebuhr P, Lund B. Radiographic case definitions and prevalence of osteoarthrosis of the hip: a survey of 4 151 subjects in the Osteoarthritis Substudy of the Copenhagen City Heart Study. *Acta Orthop Scand.* 2004 Dec;75(6):713-20.
17. Klassbo M, Larsson G, Harms-Ringdahl K. Promising outcome of a hip school for patients with hip dysfunction. *Arthritis Rheum.* 2003 Jun 15;49(3):321-7.
18. Farrar JT, Young JP, Jr., LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001 Nov;94(2):149-58.
19. Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, Kerns RD, Stucki G, Allen RR, Bellamy N, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain* 2005 Jan;113(1-2):9-19.
20. Nilsson AK, Lohmander LS, Klassbo M, Roos EM. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. *BMC.Musculoskelet.Disord.* 2003 May 30;4:10.
21. Klassbo M, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. *Scand.J Rheumatol.* 2003;32(1):46-51.
22. Kamper SJ, Ostelo RW, Knol DL, Maher CG, de Vet HC, Hancock MJ. Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. *J.Clin.Epidemiol.* 2010 Jul;63(7):760-6.

23. Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. *Psychol.Bull.* 1979 Mar;86(2):420-8.
24. de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. *J.Clin.Epidemiol.* 2006 Oct;59(10):1033-9.
25. Tubach F, Ravaud P, Baron G, Falissard B, Logeart I, Bellamy N, Bombardier C, Felson D, Hochberg M, van der HD, et al. Evaluation of clinically relevant changes in patient reported outcomes in knee and hip osteoarthritis: the minimal clinically important improvement. *Ann.Rheum.Dis.* 2005 Jan;64(1):29-33.
26. MacDonald CW, Whitman JM, Cleland JA, Smith M, Hoeksma HL. Clinical outcomes following manual physical therapy and exercise for hip osteoarthritis: A case series. *J Orthop Sports Phys Ther* 2006 Aug;36(8):588-99.
27. Peterson DH, Bergmann TF. *Chiropractic Technique: Principles and Procedures.* 2nd ed. ed. St. Louis, Missouri: Mosby, Inc.; 2002.
28. Nyfos L. [Traction therapy of osteoarthritis of the hip. A controlled study]. *Ugeskr.Laeger* 1983 Sep 12;145(37):2837-40.
29. Marques B, Toldbod M, Ostrup EL, Bentzen L, Gjorup T, Gylding-Sabroe JP, Leopold M, Riis P. [The effect of naproxen compared with that of traction in patients with osteoarthritis of the hip. A single-blind controlled study]. *Ugeskr.Laeger* 1983 Sep 12;145(37):2840-4.
30. Vaarbakken K, Ljunggren AE. Superior effect of forceful compared with standard traction mobilizations in hip disability? *Adv.Physiother.* 2007 Sep;9(3):117-28.
31. Arvidsson I. The hip joint: forces needed for distraction and appearance of the vacuum phenomenon. *Scand.J.Rehabil.Med.* 1990;22(3):157-61.
32. Fernandez-de-Las-Penas C, Alonso-Blanco C, Cleland JA, Rodriguez-Blanco C, Albuquerque-Sendin F. Changes in pressure pain thresholds over C5-C6 zygapophyseal joint after a cervicothoracic junction manipulation in healthy subjects. *J Manipulative Physiol Ther* 2008 Jun;31(5):332-7.
33. Teodorczyk-Injeyan JA, Injeyan HS, Ruegg R. Spinal manipulative therapy reduces inflammatory cytokines but not substance P production in normal subjects. *J.Manipulative Physiol Ther* 2006 Jan;29(1):14-21.
34. Vernon HT, Dhimi MS, Howley TP, Annett R. Spinal manipulation and beta-endorphin: a controlled study of the effect of a spinal manipulation on plasma beta-endorphin levels in normal males. *J.Manipulative Physiol Ther* 1986 Jun;9(2):115-23.
35. Hoeksma HL, Dekker J, Runday HK, Heering A, van der LN, Vel C, Breedveld FC, van den Ende CH. Comparison of manual therapy and exercise therapy in osteoarthritis of the hip: a randomized clinical trial. *Arthritis Rheum.* 2004 Oct 15;51(5):722-9.
36. Hansson EE, Jonsson-Lundgren M, Ronnheden AM, Sorensson E, Bjarnung A, Dahlberg LE. Effect of an education programme for patients with osteoarthritis in primary care--a randomized controlled trial. *BMC.Musculoskelet.Disord.* 2010;11:244.

37. Allen KD, Oddone EZ, Coffman CJ, Datta SK, Juntilla KA, Lindquist JH, Walker TA, Weinberger M, Bosworth HB. Telephone-based self-management of osteoarthritis: A randomized trial. *Ann.Intern.Med.* 2010 Nov 2;153(9):570-9.
38. Patel A, Buszewicz M, Beecham J, Griffin M, Rait G, Nazareth I, Atkinson A, Barlow J, Haines A. Economic evaluation of arthritis self management in primary care. *BMJ* 2009;339:b3532.
39. Fernandes L, Storheim K, Sandvik L, Nordsletten L, Risberg MA. Efficacy of patient education and supervised exercise vs patient education alone in patients with hip osteoarthritis: a single blind randomized clinical trial. *Osteoarthritis.Cartilage.* 2010 Oct;18(10):1237-43.
40. Stratford PW, Kennedy DM. Performance measures were necessary to obtain a complete picture of osteoarthritic patients. *J.Clin.Epidemiol.* 2006 Feb;59(2):160-7.
41. Wright AA, Hegedus EJ, Baxter GD, Abbott JH. Measurement of function in hip osteoarthritis: developing a standardized approach for physical performance measures. *Physiother.Theory.Pract.* 2011 May;27(4):253-62.
42. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. *J.Clin.Epidemiol.* 2010 Aug;63(8):e1-37.
43. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann.Intern.Med.* 2008 Feb 19;148(4):295-309.

## **Appendix 1. Protocols for patient education (PE), manual therapy (MT) and minimal control intervention (MCI)**

*Patients in all three groups receive instruction not to initiate or alter use of pain medication or use of glucosamine products during the 6-weeks intervention period.*

### **PE**

The PE program is taught by a physiotherapist having received specific training for teaching this program. It is designed by Maria Klässbo and original text and illustrations are translated into Danish with permission (a).

The program includes a total of five sessions: one initial personal interview, three group sessions and one follow-up interview. Power point presentations and anatomic models are used as teaching aids. Each patient receives a sheet of paper with recommendations on activities of daily living (ADL) and home exercises related to balance, movement and hip stretches.

#### *Initial interview (45 minutes)*

The interview is aimed for the therapist to understand the condition from the patient's view including pain experience, influence on ADL and levels of self-motivation. Ranges of reduced hip mobility and levels of coordination and balance are assessed for targeting specific exercises.

### *Group sessions*

Purpose of group sessions is to create interaction between patients and having them share individual experiences.

#### *Group session 1 (1½ hour)*

Hip anatomy is taught including purpose of cartilage, bone, joint capsule, ligaments, muscles and blood supply. Basic epidemiology includes age and gender distribution, risk factors and natural course of the disease. Diagnosis of hip OA clinically and radiographically is explained.

#### *Group session 2 (1½ hour)*

The session is initiated by a short review. Hip muscle actions, influence of locomotion and hip mobility on maintaining a healthy joint as well as how OA affects muscle function, range of motion (ROM) and movement are explained. Advice is given on keeping an active lifestyle and activities like swimming, cycling and walking are recommended.

#### *Group session 3 (1½ hour)*

The session is initiated by a short review. The main lecture theme is pain. Which tissue is pain sensitive and what signifies pain. Discussions are initiated on self-management of pain and pros and cons of pharmacological pain management. Different non-pharmacological treatment options are covered including, acupuncture, physiotherapy and surgery.

#### *Follow-up interview (½ hour)*

The purpose of this interview is to uncover unanswered questions and to sustain patients in exercise regimes.

Exercises in the program are to be performed daily.

## **MT**

The protocol is developed by the principle investigator EP. It includes three different manual therapies; trigger point release therapy (TPPR), muscular stretching by muscle energy technique (MET) and joint manipulation.

Therapy is individualized according to examination findings of pain producing trigger points, reduced ROMs and end range assessment at each ROM. Duration of treatment sessions are 15-25 minutes twice a week for six weeks. Patients receive the three manual therapy techniques in the sequence of TPPR, MET and joint manipulation.

### *TPPR*

The aim of the TPPR is to obtain desensitisation and muscular relaxation of trigger points through digital mechanical pressure. The posterior and lateral hip muscles are palpated and trigger points are identified by locating taught and tender muscle fibres. Digital pressure is applied to trigger points until the patient senses a numbing effect of the pressure. This is normally accomplished in 1-3 minutes. The technique is described by Travell and Simons (b).

### *MET*

The aim of the MET is to obtain muscle relaxation and improve ROM through stretching. The technique initiates with the therapist taking the joint to one of its active end ranges followed by asking the patient to push the leg into the opposite direction of restriction using the antagonist muscle group. The contraction is held for 10 seconds with 20-30% of full contraction. The therapist resists this movement to achieve an

isometric contraction. This is immediately followed by an agonist contraction into the direction of resistance with the therapist assisting this movement to a “new” end range. This procedure is repeated three times ended by keeping the final position for 10 seconds. MET is applied for directions of ROM affected and can be applied to a specific ROM or coupled movements (e.g. combined flexion, abduction and external rotation). The technique is described by Chaitow (c).

### *Joint manipulation*

The aim of joint manipulation is to affect hip musculature and joint capsule through forceful distraction also known as high volume low amplitude (HVLA) thrusts. The therapist places the joint in individual or combined ROMs which are evaluated to be affected by reduced ROM or altered end-play feel. At end range of joint movement the joint is distracted and a HVLA thrust is applied using manual force. Combined movements are flexion with internal rotation, flexion with external rotation or flexion with translatory abduction. Manipulations can be assisted by a “drop” mechanism of the treatment table. A section of the table under the pelvic/hip region is activated and raised 2-3 cm with a spring load (tension) mechanism. The level of tension can be set pending the weight of the patient and the force applied by the therapist. Three different techniques are directed at distracting the joint. One places the leg in a position of 10-15 degrees abduction and 20-30 degrees flexion. The other in a “loose packed” position of 25-35 degrees of abduction, 20-30 degrees of flexion and 30-40 degrees of external rotation. The third in a position with 20-25 degrees of abduction and 0-10 degrees of flexion with the knee in slight flexion. To achieve distraction of the hip joint the therapist’s hands are placed either around the distal ankle or distal femur. The technique is described by Peterson and Bergmann (d). Each manipulation can be applied 1-3 times pending evaluation of the therapist.

## **MCI**

Patients receive a pamphlet advising not to initiate or alter use of pain medication, NSAID or glucosamine products during the intervention period and instructions not to initiate other treatment for their hip in the same period. The pamphlet includes the sheet with exercises from the PE group and patients receive a 5-10 minutes instruction on the exercises.

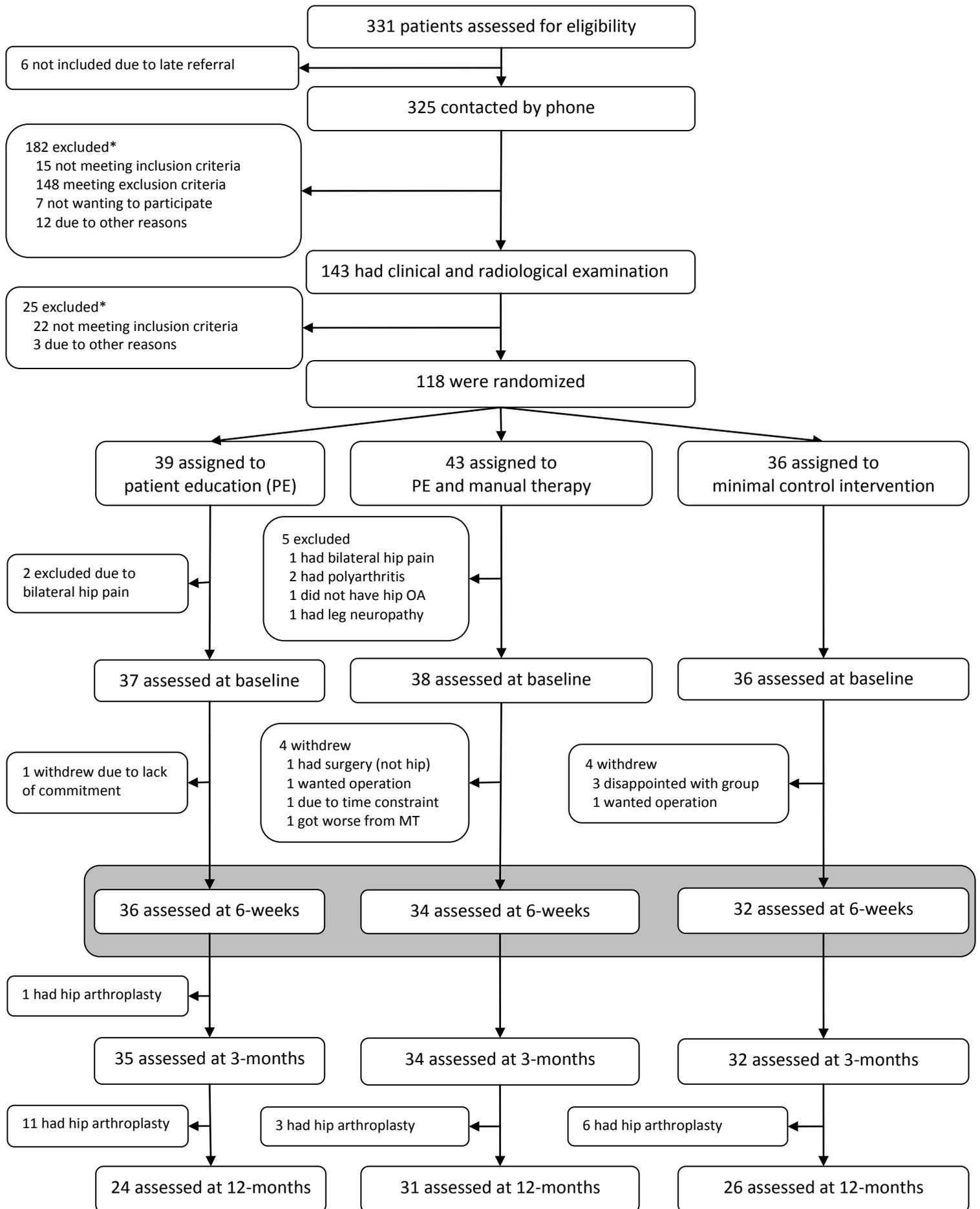
a. Klassbo M, Larsson G, Harms-Ringdahl K. Promising outcome of a hip school for patients with hip dysfunction. *Arthritis Rheum.* 2003 Jun 15;49(3):321-7.

b. Simons DG, Travell JG, Simons LS. General Overview. In *Myofascial Pain and Dysfunction, The Trigger Point Manual*, volume 1. Upper Half of Body. second edition ed. Williams & Wilkins; 1999. p. 11-93.

c. Chaitow L. MET and the treatment of joints. In *Muscle Energy Technique*. 2 ed. Edinburgh: Churchill Livingstone; 2001. p. 159-95.

d. Peterson DH, Bergmann TF. *Chiropractic Technique: Principles and Procedures*. 2nd ed. ed. St. Louis, Missouri: Mosby, Inc.; 2002.

**Figure 1. Chart of patient enrolment and randomization. Primary end point indicated at six weeks.**



\*List of excluded patients is specified in appendix 2

Shaded area indicates primary end point for primary outcome

## Appendix 2. Non-included or excluded patients prior to randomization

Reason for exclusion	(n)
Not meeting inclusion criteria	37
- Age < 40 or > 80 years	12
- Hip pain < 3 months	2
- No radiographic OA	22
- Not able to read or write Danish	1
Meeting exclusion criteria	148
- Bilateral hip pain	45
- Low back pain > hip pain	18
- Hip dysplasia: Center edge angle < 25 and AA angle > 10	14
- Polyarthritis	11
- Indication of hip surgery expected within 6 months	7
- Manual therapy < 12 months	20
- Previous hip or knee arthroplasty	8
- Severe cerebrovascular disease	3
- Lower leg neuropathy	2
- Malignancies	2
- Rheumatoid arthritis	1
- Local knee pain on same side of hip pain	2
- Pain severity < 3 on a numerical rating scale	8
- Other condition than hip OA appearing to be the cause of pain	
- Spinal stenosis	5
- Trochanteric bursitis	2
Not wanting to participate	7
Other reasons, n = 15	15
- Outside of recruitment area	10
- Contraindication for manual therapy	2
- Not able to perform exercises due to severe asthma	1
- Fear of hospitals	1
- BMI > 45	1
Referral after end of inclusion	6

**Table 1. Patient characteristics at baseline for patients with hip OA treated with patient education, patient education and manual therapy compared to a minimal control intervention.**

	Patient education*	Patient education + manual therapy*	Minimal control intervention*
Number of patients per group	<b>37</b>	<b>38</b>	<b>36</b>
Age (years), mean (SD)	65.5 (7.3)	65.8 (8.5)	62.5 (9.4)
Gender (female), n (% within group)	14 (38)	17 (45)	17 (47)
BMI (kg/m <sup>2</sup> ), mean (SD)	27.4 (3.4)	26.3 (3.6)	26.7 (4.2)
- BMI ≤ 25, n (% within group)	9 (23.7)	15 (39.5)	14 (36.8)
- BMI > 25, n (% within group)	28 (38.4)	23 (31.5)	22 (30.1)
Involved side right/left (n)	17 / 20	26 / 12	24 / 12
Duration of symptoms (months) mean (SD)	32 (25)	26 (26)	37 (50)
- Range (months)	6 – 96	4 – 120	4 – 300
Minimal JSW for involved joint (mm) mean (SD)	1.46 (1.11)	1.56 (1.05)	1.61 (1.11)
Minimal JSW < 2.00 (n)	26	27	23
Minimal JSW difference > 25% (n)	9	10	9
Minimal JSW difference < 25% and > 10% (n)	2	1	4
Pain medication, n (% within group)	20 (54)	16 (42)	15 (42)
Employed (n)	12	14	18
Unemployed (n)	0	0	1
Retired (n)	24	24	17
Health related pension (n)	1	0	0
Current sick leave due to the hip (n)	0	0	1
<i>Recruitment</i>			
GP, n (% within group)	33 (89.2)	31 (81.6)	30 (83.3)
Chiropractor, n (% within group)	3 (8.1)	5 (13.2)	4 (11.1)
Orthopaedic surgeon, n (% within group)	0	0	1 (2.8)
Self referral, n (% within group)	1 (2.7)	2 (5.3)	1 (2.8)

\*no significance between groups, p>0.05

**Table 2. Drop-out characteristics at 6-weeks. Numbers, mean and SD.**

	<b>PE*</b>	<b>PE/MT*</b>	<b>MCI*</b>
Numbers per group	1	4	4
Age, mean (SD)	56	71.8 (3.3)	63.2 (11.0)
Pain severity, mean (SD)	7	5.8 (2.2)	6.5 (1.7)

PE = Patient education, MT = Manual therapy, MCI = Minimal control intervention

**Table 3. Mean scores of pain, HOOS and ROM at baseline, 6 weeks, 3 and 12 months for the 3 intervention groups: PE\*, PE/MT\* and MCI\*. Means, SD.**

Variable	PE	PE/MT	MCI
<b>Mean NRS pain score</b>			
Baseline	5.1 (2.0)	5.4 (2.4)	5.8 (1.6)
6 weeks	5.3 (2.3)	3.4 (2.4)	5.3 (1.7)
3 months	5.5 (2.5)	4.0 (2.2)	5.6 (2.0)
12 months	4.9 (2.5)	4.0 (2.5)	4.6 (2.2)
<b>Mean HOOS-pain</b>			
Baseline	64 (14)	62 (17)	59 (14)
6 weeks	64 (16)	80 (16)	64 (13)
3 months	64 (18)	76 (16)	61 (17)
12 months	66 (21)	77 (15)	69 (15)
<b>Mean HOOS-symptoms</b>			
Baseline	62 (17)	61 (18)	59 (15)
6 weeks	61 (19)	76 (18)	63 (16)
3 months	59 (20)	74 (17)	58 (18)
12 months	64 (25)	72 (17)	67 (18)
<b>Mean HOOS-ADL</b>			
Baseline	68 (15)	68 (20)	64 (15)
6 weeks	69 (18)	84 (16)	70 (15)
3 months	69 (18)	80 (17)	66 (18)
12 months	69 (21)	79 (16)	73 (17)
<b>Mean HOOS-Sport/rec.</b>			
Baseline	53 (22)	55 (21)	49 (21)
6 weeks	56 (23)	76 (20)	60 (18)
3 months	54 (23)	73 (19)	55 (18)
12 months	60 (26)	69 (21)	54 (16)
<b>Mean HOOS-QoL</b>			
Baseline	53 (18)	52 (17)	46 (12)
6 weeks	51 (18)	64 (17)	51 (12)
3 months	52 (20)	62 (16)	49 (17)
12 months	56 (22)	59 (15)	54 (16)
<b>Mean ROM -flexion</b>			
Baseline	106 (15)	105 (13)	109 (13)
6 weeks	106 (14)	110 (13)	113 (11)
3 months	107 (13)	111 (13)	110 (13)
12 months	107 (16)	109 (18)	113 (11)
<b>Mean ROM abduction-adduction</b>			
Baseline	41 (8)	41 (8)	42 (9)
6 weeks	40 (8)	44 (8)	42 (8)
3 months	41 (9)	44 (9)	42 (9)
12 months	43 (9)	45 (7)	43 (10)
<b>Mean ROM internal-external rotation</b>			
Baseline	64 (15)	65 (14)	65 (12)
6 weeks	67 (17)	67 (18)	71 (11)
3 months	64 (18)	71 (14)	69 (12)
12 months	67 (16)	69 (13)	68 (12)

PE = Patient education, MT = Manual therapy, MCI = Minimal control intervention

**Table 4. Change scores for each group from baseline to 6 weeks and 12 months, and mean differences and effect sizes of pain, HOOS and ROM at 6 weeks and 12 months for PE\* versus MCI and PE/MT\* versus MCI\*. Means, SD, mean differences, 95% CIs, significance levels, effect sizes and 95% CIs.**

Variable	PE (SD)	PE/MT (SD)	MCI (SD)	Difference, PE vs. MCI (95% CI)	P value	Effect size (95% CI)	Difference, PE/MT vs. MCI (95% CI)	P value	Effect size (95% CI)
<b>NRS</b>									
6 weeks	0.3 (1.9)	-1.9 (2.3)	-0.3 (1.5)	-0.0 (-1.0 – 0.9)	>0.05	-0.02 (-0.49 – 0.46)	-1.9 (-2.9 – -0.9)	<0.05	-0.92 (-1.42 – -0.41)
12 months	0.5 (2.3)	-1.2 (2.7)	-1.0 (2.0)	-0.1 (-1.1 – 0.9)	0.97		-1.1 (-2.1 – -0.1)	0.03	
<b>HOOS-pain</b>									
6 weeks	-1 (11)	18 (13)	3 (13)	0.7 (-6 – 7)	>0.05	0.01 (-0.47 – 0.49)	17 (11 – 23)	<0.05	1.08 (0.56 – 1.59)
12 months	-3 (13)	13 (19)	8 (11)	2 (-6 – 9)	0.84		10 (3 – 18)	0.01	
<b>HOOS-symptoms</b>									
6 weeks	-1 (15)	15 (15)	4 (11)	-2 (-10 – 5)	>0.05	-0.13 (-0.61 – 0.34)	13 (5 – 20)	<0.05	0.75 (0.25 – 1.25)
12 months	-2 (17)	9 (16)	8 (13)	-1 (-9 – 8)	0.98		8 (0 – 16)	0.0498	
<b>HOOS-ADL</b>									
6 weeks	1 (10)	15 (16)	5 (13)	0 (-7 – 6)	>0.05	-0.05 (-0.53 – 0.42)	14 (7 – 20)	<0.05	0.85 (0.34 – 1.36)
12 months	-3 (13)	10 (19)	7 (13)	1 (-8 – 9)	0.98		9 (1 – 17)	0.02	
<b>HOOS-Sport/rec.</b>									
6 weeks	2 (14)	21 (18)	11 (18)	-4 (-12 – 4)	>0.05	-0.20 (-0.67 – 0.28)	17 (8 – 25)	<0.05	0.87 (0.36 – 1.37)
12 months	-1 (16)	11 (22)	7 (19)	-1 (-11 – 9)	0.93		12 (2 – 22)	0.02	
<b>HOOS-QoL</b>									
6 weeks	-2 (11)	12 (18)	4 (10)	1 (-6 – 7)	>0.05	0.04 (-0.44 – 0.52)	13 (6 – 20)	<0.05	0.88 (0.37 – 1.38)
12 months	-4 (18)	6 (17)	6 (13)	3 (-5 – 11)	0.60		10 (2 – 17)	0.01	
<b>ROM -flexion</b>									
6 weeks	-1 (11)	-6 (15)	-3 (7)	-7 (-12 – -1)	<0.05	-0.54 (-1.03 – 0.04)	-3 (-9 – 2)	>0.05	-0.26 (-0.75 – 0.23)
12 months	-1 (12)	-5 (16)	-2 (10)	-5 (-11 – 2)	0.19		-3 (-8 – 3)	0.49	
<b>ROM abduction-adduction</b>									
6 weeks	1 (6)	-3 (7)	1 (8)	-2 (-6 – 1)	>0.05	-0.29 (-0.77 – 0.20)	2 (-1 – 5)	>0.05	0.25 (-0.25 – 0.74)
12 months	-4 (5)	-3 (8)	1 (8)	-1 (-5 – 3)	0.71		1 (-3 – 5)	0.78	
<b>ROM internal-external rotation</b>									
6 weeks	-3 (9)	-2 (13)	-4 (12)	-4 (-10 – 2)	>0.05	-0.29 (-0.78 – 0.20)	-4 (-11 – 2)	>0.05	-0.28 (-0.78 – 0.22)
12 months	0 (9)	-4 (11)	0 (11)	-3 (-10 – 4)	0.62		0 (-7 – 7)	0.99	

PE = Patient education, MT = Manual therapy, MCI = Minimal control intervention

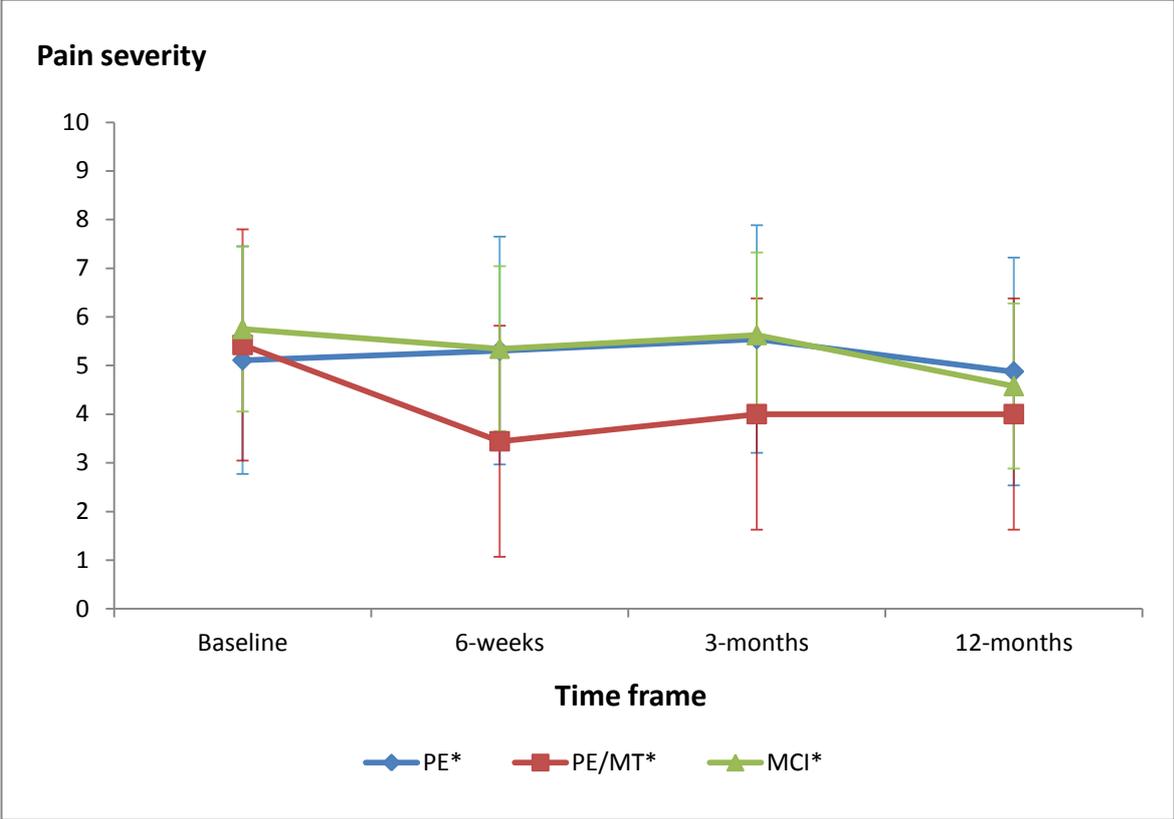
**Table 5. Mean difference and effect size for NRS, HOOS and ROM at 6 weeks between PE\* and PE/MT\*, mean differences, 95% CIs, significance levels, Cohen’s d and 95% CIs.**

Variable	Mean difference, PE vs. PE/MT (95% CI)†	P value	Effect size (95% CI)
NRS pain	-1.9 (-2.9 – -0.8)	<0.05	0.79 (0.30 – 1.27)
HOOS-pain	16 (10 – 23)	<0.05	0.97 (0.47 – 1.46)
HOOS-symptoms	15 (7 – 23)	<0.05	0.82 (0.33 – 1.30)
HOOS-ADL	14 (7 – 21)	<0.05	0.84 (0.34 – 1.32)
HOOS-Sport/rec.	21 (12 – 30)	<0.05	0.94 (0.45 – 1.44)
HOOS-QoL	12 (5 – 20)	<0.05	0.72 (0.23 – 1.20)
ROM flexion	4 (-2 – 9)	>0.05	0.28 (-0.20 – 0.75)
ROM abduction-adduction	4 (0 – 8)	<0.05	0.53 (0.04 – 1.00)
ROM internal-external rotation	0 (-6 – 7)	>0.05	0.01 (-0.49 – 0.46)

\*PE = Patient education, MT = Manual therapy

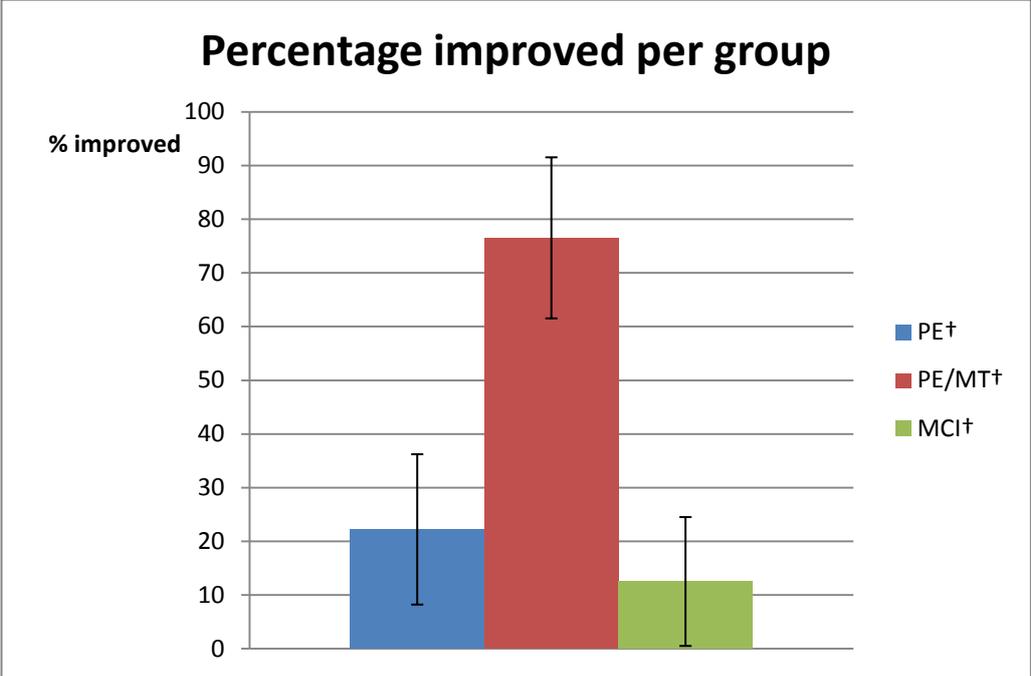
†Based on ANCOVA, bonferroni corrected

**Figure 2. Pain severity on an 11-box numeric rating scale at baseline, 6-weeks, 3- and 12-months including SDs.**



PE = Patient education, MT = Manual therapy, MCI = Minimal control intervention

**Figure 3. Global perceived effect of interventions. Percentage of patients per group categorized\* as improved including 95% confidence intervals.**



\*Improved (much better and better). Not improved (little better, no change, little worse, worse and much worse)

† PE = Patient education, MT = Manual therapy, MCI = Minimal control intervention