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OPTIMIZATION OF CARE IN ORTHOPAEDICS AND NEUROSURGERY

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OPTIMIZATION OF CARE IN ORTHOPAEDICS AND NEUROSURGERY

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Chapter 1

General introduction

Many decisions are made in health care. For example when a patient is diagnosed with a certain disease, the patient and health care provider are facing multiple decisions. One of these decisions for some musculoskeletal non-acute conditions, is to choose between non-surgical and surgical treatments. Surgery is then often not the first treatment of choice. Initial treatment includes non-surgical treatments and surgery is only considered if the patient does not respond sufficiently to non-surgical treatment. In the ideal world, all recommended non-surgical treatments for these conditions would be used first and surgery is only performed when non-surgical treatments are not effective enough to reduce the patient's complaints. However, decision making in daily practice is far more complex and the decision to continue non-surgical treatments or to perform surgery needs to be customized, such as in Mary's case.

Mary (45) suffers from pain and loss of function due to clinical and radiological osteoarthritis (OA) in her right knee. She is divorced, lives with her two children (8 and 10 years old) in an apartment on the third floor without an elevator. She is not able to work as a cleaning lady anymore. Her supervisor prefers that she receives a total knee arthroplasty (TKA), so that she can go back to work earlier. She is obese (Body Mass Index 37) and her general practitioner (GP) advices her to visit a dietician and a physical therapist to lose weight and exercise, which may reduce her complaints. However, her health insurance company does not cover visits at the dietician or the physical therapist and she cannot afford to pay for these visits herself. She uses painkillers every day, but these do not relieve the pain sufficiently. Her neighbor had a TKA and told her that it relieves the pain and improved his function. Therefore, she asks her GP to refer her to an orthopaedic surgeon for a TKA. The orthopaedic surgeon listens to Mary's story and finds it difficult to decide. She did not receive all recommended non-surgical treatments as described in guidelines (e.g. physical therapy, dietary advices) and he prefers to follow these guidelines. He also knows that the lifespan of a prosthesis is limited. Mary is only 45 years old and if she reach the average life expectancy it is certain that she needs a revision in the future with less successful outcomes. She tells him that she has no choice and needs a quick solution since she cannot work, climb the stairs to her apartment or take care of her children. If he does not perform the surgery, she will ask his colleague in another hospital to perform the surgery.

Mary's case shows that there are multiple factors involved in the decision making regarding the choice between different treatments, in this case non-surgical versus surgical treatment. Due to all these different factors, variation in health care may exist, meaning that the provided care differs for patients with similar health problems [1]. Sometimes variation in health care is desirable [1] as a consequence of disease severity, duration of complaints or preferences of the patient, such as in Mary's case. In this case the decision to continue non-surgical treatments or to perform surgery care needs to be customized. However, unwarranted practice variation also exists. For example when receiving surgery depends on the patient's geographical region. Research has shown that patients in regions with a relative high number of medical specialists receive more treatments [2]. Such practice variation is often a sign of suboptimal care [3]. National and international initiatives for reducing practice variation emphasize the importance to search for possible strategies to optimize health care and thereby reduce unwarranted practice variation.

Hip and knee OA and sciatica are both non-acute conditions in which the decision of non-surgical versus surgical treatment is complex. This is not only illustrated by the large practice variation in surgery rates for both conditions across regions in the Netherlands [3,4], but also across different countries. Reduction of practice variation may make health care more efficient, as non-surgical treatment is mostly less costly. This is needed since the demand for care is increasing, parallel with health care costs. Furthermore, both conditions also have a relatively heavy economic burden on the health care macro budget. However, the exact issues being faced regarding non-surgical treatment and surgery are also different between hip and knee OA on the one hand and sciatica on the other hand. These issues determine on their turn how care can be optimized and which strategies are the most suitable.

Treatment of hip and knee osteoarthritis

OA is a degenerative joint disease primarily characterized by loss of articular cartilage. It is diagnosed by clinical and radiological examination. However, not all patients with symptoms also have radiological hip or knee OA and not all patients with radiological hip or knee OA have symptoms [5]. In the Netherlands, the prevalence of knee OA was 3.6% (62% females) and 2.1% (63% females) for hip OA in 2011 [6]. Due to the ageing society and obesity, the prevalence of hip and knee OA is still increasing, in parallel with health care costs. This will make the magnitude of the existing issues even larger in the future.

Patients with symptomatic hip or knee OA suffer from pain and loss of function. In the Netherlands, first treatment of these patients is usually provided by the general practitioner (GP) (figure 1). According to the (inter)national evidence based guidelines, the GP will start with non-surgical treatment, including pharmacological options (e.g. the use of acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injections) and non-pharmacological options (e.g. physical therapy, patient education, and weight loss intervention) [7-11]. These non-surgical treatments aim to prevent progression and reduce symptoms such as joint pain and impairment of functions [11]. As it was shown that non-surgical treatments in hip and knee OA care

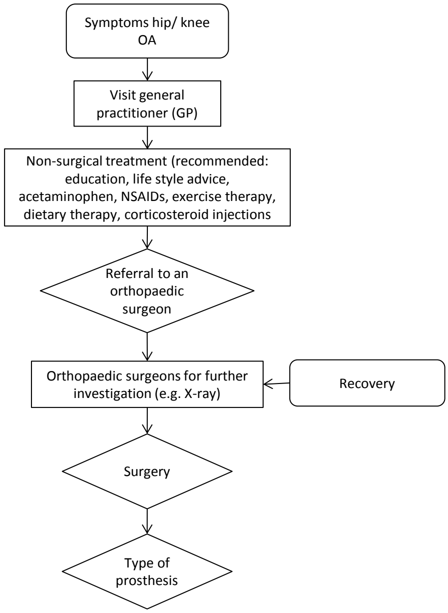

Figure 1. Care trajectory hip and knee OA

are not optimally used in primary care, a stepped-care BART (Beating osteoARThritis) strategy was developed [12,13]. The first step consists of education, life style advice, and acetaminophen. If the treatment options in the first step are not sufficient, treatment options in the second step can be considered (exercise therapy, dietary therapy, and non-steroidal anti-inflammatory drugs). Multidisciplinary care, intra-articular injections, and TENS are treatment options in the third step and could be considered if treatment options in step one or two are ineffective.

Patients are referred to an orthopedic surgeon if they do not respond sufficiently to non-surgical treatment options. Together with the orthopaedic surgeon, the decision will be made to start/continue non-surgical treatments or to perform a surgery depending on previously received treatments and disease severity.

Treatment of sciatica

Sciatica is a common disorder with a prevalence reported from 1.2% up to 43% depending on its definition [14]. Sciatica patients have pain radiating into the leg, but definitions vary widely in terms of pain distribution and/or pain duration. Sciatica is mostly caused by a herniated disc with compression of the nerve root, which gives radiating leg pain. In the Netherlands, yearly 75,000 persons develop symptoms of sciatica (almost 6 on the 1000 persons) of whom approximately 10,000 are treated surgically [15].

In the Netherlands, sciatica patients are initially diagnosed by GPs and advised to continue daily activities with or without physical therapy (non-surgical treatment) (figure 2). Seventy percent of patients with sciatica spontaneously recover in the first 6–8 weeks or with non-surgical treatments [16]. Non-surgical treatment for sciatica is focused at pain reduction and consists of analgesics such as NSAIDs and physical therapy and the advice to stay active until spontaneous recovery from sciatica occurs. Other treatments that are not supported by high quality evidence or clinical guidelines but (widely) used are spinal manipulation, transcutaneous electrical nerve stimulation (TENS), acupuncture and epidural injections of glucorticoids. The Dutch sciatica guideline advices that in the first 6–8 weeks surgery is only an option when a patient suffers from severe neurologic symptoms. After these 6–8 weeks the Dutch multidisciplinary sciatica guideline recommends that the team of professionals involved in sciatica care and patients jointly decide about treatment, i.e., surgery or prolonged non-surgical treatment, based on the evidence regarding associated risks and benefits and preference of the patient (i.e. shared decision making (SDM)) [17].

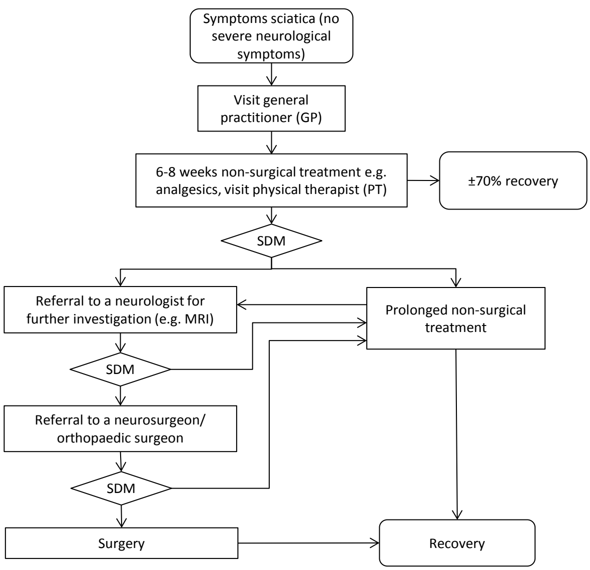

Figure 2. Care trajectory and shared decision making (SDM) in sciatica

The neurologist evaluates the presence of a radicular pain syndrome and may order an MRI to visualize the affected spinal nerve(s) and to judge possible compression. If the MRI confirms a nerve compressing herniated disc, a surgical intervention can be considered. During surgery the disc herniation is removed. A large, randomized clinical trial showed no significant difference in clinical outcomes between non-surgical treatment and surgery after 1 and 2 years in patients with sciatica [18]. Other, low quality studies showed conflicting results [19]. However, surgery leads to more rapid relief from the pain, whereas non-surgical treatment is less invasive [18] but takes patients longer to recover. Furthermore, surgery is more costly but cost-effective because of the rapid relief from the pain [20]. It is unclear whether delaying surgery reduces the chance of full recovery or that this delay gives sciatica time to resolve spontaneously [21]. This leaves the decision up to the patient and health care providers.

Part 1: Implementation of evidence based guidelines

Even though guidelines are based on the best available evidence, it is known from the literature that health care providers do not always follow guidelines [22-24]. As the evidence regarding use of non-surgical treatment and when to perform surgery, is already specific and included in the guideline, efforts can be taken to implement these guidelines. To implement guidelines and thereby optimize the quality of care, it is important to gain insight into reasons why guidelines are not always followed (i.e. barriers and facilitators). This is the focus of part 1 of this thesis.

Implementation can be described as a planned process and systematic introduction of, in our case, guidelines. The aim being that these are given a structural place in professional practice, in the functioning of organizations or in health care structure [25]. From the literature it is known that implementation of guidelines is influenced by several barriers and facilitators on the levels of the innovation, the professional, the patient, the social context, organizational context and the external environment political and economic factors [26]. Mary's case shows how multiple factors involved in the decision making act on different levels such as the micro level (i.e. the individual patient or the professional) and the macro level (i.e. the population, the insurance company and the environment). On a micro level, the decision making may depend on disease severity, working situation, family situation, financial situation, other health complaints or on the opinion or characteristics of the health care provider and their social context. On a macro level it may depend on organizational and economic factors such as the length of the waiting list, and insurance. All these factors may complicate the optimal use of non-surgical care and optimal timing of surgery with the best possible outcomes after surgical care. Therefore, we need to reveal barriers and facilitators that may hinder or facilitate the use of guidelines. Based on these barriers and facilitators an implementation strategy can be developed [27], which is likely to be more effective for the uptake of guidelines [28-30]. The specific barriers and facilitators are likely to differ between conditions like hip and knee OA and sciatica, based on the evidence already available in the different guidelines.

Implementation of the hip and knee osteoarthritis guideline

A specific recommendation about timing of surgery and use of non-surgical treatment is not provided in the hip and knee OA guideline [31]. It is stated that patients should first receive non-surgical treatment and should only be referred to the orthopedic surgeon if they do not respond sufficiently to non-surgical treatment options. However, previous studies showed that non-surgical treatments are underused in primary care [32-36]. Therefore, orthopaedic surgeons have an important role in ensuring that all recommended non-surgical treatments have been used before considering a surgical intervention.

The issues faced here are the extent to which patients have received all recommended non-surgical treatments before undergoing surgery, and if not, to gain more insight into barriers and facilitators for the use of non-surgical treatments among both patients and orthopedic surgeons. Including solutions for these barriers and facilitators in the implementation strategy can thus optimize the non-surgical treatment given to hip and knee OA patients.

Implementation of the sciatica guideline

The sciatica guideline is far more specific than the hip and knee OA guideline on both the use of non-surgical treatment as well as on the timing of surgery [17]. The use of non-surgical treatment and the timing of surgical treatment are specifically described in the guidelines. Still, large practice variation remains in surgery rates ranging from 19 to 319 per 100,000 inhabitants in 2012 in the Netherlands [4], unlikely to be explained by differences in case mix and patient preferences. It is more likely that noncompliance with the evidence-based guidelines regarding SDM is responsible for the varying surgery rates, since SDM may diminish this variation.

The issue here seems to be more the extent to which SDM is used. The recommendation to use SDM is not as easy as it may sound. Figure 2 shows that SDM could take place at different moments in the care trajectory and with multiple health care providers, so one of the issues may be when SDM should take place and which health care provider is responsible for using SDM to choose between (prolonged) non-surgical treatment or surgery. This makes SDM in sciatica care complicated. Therefore, it is important to gain insight into specific barriers and facilitators for use of SDM to improve implementation of the sciatica guidelines.

Part 2: The optimization of surgical care in hip and knee osteoarthritis

Guidelines for patients with hip and knee OA do not include specific information on when to perform a THA or TKA. As evidence about optimal timing of THA or TKA is still lacking, more evidence is needed on which factors predict the outcome after surgery. Using non-surgical treatments first may delay or diminish the need for surgical intervention in hip and knee OA patients. This is important given the limited lifespan of a prosthesis and the fact that outcomes are usually worse after revision than after primary arthroplasty [37]. However, the question is how long the surgery can be delayed without causing worse outcomes. This depends on the indications to perform surgery and the determinants for having the best possible patient outcomes after surgery. Do these differ between patient groups so that surgery is performed earlier for some patients? This is currently unknown and needed as evidence to decide on optimal timing of surgery. Therefore, part 2 of this thesis focusses on studying criteria and determinants to reach the best possible outcomes after surgical care. These new pieces of evidence can then be included in future guidelines.

Issues on when to perform surgery

The preoperative status of patients with hip or knee OA who have had THA or TKA may vary [3,38-40], suggesting that it is unclear when to perform a surgery. Therefore, insight is needed into the evidence base of indication criteria for primary THA and TKA in OA patients to determine whether it is possible for the orthopaedic surgeon to make an evidence-based decision about surgery. In addition, it is important to know which patients reach the best postoperative outcomes. Preoperative variables that predict the best outcomes were assessed before in a number of studies, but an overview is lacking. Furthermore, identified prognostic variables differed, and also gave contradictory results regarding the direction of the association. This may be due to the fact that some studies suffered from a lack of power, while other studies did not take independent effects (e.g. no correction for confounders) of prognostic variables into account. It is important to generate more understanding of these variables and their role on the outcome of a THA and TKA. For example should a patient first lose weight like the GP advised Mary? Or optimize preoperative status (e.g. health related quality of life, function or pain)? Having more reliable evidence on which variables predict the outcome after THA/TKA, may contribute to discussions on optimal timing of THA/TKA to achieve the best possible postoperative outcome in specific patient groups. This is important especially because still 10-20% of the patients is not satisfied after primary THA/TKA [41-44], possibly caused by not achieving the expected outcome.

Type of prosthesis

If the decision is made to replace a joint, the orthopaedic surgeon has to decide which implant should be used to reach the best possible outcomes. In recent decennia an expansion of technological developments in prostheses have seen, usually introduced into clinical practice without appropriate assessment [45]. One of these new developments is the mobile (meniscal or rotating) bearing TKA. The mobile bearing TKA with a polyethylene insert has some freedom of movement. Compared with the more traditional fixed bearing TKA, the mobile bearing has a rotating platform that allows the knee to flex and extend (like the fixed bearing TKA) and to twist and turn. Contradictory views exist as to whether the mobile bearing prosthesis will improve functionality as compared with the fixed bearing prosthesis for cruciate retaining TKA and it is therefore important to compare these two types of knee prostheses to determine which one leads to the best postoperative outcomes in patients.

Brief outline of this thesis

This thesis aims to contribute to the optimal use of non-surgical treatment and timing of surgery among hip and knee OA and sciatica patients. In the first part we search for strategies to improve guideline uptake in hip and knee OA and sciatica care. For hip and knee OA this includes the implementation of non-surgical treatment, as recommended in guidelines. The study design of this problem analysis study regarding the use of non-surgical treatments in hip and knee OA is described in Chapter 2. In Chapter 3 the extent of non-surgical treatment use in hip and knee OA in orthopaedic practice is examined, to determine the magnitude of the problem. In Chapter 4, barriers and facilitators to use non-surgical treatments in hip and knee OA are assessed.

In sciatica care, the optimization of care is addressed by studying the extent to which SDM is used in the consideration of prolonged non-surgical care or surgery. The design of this study is described in Chapter 5. Chapter 6 describes barriers and facilitators to implement shared decision making in multidisciplinary sciatica care, based on qualitative interviews. These barriers and facilitators are ranked in Chapter 7, to assess which barriers and facilitators found in the qualitative interviews are most important to be included in an implementation strategy that will improve the use of shared decision making in sciatica care.

In the second part of this thesis, a search for new evidence related to the question of optimal timing of THA/ TKA in hip and knee OA patients is done, as this is currently not described specifically in the guidelines. First, the availability and evidence base of indication criteria for primary THA and TKA is assessed in hip and knee OA in Chapter 8 to see if it is possible to make an evidence-based decision about surgery. Chapter 9 gives an overview of the available evidence from previous studies on which factors predict outcomes after THA, to guide decisions on when surgery is most effective in specific patient groups. Subsequently, Chapter 10 contributes to the availability of more evidence by pooling data from existing cohorts in the Netherlands to determine prognostic factors for outcomes after a THA and TKA. When the final decision is made for surgery Chapter 11 describes which type of prosthesis should be used in terms of achieving the best outcomes for patients by performing a meta-analysis of mobile versus fixed bearing TKA. In Chapter 12 a discussion is given on the overall findings and its implications.

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Part 1

Implementation of evidence based guidelines of non-surgical care in osteoarthritis and sciatica care

Chapter 2

Designing a strategy to implement optimal conservative treatments in patients with knee or hip osteoarthritis in orthopedic practice: a study protocol of the BART-OP study

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Implementation Science 2014, 9:22

ABSTRACT

Background

National and international evidence-based guidelines for hip and knee osteoarthritis recommend to start with (a combination of) conservative treatments, followed by surgical intervention if a patient does not respond sufficiently to conservative treatment options. Despite these recommendations, there are strong indications that conservative treatments are not optimally used in orthopedic practice. Our study aims to quantify the use of conservative treatments in Dutch orthopedic practice and to explore the barriers and facilitators for the use of conservative treatments that should be taken into account in a strategy to improve the embedding of conservative treatments in hip and knee osteoarthritis in orthopedic practice.

Methods

This study consists of three phases. First, current use of conservative treatments in patients with hip and knee osteoarthritis will be explored using an internet-based survey among at least 100 patients to identify the underused conservative treatments. Second, barriers and facilitators for the use of conservative treatments in orthopedic practice will be identified using semi-structured interviews among 10 orthopedic surgeons and 5 patients. The interviews will be followed by an internet based survey among approximately 450 orthopedic surgeons and at least 100 patients in which the identified barriers and facilitators will be ranked by importance. Finally, an implementation strategy will be developed based on the results of the previous phases using intervention mapping.

Discussion

The developed strategy is likely to result in an optimal and standardized use of conservative treatment options in hip and knee osteoarthritis in orthopedic practice, because it is focused on identified barriers and facilitators. In addition, the results of this study can be used as an example for optimizing the use of conservative care in other patient groups. In a subsequent study, the developed implementation strategy will be assessed on its effectiveness, feasibility and costs.

BACKGROUND

Osteoarthritis (OA) is a degenerative joint disease primarily characterized by progressive loss of articular cartilage. It leads to pain and loss of function [1]. Approximately 10% of men and 18% of women older than 60 years have OA [2]. Symptomatic OA of the knee and the hip have the highest prevalence within the group of arthritis. Due to the ageing society and obesity, the prevalence of hip and knee OA is still increasing [3].

In 2009, 154 patients per 100,000 persons received a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA), and 118 patients per 100,000 persons received a TKA in Western countries [4]. However, the lifespan of a prosthesis is limited. The revision rate after a TKA or THA is 12.9% after ten years [5], and revision arthroplasty is less successful than primary TKA or THA [6]. Therefore, it is important to delay the primary TKA or THA, by optimizing the use of conservative treatment options, especially in young people.

National and international evidence-based guidelines for hip and knee OA recommend to start with (a combination of) conservative treatments [7-11]. Conservative treatments include pharmacological options, (e.g., the use of analgesics, non-steroidal anti-inflammatory drugs and steroid injection therapy) and non-pharmacological options (e.g., physical therapy, patient education and weight loss interventions). Conservative treatments aim to prevent progression and reduce symptoms such as joint pain and impairment of functions [11]. If persons do not respond (sufficiently) to conservative treatment options, joint replacement (i.e. THA or TKA) can be considered. Despite the recommendation in guidelines to start with conservative treatments and only use surgical intervention if a patient does not respond sufficiently to conservative treatment options, the use of conservative treatments in daily practice is suboptimal [12-15]. For example a study showed that conservative treatments were not fully exploited in 81% of the patients who were referred to specialized knee/hip OA outpatient clinics [12]. Information about conservative treatments patients receive in orthopedic practice is lacking. Furthermore, surgery rates are rising [16]. TKA and THA in patients with OA increased with 196% and 50% respectively between 1995 and 2005 in the Netherlands [16]. In addition, large variation exists in preoperative status (e.g., disease severity) across different centers in Europe and Australia, which suggests differences in the timing of surgery [17,18]. Optimal use of conservative treatments could reduce these differences.

A few models of care were developed to optimize the use of conservative treatments. In Australia, a clinical pathway model and clinician and patient toolkits were developed to support implementation of nonsurgical management of hip and knee OA [19]. However, in Australia, rheumatologists play a leading role, while in the Netherlands the orthopedic surgeon is responsible for OA treatment in hospital care. In the Netherlands, a stepped-care strategy (SCS), based on (inter)national guidelines [20,21] is developed to facilitate the use of conservative treatments in three steps in primary care [22,23]. The first step consists of education, life style advice, and acetaminophen. If the treatment options in the first step are not sufficient, treatment options in the second step can be considered (exercise therapy, dietary therapy, and non-steroidal anti-inflammatory drugs). Multidisciplinary care, intra-articular injections, and transcutaneous electrical nerve stimulation are treatment options in the third step and could be considered if treatment options in step one or two are ineffective. After implementation of the SCS, most recommended conservative treatments seem to be well used, except dietary therapy [23]. Both studies provide evidence to promote the use of conservative treatments in primary care or in a setting where the rheumatologists play a leading role, but strategies for the optimization of conservative treatments in orthopedic care are still lacking. Information about the current use of conservative treatments, and barriers and facilitators influencing the adoption of conservative treatments in orthopedic practice is needed to develop a tailored implementation strategy focused on orthopedic care.

In the Netherlands, patients with OA are usually treated by the general practitioner. According to guidelines patients should be referred to the orthopedic surgeon if they do not respond sufficiently to conservative treatment options. In orthopedic practice, the decision will be made to start/ continue conservative treatments or to perform a surgery depending on previous received treatments and disease severity. The leading role of an orthopedic surgeon could result in other barriers and facilitators compared to a setting where the rheumatologists play a leading role. This subsequently results in another strategy to improve the embedding of conservative therapies in hip and knee OA in orthopedic practice. While rheumatologists and general practitioners only provide conservative treatments in OA, orthopedic surgeons can provide both conservative treatments and surgical interventions. It is unclear to what extent factors such as lack of information about conservative treatment options, increasing number of orthopedic surgeons [16], or patient preferences play a role. It is important to explore these factors for the development of a tailored implementation strategy, so that orthopedic surgeons will provide underused treatment options in primary care, such as dietary therapy. Part of this implementation strategy could be the SCS or a clinical pathway model as used in previous implementations.

Objective

The BART-OP study (Beating osteoARThritis in the Orthopedic Practice) aims to quantify the use of conservative treatments in Dutch orthopedic practice before THA or TKA and to explore the barriers and facilitators for the use of conservative treatments that should be taken into account in a strategy to improve the embedding of conservative treatments in hip and knee OA in orthopedic practice.

To reach the aim of this study, we formulated the following research questions:

1. What is the current use of conservative treatments, before patients receive a surgery, in orthopedic practice?
2. Which barriers and facilitators influence the use of conservative treatments in orthopedic practice?
3. What is an appropriate tailored implementation strategy for the embedding of conservative treatments in orthopedic practice?

In a subsequent study, the developed implementation strategy will be assessed on its effectiveness, feasibility and costs.

METHODS

This study consists of three phases to be executed in one year:

A. The analysis of current use of conservative treatments, before patients receive a surgery in orthopedic practice (months 1 to 9).
B. Identification of barriers and facilitators for non-optimal conservative treatments, using two steps (months 1 to 9).

   i. Barriers and facilitators for non-optimal conservative treatments are explored with interviews among orthopedic surgeons and patients.
   ii. Identified barriers and facilitators are ranked by importance in a survey among a representative sample of orthopedic surgeons and patients.

C. The development of the implementation strategy based on the results of phases A and B (months 9 to 12).

The study design, study population, analysis and outcome measures are described per study phase.

Phase A. The analysis of current use of conservative treatments before patients receive a surgery in orthopedic practice

Study design

To analyze the current use of conservative treatments, before patients undergo THA or TKA in orthopedic practice, an internet-based survey among patients will be performed. The survey will include questions about which conservative treatment options are used before surgery. This information is needed to be able to focus the implementation strategy on the right conservative treatments. The content of the survey will be developed based on the Dutch guideline of OA of the hip and knee [11]. Reminders to non-responders will be sent after two weeks and again after four weeks.

Study population

The survey will be sent to a sample of at least 100 patients living in different regions of the Netherlands. Inclusion criteria for patients are: age ≥18 years, a doctor's diagnosis of hip or knee OA, and who have had a TKA or THA no longer than 12 months ago or are on the waiting list for surgery within the next 3 months. Patients with an inability to understand written Dutch will be excluded from the study. We will sample these patients using advertisements in local newspapers, and at websites or newsletters of patient associations.

Analysis

Descriptive statistics will be used to describe the current use of conservative treatment options in orthopedic practice. Independent t-tests or Mann Whitney U tests for continuous variables and Chi square tests or Fisher's exact tests for proportions are used to analyze differences in the frequency of use between different regions or other conditions.

Outcome measures

The main outcome measure is the percentage of patients in whom the conservative treatment options are applied optimally before they undergo surgery, as described in the guideline. These results will help us to focus the implementation strategy, developed in phase C, on the right conservative treatments.

Phase B. Identification of barriers and facilitators for non-optimal treatment

Study design

Two steps will be taken to identify barriers and facilitators associated with the non-optimal use of conservative treatments. First, semi-structured interviews among orthopedic surgeons and patients will be performed to explore all relevant barriers and facilitators for non-optimal conservative therapy. The interview questions will be based on the Theoretical Domains Interview framework (TDI) [24]. The TDI framework includes 12 theoretical construct domains derived from 33 psychological theories, and covering 128 explanatory constructs that enhance implementation of evidence-based practice [24]. In addition, barriers and facilitators reported in a previous study about the use of the SCS to optimize hip and knee OA in primary care [25] are included in the interview questions. Second, an internet-based survey will be held among a selection of orthopedic surgeons (n≈400) and sample of patients (n≥100) to rank barriers and facilitators identified in the interviews on importance. The survey will include questions to determine which of these barriers and facilitators are associated with the use of conservative treatments.

Study population

For the semi-structured interviews, we anticipate interviewing 10 orthopedic surgeons involved in hip and knee surgery and 5 patients who have had a THA or TKA no longer than 12 months ago (≥18 years, and able to understand oral Dutch). If we do not reach data saturation after these interviews (three consecutive interviews without new barriers or facilitators [26]), we will continue interviewing until data saturation is reached. To obtain contrasting views on barriers and facilitators, we will apply purposive sampling. First, we will purposively select orthopedic surgeons and patients from Dutch regions with high surgery rates and from Dutch regions with relatively low surgery rates based on the report of Van Beek et al. (2010) about variation in clinical practice [27]. In addition, we will select orthopedic surgeons in such a way as to ensure diversity of hospital type (public hospitals and academic hospitals). It is important to include orthopedic surgeons of public and academic hospitals, because this may reveal other facilitators and barriers. For the internet based survey, Dutch orthopedic surgeons listed in the registry of the Dutch Orthopedic Association (NOV) or the Dutch medical address book will be approached for participation. Inclusion criteria are: involved in hip or knee OA, and access to email address. Patients (n≥100) are recruited using advertisements in local newspapers. Included are patients: ≥18 years who have had total hip or knee surgery no longer than 12 months ago, or are on the waiting list for receiving a THA or TKA. Patients with an inability to understand oral Dutch will be excluded from the study.

Analysis

The semi-structured interviews will be audio-taped and transcribed in full for analysis. The interviews will be analyzed by two researchers using open coding to ensure that we find all barriers and facilitators for the non-optimal use of conservative therapy. This qualitative analysis will be executed using the software package ATLAS.ti (ATLAS.ti Scientific Software Development GmBH, Berlin, Germany) for this qualitative analysis.

The subsequent survey data will allow us to rank the importance of barriers and facilitators and their relationship with the use of conservative treatments. These relationships will be assessed using multiple regression analysis. We will use SPSS 20.0 for analysis.

Outcome measures

A list of the most relevant barriers and facilitators for the optimal use of conservative treatments in orthopedic practice before patients with hip or knee OA receive THA or TKA.

Phase C. The development of the implementation strategy

Study design

The results of the previous phases will be used to develop a tailored implementation strategy for the optimal use of conservative treatments in orthopedic practice in patients with hip or knee OA. The results of phase A will show at which type(s) of conservative treatment the strategy should be aimed. Phase B results will show the most relevant barriers and facilitators that should be taken into account in the development of the strategy. From literature, it is known that, in general, multifaceted strategies are more effective than single strategies [28,29]. Assuming this, and our expectation that several barriers on different theoretical domains will be found, it is very likely that the developed implementation strategy includes several components directed at different levels (i.e. knowledge or social influences). Furthermore, it is expected that the strategy components will include educational outreach, an interactive educational strategy, and/or patient-specific strategies, because these facets seem to be promising for implementation [28].

In the development process, the project team will use the intervention mapping approach of Bartholomew et al. [30]. This method begins with the creation of matrices, in which the performance objectives are set against the most important factors that hinder or facilitate the adoption of conservative treatments. Subsequently, the project team will brainstorm about the strategy components needed to achieve the performance objective in the presence of the barrier or facilitator mentioned in the matrix. The cells of the matrices are then gradually filled with implementation strategy components [30]. Next, the project team will translate the formulated strategy components into practical strategies.

Analysis

The study group meeting will be summarized. The project members will receive a summary of the meeting and the formulated implementation strategy and will be asked whether the summary and implementation strategy is consistent with the conclusions reached in the meeting.

Outcome measures

A tailored implementation strategy for the embedding of conservative treatments in orthopedic practice in patients with hip or knee OA.

Ethical approval

This study protocol was presented to the Medical Ethical Committee of the Leiden University Medical Center (CME P13.087/NV/nv). An exemption was obtained, as ethical approval for this type of study is not required under Dutch law.

DISCUSSION

2

The goal of this study is to develop a tailored implementation strategy to optimize the use of conservative treatments in hip and knee OA in patients referred to the orthopedic surgeon.

Several studies have been performed to develop and test implementation strategies, including identification of barriers that prevent implementation [31-33]. They all conclude that a prior inventory of barriers to develop a tailored implementation strategy is useful and can confirm whether barriers differ in different settings. Prior inventory thereby reduces the number of costly trials evaluating different implementation strategies [28,32,34]. Although previous studies already explored barriers for the use of conservative treatments, these studies were performed in other settings, and not focused on orthopedic care. Furthermore, the uptake of several implementation activities was poor, since only 9% of the participating GPs were present at the seminar [23]. It was very difficult to reach all GPs in seminars. This could be easier in orthopedic practice. Orthopedic surgeons may have more interest in OA, because it is part of their specialization whereas for GPs it is one of the many health problems in their daily practice. This highlights the importance of optimizing the use of conservative treatments in orthopedic practice as well, so that patients will receive optimal treatment options in orthopedic practice if conservative care was suboptimal in their primary care trajectory. Our study and the study performed in primary care together will provide useful information for the development of interventions based on the full spectrum of barriers and facilitators in primary care and orthopedic practice. This is important because a multidisciplinary approach is likely to be more effective to obtain optimal conservative therapy [35].

A strength of this study is the purposive sampling of orthopedic surgeons of regions with low and high surgery rates, because they could have contrasting views on barriers and facilitators. We think that this will reveal most barriers and facilitators for the implementation of the optimal use of conservative treatments in hip and knee OA in orthopedic practice. A limitation may be the selection of patients. Patients will be recruited via advertisement, which can lead to selection bias, because patients who respond to the advertisements may perceive other barriers and facilitators as most important compared to non-responders. Furthermore, the use of an internet-based survey could also induce selection bias. Knee and hip OA increases with age [3], but not all elderly persons do have internet or an email address. This can lead to the selection of younger persons compared to the average age of OA patients, while elderly persons may perceive other barriers and facilitators as most important. We will assess the impact of selection bias by comparing elderly respondents with younger ones. If they perceive the same barriers and facilitators we can conclude that the impact of this type of selection bias does not influence our results.

The developed strategy is likely to result in an optimal and standardized use of conservative treatment options in hip and knee OA in orthopedic practice. In addition, the results of this study can be used as an example for optimizing the use of conservative care in other patient groups. In a subsequent study, the developed implementation strategy will be assessed on its effectiveness, feasibility and costs.

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Chapter 3

Variation in use of non-surgical treatments among osteoarthritis patients in orthopaedic practice: a questionnaire study among patients and orthopaedic surgeons to inform quality improvement strategies

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ABSTRACT

Objectives

National and international evidence-based guidelines for hip and knee osteoarthritis (OA) recommend to start with non-surgical treatments, followed by surgical intervention if a patient does not respond sufficiently to non-surgical treatments, but there are indications that these are not optimally used. The aim of this study was to assess the extent to which all recommended non surgical treatments were used by patients with hip or knee OA who receive(d) a total hip or knee replacement, as reported by patients and orthopaedic surgeons.

Setting

We performed two cross-sectional internetbased surveys among patients and orthopaedic surgeons throughout the Netherlands.

Participants

195 OA patients either have undergone total knee arthroplasty or total hip arthroplasty no longer than 12 months ago or being on the waiting list for surgery with a confirmed date within 3 months and 482 orthopaedic surgeons were invited to participate.

Primary and secondary outcome measures

The use of recommended non-surgical treatments including education about OA/ treatment options, lifestyle advice, dietary therapy, physical therapy, acetaminophen, NSAIDs and glucocorticoid injections.

Results

174 OA patients (93%) and 172 orthopaedic surgeons (36%) completed the surveys. Most recommended non-surgical treatments were given tothe majority of patients (eg, 80% education about OA, 73% physical therapy, 72% acetaminophen, 80% NSAIDs). However, only 6% of patients and 10% of orthopaedic surgeons reported using a combination of all recommended treatments. Dietary therapy was used least frequently. Only 11% of overweight and 30% of obese participants reported having received dietary therapy and 28% of orthopaedic surgeons reported to prescribe dietary therapy to overweight patients.

Conclusions

While most recommended non-surgical treatments were used frequently as single therapy, the combination is used in only a small percentage of OA patients. Especially,

use of dietary therapy may be improved to help patients manage their symptoms, and potentially delay the need for joint arthroplasty.

INTRODUCTION

Patients with symptomatic hip or knee osteoarthritis (OA) suffer from pain and loss of function for which treatment is required. Different treatment options are available, surgical and non-surgical treatments. For patients, good quality of care is achieved if their symptoms are managed in the short term, but also taking into account which treatment option results in the best long-term patient outcomes. As the lifespan of a prosthesis is limited, and patient outcomes after revision arthroplasty are not as good as after primary surgery [1], it is generally acknowledged that total hip arthroplasty (THA) and total knee arthroplasty (TKA) should not be performed too early. For this reason, evidence based guidelines recommend to start with non-surgical treatments (eg, education, physical therapy, non-steroidal anti-inflammatory drugs (NSAIDs))[2-6], and to use surgical intervention only if a patient does not respond sufficiently to non-surgical treatment options in the context of end stage OA [7-13]. These recommendations are all based on the large body of evidence supporting the effectiveness of these non-surgical treatments to help patients with hip and knee OA manage their symptoms and preserve joint function [14].

Despite these guidelines, several studies have suggested that the use of non-surgical treatments in patients with hip or knee OA can be improved [7,15-18]. For instance, Snijders et al. [7] demonstrated that 81% of patients with hip or knee OA did not receive all non-surgical treatments in the primary care setting. However, patients with OA may receive non-surgical treatments later on in the care trajectory from their orthopaedic surgeon once referred to specialist care. In the Netherlands, patients with OA are usually treated by the general practitioner. According to guidelines, patients should be referred to the orthopaedic surgeon if they do not respond sufficiently to non-surgical treatment options. In orthopaedic practice, the decision will be made to start/continue non-surgical treatments or to perform a surgery depending on previous received treatments and disease severity. Therefore, orthopaedic surgeons have an important role in ensuring optimal care of patients with OA by confirming whether recommended non-surgical treatments have been exhaustedly used before considering a surgical intervention. Furthermore, surgical interventions, like a THA and TKA do not have good patient reported outcome in about 10-20% of patients [19-22]. This stresses even more the importance of good non-surgical treatment modalities before implant surgery is encountered. McHugh et al. [23] examined which treatments patients with OA used throughout the care trajectory, both before and while on the waiting list for a TKA or THA, and showed that only 10% of the patients had received information on pain management with the consequence that some patients used their own regime to take analgesics. This in turn may have led to insufficient effects of analgesics. However, they did not investigate the full range of non-surgical treatments and the estimates were reported by patients, so that the information may have been given to them but not remembered.

Given the known effectiveness of non-surgical treatments individually and for some combinations (eg, physical therapy with dietary therapy [24]), use of the full range of available recommended non-surgical treatments may improve patient outcomes [2-6], thereby improving quality of care, and postpone the need for surgery which would reduce chances for a revision with worse patient outcomes than primary surgery. What is currently lacking and needed to provide a complete view, is an assessment of the full range of non-surgical treatments as well as including both patients' and orthopaedic surgeons' perspectives, as these may differ.

Therefore, the aim of this study was to assess the extent to which all recommended non-surgical treatments were used by patients with hip or knee OA as reported by patients and orthopaedic surgeons, both as a single option and in combination.

MATERIALS AND METHODS

Study design

We performed two cross-sectional internet-based surveys in November and December 2013 and January 2014 to assess the use of non-surgical treatments in orthopaedic practice as reported by both patients and orthopaedic surgeons.

Population

Patients

A total of 195 patients were invited by email to participate in the survey, to estimate a previously reported 19% use of non-surgical treatments among 47,000 patients with hip and knee OA annually in the Netherlands [25], with a 5% margin of error. Patients were recruited via advertisements in local newspapers across the Netherlands, and through the websites or newsletters of patient associations. Patients who volunteered to participate in the survey in reaction to the advertisements were dialed by the research team to provide information about the study, to answer questions and to ask whether they approved for participation. In addition, patients received written information before the start of the survey and the availability to stop during the study. In addition, patients received written information before the start of the survey and the availability to stop during the study. Inclusion criteria for patients were: age ≥ 18 years, a doctor's diagnosis of hip or knee OA, and either have undergone TKA or THA no longer than 12 months ago or being on the waiting list for surgery with a confirmed date within 3 months. Patients who were unable to understand written Dutch or who had undergone or were scheduled for revision surgery were excluded from the study. Patients who initially indicated that they wanted to participate but did not respond, were sent two reminders, one after one and a half weeks, and if still no response again after 3 weeks. Participants who completed the questionnaire received a 10 euro gift card as an incentive.

Orthopaedic surgeons

All 482 Dutch orthopaedic surgeons listed in the registry of the Netherlands Orthopaedic Association (NOV) and/ or the Dutch medical address book with an email address received an invitation to participate. All orthopaedic surgeons who treated patients with hip or knee OA were eligible. Orthopaedic surgeons who did not respond received two reminders, one after one and a half weeks and if still no response again after 3 weeks. Orthopaedic surgeons did not receive an incentive for their participation.

Survey development

Survey for patients

The survey for patients included questions about general patient characteristics, general health and symptoms of OA, and non-surgical treatment for OA. Patient characteristics included: age, gender, region of residence (north, middle, and south), educational level [basic education (none or only primary education), intermediate education (prevocational secondary education, senior secondary vocational training, senior secondary general education, pre-university education), or high education (higher professional education or university (bachelor, master, or PhD degree)], work situation (paid work or not), height (cm) and weight (kg) to calculate the body mass index (BMI), and type of insurance (basic and/ or additional coverage for care such as physical therapy, glucosamine sulfate and hyaluronic acid). Furthermore, the survey included general and disease-specific health questions, such as duration of OA and duration of complaints of the affected joint, comorbidities, average pain during 6 months before surgery, measured on a 0 (no pain)-10 (unbearable pain) scale, and patient-perceived reasons for surgery.

Questions about healthcare use included all non-surgical options before joint replacement surgery as described in the Dutch stepped-care strategy (SCS) and were formulated as follows: “Did you receive the following treatments for the complaints of your affected joint before joint replacement surgery?”. The SCS is based on (inter)national guidelines [26,27]. The first step consists of education, life style advice, and acetaminophen. If the treatment options in the first step are not sufficient, treatment options in the second step can be considered (exercise therapy, dietary therapy, and NSAIDs).

Multidisciplinary care, intra-articular injections, and transcutaneous electrical nerve stimulation (TENS) are treatment options in the third step and could be considered if treatment options in step one or two are ineffective.

In the survey these non-surgical treatments were formulated as follows: education about the disease osteoarthritis, education about the possible treatment options in osteoarthritis, lifestyle advices (ie, stay active, lose weight), physical therapy/ exercise therapy, acetaminophen, anti-inflammatory painkillers (eg, NSAIDS such as Celebrex, Diclophenac, Cataflam, Voltaren), tramadol (eg, Tramal, Tramagetic, Tradonal, Zaldiar), multidisciplinary care (care of different health care providers at the same time, for example in a revalidation centre), injections in the knee, TENS (therapy that uses electrical current on the skin). Patients could choose one or more of the following answers: yes, received from the orthopaedic surgeon; yes, received from another healthcare provider; yes, received on my own initiative; no.

Survey for orthopaedic surgeons

The survey for orthopaedic surgeons included questions about their background characteristics, and the prescription of non-surgical treatments. Characteristics of orthopaedic surgeons included: age, gender, work region, work setting, years of working experience as an orthopaedic surgeon, number of new patients with hip/ knee OA seen per month. Questions about prescribed treatments included all non-surgical options described in the SCS [26,27] and were formulated as follows: "If patients did not receive the following non-surgical treatments, do you prescribe these treatments?" In case of physical therapy or dietary therapy we asked whether they referred patients, rather than initiating this treatment themselves. Orthopaedic surgeons could choose one of the following answers: never, sometimes, often, or (almost)always.

Analysis

Descriptive statistics were used to describe the characteristics of respondents, and the use of non-surgical treatments from the patients' or orthopaedic surgeons' perspectives. From the patient perspective we distinguished the use of non-surgical treatments prescribed by any healthcare provider, by the orthopaedic surgeon, or undertaken by their own initiative. From the orthopaedic surgeon perspective we dichotomised the answers into 'prescribed' (often/ almost always) and 'not prescribed' (never/ sometimes).

To assess the use of non-surgical treatments, we made a distinction between non-surgical treatments recommended by various organisations (eg, OARSI, EULAR, AAOS, NOV)[14,16] and other non-surgical treatments. The recommended non-surgical treatments were education about OA, education about different treatment options, lifestyle advice, (referral to) dietary therapy, physical therapy containing exercises, acetaminophen, NSAIDs, and glucocorticoid injections. Other non-surgical treatments included glucosamine sulfate, tramadol, multidisciplinary care, TENS, and hyaluronic acid injections (for knee OA). These treatments are not supported by high quality evidence or clinical guidelines, but are nevertheless sometimes recommended and used by patients with OA. BMI of patients was classified into normal weight if BMI<25 kg/m2, overweight if BMI≥25 <30 kg/m2, and obese if BMI ≥30 kg/m2 to assess whether dietary therapy was indicated. If BMI was unknown, we assumed that dietary therapy was not indicated for that patient.

For each non-surgical treatment, we calculated the percentage of patients who had received this treatment, and the percentage of orthopaedic surgeons who always/ often prescribed this treatment for their patients. In addition, we calculated the percentage of participants who received/ prescribed the recommended non-surgical treatments listed in each step of the Dutch SCS including the previous steps (conditional percentage). The proportion of patients and orthopaedic surgeons using each non-surgical treatment was compared using the Chi square test.

In addition, we explored whether patients and orthopaedic surgeons using all recommended treatments differed from those who did not, in age, gender, region of residence, BMI, and level of education (for patients) and on differences in age, gender, work region, work setting, years of working experience, and number of new patients with hip/knee OA seen per month (for orthopaedic surgeons). We also explored differences in use of each treatment between patients with THA and TKA. The independent t-test or Mann Whitney U tests for continuous variables and χ^2 tests or Fisher's exact tests for proportions was used to compare differences between subgroups. Significance testing was done two-sided at α=0.05. SPSS V.20.0 was used for analyses.

Ethics

This study protocol was presented to the Medical Ethical Committee of the Leiden University Medical Center (CME P13.087/NV/nv). Ethical approval for this type of study is not required under the Dutch law.

RESULTS

Response

A total of 182 patients (response rate of 93%) completed the survey. Eight patients were subsequently excluded from the analyses, because they did not fulfil the inclusion criteria. This left 174 patients (89%) included in the final analyses.

One hundred and eighty one (response rate of 38%) orthopaedic surgeons completed the questionnaire. Nine orthopaedic surgeons were excluded because they indicated they did not see patients with OA in consultations. Thus a total of 172 (36%) orthopaedic surgeons were included in the final analyses.

Characteristics of the population

Patients

Characteristics of patients who completed the questionnaire are described in table 1. The majority of the participants were female, 26% were obese (BMI≥30 kg/m2) and thus indicated for dietary therapy. Most of the respondents had already undergone THA or TKA at the time of recruitment, and a significant proportion of patients reported a duration of symptoms for more than five years. Almost all patients had additional insurance coverage, meaning that physical and dietary therapy was likely to be covered by their insurance rather than being subject to out of pocket expenses.

Table 1. Characteristics of included patients with hip or knee OA

Characteristics	Patients (n=174)
Age in years (mean, SD)	64 (7.7)
Female, n (%)	125 (72)
Body mass index (BMI), n (%)	
<25	36 (21)
≥25 <30	84 (48)
≥30	46 (26)
Missing	8 (5)
Knee OA, n (%)	94 (54)
Joint replacement (THA or TKA), n (%)	
Yes	169 (97)
Within 3 months	5 (3)
First joint replacement, n (%)	132 (73)
Duration of complaints of affected hip/ knee, n (%)	
< 1 year	13 (8)
1-5 years	86 (49)
6-10 years	42 (24)
11-20 years	25 (14)
>20 years	8 (5)
Pain before surgery, mean (SD)*	7.16 (1.8)
Comorbidities, n (%)	
Diabetes	10 (6)
Stroke, cerebral hemorrhage, cerebral infarct	5 (3)
Cancer	10 (6)
Cardiovascular disease	12 (7)
Migraine or severe headaches	17 (10)
High blood pressure	57 (33)

Characteristics	Patients (n=174)
Asthma, chronic bronchitis, emphysema	14 (8)
Chronic joint inflammation	32 (18)
Other	20 (11)
Education, n (%)	
Basic	6 (3)
Intermediate	120 (69)
High	47 (27)
Missing	1 (1)
Paid work, yes n (%)	55 (32)
Region of residence, n (%)	
North	70 (40)
Middle	55 (32)
South	49 (28)
Living situation, n (%)	
Live alone	39 (22)
Live with others	135 (78)
Type of insurance, n (%)	
Basic only	4 (2)
Basic with additional coverage	170 (98)

* Average pain during six months before surgery measured on a 0 (no pain)-10 (unbearable pain) scale. BMI, body mass index; OA, osteoarthritis; THA, total hip arthroplasty; TKA, total knee arthroplasty.

Orthopaedic surgeons

The characteristics of the orthopaedic surgeons who completed the questionnaires are presented in table 2. On average, they had been working for 13 years (SD 8) as an orthopaedic surgeon, and saw an average of 25 new patients with hip OA (SD 24) and 31 (SD 22) new patients with knee OA per month. Orthopaedic surgeons from various parts of the country and different hospital types were included in the sample.

Table 2. Characteristics of orthopaedic surgeons who treated patients with hip or knee OA

Characteristics	Orthopaedic surgeons (n=172)
Age in years, mean (SD)	48.4 (8.6)
Female, n (%)	16 (9%)
Years working as an orthopaedic surgeon; mean (SD)	12.8 (8.0)
New patients with primary hip OA seen per month; mean (SD)	25.1 (22.2)
New patients with primary knee OA seen per month; mean (SD)	31.3 (23.9)
Work region*, n (%)	
North	54 (31)
Middle	82 (48)
South	41 (24)
Setting*, n (%)	
General hospital	89 (52)
University medical center	13 (8)
Private clinic	20 (12)
Teaching hospital	54 (31)
Other	7 (4)

* Multiple options possible, so the sum of percentages may be larger than 100%.
OA, osteoarthritis.

Use of recommended non-surgical treatments

Table 3 shows the percentage of patients that received recommended and non-recommended non-surgical treatments as reported by patients.

The most frequently received non-surgical treatments were education about OA (80%), physical therapy (73%), acetaminophen (72%), education about different treatment options (66%) and NSAIDs (64%). Of these, education about OA and education about different treatment options were mostly received from the orthopaedic surgeon (table 3), whereas the other treatments were received from another healthcare professional, or patients own initiative. Dietary therapy was used least frequently, even when non-overweight patients were excluded. Only 11% of overweight patients and 30% of the obese patients reported they had received dietary therapy. A minority of these patients was referred to a dietician by their orthopaedic surgeon (table 3).

In addition, looking at the conditional percentage in table 4, only 33% of the patients received all recommended treatments in step 1 of the SCS, and eleven (6%) patients reported to have received all recommended treatments in step 1 and 2 of the SCS. Because many patients did not remember which type of injection they received, we excluded glucocorticoid injections and did not calculated the conditional percentage of step 1, 2 and 3 together.

Table 3. Received recommended and non-recommended non-surgical treatments by patients as reported by patients

		Received by*		
Non-surgical treatment	**Received, n (%)**	**Orthopaedic surgeon, n (%)**	**Other health care professional, n (%)**	**Own initiative, n (%)**
Education about OA	139 (80)	95 (68)	30 (22)	31 (22)
Education about different treatment options	115 (66)	80 (70)	27 (23)	21 (18)
Lifestyle advice	107 (62)	37 (35)	40 (37)	40 (37)
Dietary therapy, if indicated				
BMI ≥25 <30	9 (11)	2 (22)	3 (33)	5 (56)
BMI ≥30	14 (30)	1 (7)	7 (50)	6 (43)
Physical therapy	127 (73)	33 (26)	70 (55)	36 (28)
Contained exercises	*116 (91)*			
Acetaminophen	125 (72)	26 (21)	30 (24)	73 (58)
NSAIDs	111 (64)	43 (39)	51 (46)	19 (17)
Tramadol	44 (25)	21 (48)	24 (55)	1 (2)
Glucosamine sulfate	58 (33)	7 (12)	9 (16)	46 (79)
Multidisciplinary care	12 (7)	4 (33)	8 (67)	1 (8)
TENS	10 (6)	0	10 (100)	0
Intra-articular injections (knee OA n=94)	54 (57)	46 (85)	12 (22)	0
Glucocorticoid	*28 (30)*			
Hyaluronic acid	*7 (7)*			
Unknown	*20 (37)*			

* Multiple options possible, thus the sum of orthopaedic surgeon, other health care professional and own initiative can be >100%. BMI, body mass index; NSAIDs, non-steroidal anti-inflammatory drugs; OA, osteoarthritis; TENS, transcutaneous electrical nerve stimulation.

Reasons for surgery according to patients (multiple answers possible) were: pain could not be controlled with painkillers (55% of the patients), insufficient effect of other treatments (eg, physical therapy, dietary advice) (51%), duration of symptoms (41%), difficulties with daily activities (75%) or other reasons (17%) (eg severe cartilage loss, difficulties with sports, immobility).

Table 4. Conditional percentage of patients receiving recommended non-surgical treatments in stepped care strategy as reported by patients

Recommended non-surgical treatments in stepped care strategy	Conditional n (%)
Step 1: education about OA+education about different treatment options+lifestyle advice+acetaminophen	57 (33)
Step 1+2: step 1+(referral to) dietary therapy, when indicated+physical therapy+NSAIDs	11 (6)
Step 1, 2+3: step 1+ 2 + intra-articular injections (for knee OA n=94)	n/c

n/c: not calculated, because many patients did not know which type of injection they received. NSAIDs, non-steroidal anti-inflammatory drugs; OA, osteoarthritis.

Table 5 shows the percentage of orthopaedic surgeons that often or always prescribes recommended non-surgical treatments as reported by orthopaedic surgeons. Orthopaedic surgeons often reported to prescribe lifestyle advice (98%), education about different treatment options (95%), education about OA (87%), and acetaminophen (64%). However, table 6 shows that only 96 (56 %) of the orthopaedic surgeons reported prescribing all recommended treatments in step 1 of the SCS, 17 (10%) reported prescribing all recommended treatments in step 1 and 2, and 10 (6%) reported prescribing all recommended treatments in step 1, 2 and 3, if the patient had not received these treatments in their previous care trajectory. As among patients, dietary therapy was reported as the least prescribed treatment (reported by 28% of the orthopaedic surgeons), followed by intra-articular injections (43%) and physical therapy (54%).

Table 5. (Often or always) Prescribed recommended non-surgical treatments, as reported by orthopaedic surgeons

Recommended non-surgical treatments	Population n (%)
Participants	**172**
Education about OA	149 (87)
Education about different treatment options	163 (95)
Lifestyle advice	168 (98)
(Referral to) dietary therapy, when indicated	49 (28)
Physical therapy	93 (54)
Acetaminophen	112 (64)
NSAIDs	102 (59)
Intra-articular injections	74 (43)

NSAIDs, non-steroidal anti-inflammatory drugs; OA, osteoarthritis.

Table 6. Conditional percentage of orthopaedic surgeons who prescribe recommended non-surgical treatments in stepped care strategy

Recommended non-surgical treatments in stepped care strategy	Conditional n (%)
Step 1: education about OA+education about different treatment options+lifestyle advice+acetaminophen	96 (56)
Step 1+2: step 1+(referral to) dietary therapy, when indicated+physical therapy+NSAIDs	17 (10)
Step 1, 2+3: step 1+2+intra-articular injections (for knee OA n=94)	10 (6)

NSAIDs, non-steroidal anti-inflammatory drugs; OA, osteoarthritis.

No differences were found between patients receiving and not receiving all recommended non-surgical treatments in any of the patient characteristics tested. Similarly, no differences were found between orthopaedic surgeons prescribing and not prescribing all recommended non-surgical treatments in any of their characteristics. Patients with knee OA received acetaminophen more often than patients with hip OA (80% vs 63% respectively ($p=0.01$)), but no differences were found in the use of other treatments. Furthermore, comparing patients and orthopaedic surgeons, no differences were found in the proportion using education about OA ($p=0.09$), acetaminophen ($p=0.18$), NSAIDs ($p=0.39$), and the percentage using all recommended non-surgical treatments ($p=0.22$). A smaller percentage of patients compared to orthopaedic surgeons reported having received/prescribed education about different treatment options ($p<0.001$), lifestyle advice ($p<0.001$) and dietary therapy ($p=0.03$). The use of physical therapy on the other hand was reported to have been received by more patients than being prescribed by orthopaedic surgeons (73% vs 54% ($p<0.001$)).

Use of other non-surgical treatments

Glucosamine sulfate was the most frequently used other non-surgical treatment, reported by 33% of patients, and mostly (79%) used on their own initiative. Multidisciplinary care (7%) and TENS (6%) were the least often reported other treatments. Thirty-three percent of the patients who received multidisciplinary care were referred by their orthopaedic surgeon, and none of the patients who used TENS was referred by their orthopaedic surgeon. Overall, orthopaedic surgeons rarely prescribed any of these treatments not recommended by published OA guidelines, the highest percentage (8%) was for the recommendation of glucosamine sulfate.

DISCUSSION

Our study showed that although most recommended non-surgical treatments seem to be frequently used as a single option in OA patients who receive(d) a THA or TKA, only a small percentage of patients received all recommended non-surgical treatments. For that matter, only 6% of patients and 10% of orthopaedic surgeons reported using all recommended non-surgical treatments in step 1 and 2 of the SCS [27]. Given the known effectiveness of each of these treatments individually, use of the full range of available modalities may improve patient outcomes [2-6].

Dietary therapy was the least frequently used recommended non-surgical treatment for OA. Only 11% of overweight patients and 30% of obese patients reported having received dietary therapy, and only 28% of orthopaedic surgeons reported they would prescribe dietary therapy. Another study in the Netherlands showed that only 14% of overweight and obese patients with OA reported receiving dietary therapy [16]. This is even lower than reported in our study, but these patients were recruited by general practitioners, and thus may have subsequently received dietary therapy later on in the care trajectory for example after referral to an orthopaedic surgeon. In our study, patients had visited multiple health care providers, potentially increasing the likelihood of being offered dietary therapy when indicated. In other countries, dietary therapy seems to be more commonly used, for example 59% of physicians prescribed 'weight reduction' in a study performed in France [13], and 31% of patients with OA in a study in Canada [17]. Although the numbers are higher, the overall low rates across studies suggest that there is room for improvement. Similarly, a considerable number of patients were not prescribed physical therapy. The use of physical therapy as a non-surgical treatment could even be overestimated, because orthopaedic surgeons sometimes prescribe physical therapy as preparation before surgery instead of a non-surgical treatment to delay surgery. Dietary therapy and physical therapy are the only two recommended non-surgical treatments that an orthopaedic surgeon cannot provide himself, but for which referral is needed. Improving the use of these two treatments in orthopaedic care, may result in better quality of patient care as the combination of weight loss plus exercise is shown to provide better overall improvements in function, pain and mobility among older overweight and obese adults with knee OA compared with either intervention alone [24].

This study has some limitations. First, because of the retrospective nature of our study and the reliance on self-reported data, it is susceptible to recall bias. In an attempt to reduce this bias, we limited inclusion to patients who had a TKA or THA no longer than 12 months ago, or were scheduled for surgery within the next 3 months. Second, the use of an internet-based survey could induce selection bias. It is known that the majority of THA and TKA patients prefer pen-and-paper questionnaires, and that patients who prefer electronic questionnaires differ from patients who prefer pen-and-paper questionnaires [28]. It is possible that more elderly persons do not have internet or an email address compared to younger persons, which could have led to a selection of younger persons. The average age of patients with OA is 68.2 years [29] and our population is slightly younger, on average 64 (SD 7.7) years. However, age was not associated with the use of all recommended non-surgical treatments. Third, the use of a sample of patients responding to an advertisement may have introduced sampling bias. However, as our responding patients were distributed across different regions in the Netherlands, and had an age and gender distribution comparable to OA patients, we think that any bias that may have occurred is likely to be small. Similarly, selection bias may have occurred as a result of the low response rate (38%) among orthopaedic surgeons. However, such a response rate is comparable or higher than found in other online surveys among orthopaedic surgeons in the Netherlands [30,31]. It is possible that orthopaedic surgeons who are not interested in non-surgical treatment were less likely to complete the questionnaire or that orthopaedic surgeons overestimate their use of non-surgical treatments. This would only lead to an overestimation of non-surgical treatment use and the use may be even lower. Furthermore, the use of acetaminophen, NSAIDs and tramadol could have been overestimated, as we were not able to define a minimum for the use of these treatments (eg, at least 1 tablet per day) due to differences between recommendations. Therefore, we simply reported whether patients took acetaminophen or NSAIDs (yes/ no) without any minimum dose. However, in some cases the use was less than multiple days per month (4% for acetaminophen and 5% for NSAIDs, results not shown). In addition, 57 patients (33%) suffered from hypertension and 12 (7%) from cardiovascular diseases, both of which are contraindications to NSAIDs use [6]. This may have resulted in underestimating the use of NSAIDs or Tramadol, as these patients should be excluded from these estimates.

To our knowledge this is the first study that evaluated the full range of combinations of non-surgical treatments for OA, both from the perspective of orthopaedic surgeons and patients. While most recommended non-surgical treatments for OA were used frequently as single therapy, the combination is used in only a small percentage of OA patients who receive(d) a THA or TKA. Despite their potential for reducing symptoms of knee and hip OA, dietary therapy and physical therapy appear to be least frequently used. By increasing the use of these two non-surgical treatments, both primary care physicians and orthopaedic surgeons may be able to help patients better manage their symptoms, thereby improving quality of care and potentially postpone the need for joint arthroplasty, resulting in improved long-term patient outcomes. Future studies should focus on evaluating the reasons (barriers) why some orthopaedic surgeons do not use recommended non-surgical treatments. Such findings may be helpful in developing targeted strategies to improve the use of these treatments in orthopaedic practice and thereby to improve quality of care. Although the recommended non-surgical treatment options have been proven to be effective individually or in combination (eg, physical therapy with dietary therapy [24]), there are no published studies that investigated the combined effect of all of these treatments. Nevertheless, it has been hypothesised that optimised non-surgical treatment could result in significantly greater pain reduction, functional improvement and increase in quality of life than usual care in knee OA [32]. The results from the present study suggest that such better outcomes may be achieved in a considerable part of OA patients.

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Chapter 4

Barriers and facilitators to use non-surgical treatments for osteoarthritis patients in orthopaedic practice

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ABSTRACT

Introduction

International evidence-based guidelines for the management of patients with hip and knee osteoarthritis (OA) recommend to start with (a combination of) non-surgical treatments, and using surgical intervention only if a patient does not respond sufficiently to non-surgical treatment options. Despite these recommendations, there are strong indications that non-surgical treatments are not optimally used in orthopaedic practice. To improve the adoption of non-surgical treatments, more insight is needed into barriers and facilitators of these treatments. Therefore, this study assessed which barriers and facilitators are associated with the use and prescription of different non-surgical treatments before hip and knee OA in orthopaedic practice among patients and orthopaedic surgeons in the Netherlands.

Materials and Methods

We performed two internet-based surveys among 172 orthopaedic surgeons and 174 OA patients. Univariate association and multivariable regression techniques are used to identify barriers and facilitators associated with the use of non-surgical treatments.

Results

Most barriers and facilitators among patients were associated with the use of physical therapy, lifestyle advice and dietary therapy. Among orthopaedic surgeons, most were associated with prescription of acetaminophen, dietary therapy and physical therapy. Examples of barriers and facilitators among patients included “People in my environment had positive experiences with a surgery” (facilitator for education about OA), and “Advice of people in my environment to keep on moving” (facilitator for lifestyle and dietary advice). For orthopaedic surgeons examples were “Lack of knowledge about guideline” (barrier for lifestyle advice), “Agreements/ deliberations with primary care” and “Easy communication with a dietician” (facilitators for dietary therapy). Also the belief in the efficacy of these treatments was associated with increased prescription.

Conclusions

Strategies to improve non-surgical treatment use in orthopaedic practice should be targeted at changing the beliefs of orthopedic surgeons, communication with other OA care providers and involving patient’s environment in OA treatment.

INTRODUCTION

Patients with symptomatic knee or hip osteoarthritis (OA) may suffer from pain and loss of function, which can be treated by performing a total hip arthroplasty (THA) or total knee arthroplasty (TKA). However, these treatments should not be given too early, given the limited lifespan of a prosthesis and the less successful outcomes after revision than after primary THA or TKA [1]. Therefore, international evidence-based guidelines for hip and knee OA recommend to start with (a combination of) non-surgical treatments [2-6]. These treatments aim to prevent progression and reduce symptoms such as joint pain and impairment of functions [6]. Following the existing guidelines in the Netherlands, patients with OA are first treated by the general practitioner and referred to an orthopedic surgeon if they do not respond sufficiently to non-surgical treatment options. In orthopaedic practice, the decision will be made to continue non-surgical treatments or to perform surgery. A stepped-care strategy (SCS) based on (inter) national guidelines [7,8] was developed to facilitate the use of non-surgical treatments in three steps.

Despite recommendations and the SCS, previous studies suggest that the use of non-surgical treatments in patients with hip or knee OA can be improved [9-12]. For example, Snijders et al. [9] found that 81% of patients with hip or knee OA did not receive all non-surgical treatments in the primary care setting. Many patients may thus be referred to orthopaedic practice without having received all recommended non-surgical options. In these cases, the orthopaedic surgeon could provide additional non-surgical treatments. However, our previous study showed that only 10% of the patients in orthopaedic practice received all recommended non-surgical treatments before surgery [13]. These findings are consistent with the rising number of THA and TKA in OA patients in the Netherlands [14]. In addition, the large variation in preoperative status (e.g. disease severity) across different centers in Europe and Australia [15,16] suggests differences in timing of surgery, possibly influenced by non-surgical treatment use. An improved use of non-surgical treatments may reduce surgery rates as well as variation in preoperative status.

More insight is needed into factors that hinder (barriers) and facilitate (facilitators) the use of recommended non-surgical treatments in orthopaedic practice. Some studies have been carried out focused at identifying barriers or facilitators for a specific non-surgical treatment, [17-19], or carried out in primary care [20]. However, it is unknown whether identified factors in these studies also apply to non-surgical treatment use in orthopaedic practice. Furthermore, previous research mainly focused on barriers and facilitators at the patient level [10,21], such as people's own perceptions of the need to seek treatment [22]. However, barriers or facilitators may exist among professionals or within organizations that influence non-surgical treatment use.

Therefore, the aim of the study is to assess which barriers and facilitators are associated with the use and prescription of different non-surgical treatments before hip or knee osteoarthritis (OA) in orthopaedic practice among patients and orthopaedic surgeons.

MATERIALS AND METHODS

Study design

Cross-sectional internet-based surveys among OA patients and orthopaedic surgeons.

Survey development

To identify potential barriers and facilitators for non-surgical treatment use, semi-structured interviews were performed among 10 orthopaedic surgeons involved in hip and knee surgery and 5 patients in whom TKA or THA was performed no longer than 12 months ago. Purposive sampling was applied to obtain contrasting views and thereby identify all potential barriers and facilitators. Therefore, patients and orthopaedic surgeons were selected from Dutch regions with high and low surgery rates based on the report of Van Beek et al. [23], as participants from regions with lower surgery rates may perceive more facilitators and participants from regions with higher surgery rates more barriers. Furthermore, we selected participants from both academic and non-academic hospitals to take the possible impact of a different organization of care into account.

The interview questions were formulated to ensure the representation of all levels of the framework of Grol and Wensing [24] and the constructs of the Theoretical Domains Interview framework (TDI)[25]. The framework of Grol and Wensing distinguishes the following levels: the innovation, the professional, the patient, the social context, the organizational context, and the external environment (political and economic factors) [24]. The TDI framework includes 12 theoretical construct domains derived from 33 psychological theories and covering 128 explanatory constructs that enhance implementation of evidence-based practice[25]. In addition, previously reported barriers and facilitators in primary care [26] were included. The semi-structured interviews were audio-taped, transcribed in full and analyzed using open coding. The qualitative analysis was executed using the software package ATLAS.ti (ATLAS.ti Scientific Software Development GmBH, Berlin, Germany). A total of 35 barriers and 23 facilitators were identified during the in-depth interviews among orthopaedic surgeons and 20 barriers and 12 facilitators among patients.

Survey for patients

Population

The developed internet-based survey was sent to a sample of patients (n=195), to estimate a previously reported 19% use of non-surgical treatments among 47,000 patients with hip and knee OA annually in the Netherlands, with a 5% margin of error [13,27]. Patients were recruited via advertisements in newspapers, and at websites or newsletters of patient associations. Inclusion criteria were: age ≥ 18 years, a doctor's diagnosis of hip or knee OA, and either having TKA or THA performed no longer than 12 months ago or being on the waiting list for surgery within three months. The latter criteria were included to ensure that the decision for surgery had already been made. Patients with an inability to understand written Dutch or who had undergone revision surgery were excluded. Two reminders were sent in case of non-response, one after 1.5 weeks and again after three weeks. Participants received a ten euro gift card as an incentive upon completion of the questionnaire.

Survey

The first part of the survey included questions on patient characteristics: age, gender, region of residence (north, middle, and south), educational level (basic education (no or only primary education), intermediate education (prevocational secondary education, senior secondary vocational training, senior secondary general education, pre-university education), or higher education (higher professional education or university (bachelor, master, or PhD degree)), work situation (paid work or no paid work), height and weight to calculate the Body Mass Index (BMI), and type of insurance (basic coverage and additional coverage). All inhabitants of the Netherlands have a basic insurance coverage (legally obliged) and have the option of purchasing supplementary insurance covering additional healthcare such as physical therapy and dietary therapy, rather than being subject to out of pocket expenses. In addition, questions were included about use of each of the recommended non-surgical options (education about OA, education about different treatment options, lifestyle advice, dietary therapy, physical therapy, acetaminophen, NSAIDs, and glucocorticoid injections (only for knee OA) [28]) which were formulated as follows: "Did you receive the following treatments for your complaints on your affected joint before the joint replacement surgery?" (yes/ no). The second part of the questionnaire consisted of 32 items covering the identified barriers and facilitators from the interviews. Patients were asked to indicate the influence of each facilitator and barrier on non-surgical treatment use. Answers could be given on a 4-point Likert scale ranging from not important to very important, or to indicate "not applicable to my situation" for example for the facilitator "guidance of the exercise therapist" if the patient had never visited one. The survey was pilot tested among three patients to test whether patients understood the questions and answering categories.

Survey for orthopaedic surgeons

Population

All 482 Dutch orthopaedic surgeons listed with an email address in the registry of the Dutch Orthopaedic Association (NOV) and/or the Dutch medical address book were invited to participate. Inclusion criterion was: seeing patients with hip or knee OA. Non-responders received two reminders, one after 1.5 weeks and again after three weeks.

Survey

The first part of the survey included questions about background characteristics: age, gender, work region, work setting, years of working experience, number of new patients with hip/ knee OA per month. In addition, questions were included about prescription of each of the recommended non-surgical options and were formulated as follows: "If patients did not receive the following non-surgical treatments, do you prescribe these treatments?" In case of physical therapy and dietary therapy we asked whether they referred patients, rather than prescribe these treatments themselves. Answers could be given on a 4-point scale ranging from never to almost always. The second part of the questionnaire consisted of 58 items covering the identified barriers and facilitators from the interviews. Orthopaedic surgeons were asked to what degree each barrier and facilitator influenced the prescription of non-surgical treatments in patients with hip and/ or knee OA. Answers could be given on a 4-point Likert scale ranging from none to a large extent.

Analysis

Data from all respondents completing the survey and fulfilling the inclusion criteria were included in the analyses. Descriptive statistics showed that many patients reported barriers and facilitators as not applicable to their situation, even though a number of these seem to be applicable to any patients' situation, e.g., "The practitioner took my problem seriously". As each patient visited a practitioner, all patients should have been able to answer this question but this was not the case. Given this example, we assume that patients have misunderstood "not applicable" as "not important", and that they selected an item as important only if they felt strongly about it. It was included accordingly in the analyses. We performed a sensitivity analysis treating the answers "not applicable" as missing in the univariate analyses. In addition, barriers and facilitators for patients were dichotomized into not important (grouping answering categories not important/ a little bit important/ not applicable on my situation) and important (grouping the answering categories important/ very important), because of few observations in some cells.

For patients, we first assessed the extent to which each barrier/ facilitator was associated with the use of each non-surgical treatment using univariate logistic regression analysis, with the barrier/facilitator (not important/ important) as the independent variable and use of each recommended treatment (yes/ no) as dependent variable. For orthopaedic surgeons this was done using the Spearman rank correlation as both the independent variable (influence of barrier/ facilitator for prescription of non-surgical treatments) and the dependent variable (prescription of the different non-surgical treatments) consisted of Likert scales with a clear ordering, but without information on the distance between the 4 points on the scale.

Secondly, as individual barriers/ facilitators may be related to others we included barriers/ facilitators significantly associated with use of each non-surgical treatment into a multivariable logistic regression model ($p<0.05$). Given the multiple testing in the first step, we used the more conservative p-value of 0.05 to include barriers/ facilitators in the multivariable model, rather than the commonly used o-value of 0.10 or 0.20. For orthopaedic surgeons, we dichotomized prescribed non-surgical treatments into "provided" (often/ almost always) and "not provided" (never/ sometimes) and barriers and facilitators into "0" (not at all/ a little bit) and "1" (to a reasonable extent/ to a large extent), because of few observations in some cells. All analyses were executed using the software package SPSS (IBM SPSS Statistics, version 20.0).

RESULTS

Response and characteristics of the population

Of the 195 recruited patients, 8 did not fulfill the inclusion criteria because they did not receive a surgery in the last 12 months and were not on the waiting list to receive surgery within 3 months. Of the remaining 187 patients, 174 (93%) completed the questionnaire. Nine of the 482 orthopaedic surgeons were excluded because they did not see patients with OA in consultations and 172 (36%) completed the questionnaire. Patients who responded had an average age of 64 (SD 7.7), were mostly female (72%), overweight (78%), and intermediate educational level (69%). Five patients (3%) were still on the waiting list, the remaining 169 patients had received a joint replacement. For 73% of the 174 patients it was their first joint replacement, 54% received a total knee and the history of complaints was less than 1 year for 8%, 1-5 years for 49% and more than 5 years for 43% of the patients. Patients reported a median pain score of 8.0 before surgery on a 0 (no pain)-10 (unbearable pain) Likert scale. Almost all patients had additional insurance coverage, meaning that physical and dietary therapy was also (partly) covered by their insurance rather than being subject to out of pocket expenses.

Orthopaedic surgeons had an average age of 48.4 (SD 8.6), were mostly males (91%), had worked on average 12.8 (SD 8.0) years as an orthopaedic surgeon, and saw on average 25.1 (SD 22.2) new patients with hip OA and 31.3 (SD 23.9) patients with knee

OA per month. The majority worked at a general hospital (52%). Both patients and orthopaedic surgeons were spread across different regions of the Netherlands.

Barriers and facilitators among patients for non-surgical treatment use

Table 1 shows all barriers (-) and facilitators (+) in the survey for each level of the framework of Grol and Wensing [24] and whether patients considered these barriers and facilitators as important. Most patients reported the following facilitators as very important: "Important to exercise/ to keep on moving at home" (50.6%), "Guidance by the physical therapist" (36.8%) and "Sufficient time of the practitioner(s) to explain everything" (31.6%). Barriers reported by most patients as very important were: "Preference of practitioner for surgery" (31.6%), "Too much loss of cartilage to use non-surgical treatments" (29.9%) and "People in my environment had positive experiences with a surgery" (26.4%).

Table 2 shows univariate associations between barriers/ facilitators and non-surgical treatments. Physical therapy, lifestyle advice and dietary therapy were associated with the largest numbers of barriers and facilitators e.g. a higher use of physical therapy and dietary therapy was associated with "Because of the good contact with my treating practitioner(s), I was able to carry on with non-surgical treatments" OR 5.68 (95% CI 2.71-11.93) and OR 4.17 (95% CI 1.33-13.07), respectively. A higher "use" of lifestyle advice was associated with "Important to exercise/ to keep on moving at home" (OR 6.52 (95% CI 2.59-16.43)). Treating the answers "not applicable" as missing gave similar results in the univariate analyses (data not shown).

Only a few of these barriers and facilitators were independently and significantly associated with non-surgical treatment use in the multivariable logistic regression analysis (table 3). People in patients' environment with positive experiences with surgery was associated with an increased use of OA education, lack of trust in non-surgical treatments was associated with a decreased use of education on different treatment options, and advice of people in patients' environment to keep on moving was associated with increased use of lifestyle advice. For dietary therapy, advice of people in my environment to keep on moving and good collaboration between the practitioners were associated with an increased use. Guidance by the physical therapist increased the use of physical therapy where lack of information provision about the use of acetaminophen was associated with a decreased use.

Table 1. The importance of barriers and facilitators reported by patients for non-surgical treatment use

Barriers and facilitators	Not important n (%)	A little bit important n (%)	Important n (%)	Very important n (%)	Not applicable n (%)
Innovation					
Individual professional					
Guidance by the physical therapist (+)	5 (2.9)	8 (4.6)	53 (30.5)	64 (36.8)	44 (25.3)
The practitioner(s) took my problem serious (+)	8 (4.6)	10 (5.7)	64 (36.8)	38 (21.8)	54 (31)
Sufficient information about non-surgical treatments (+)	2 (1.1)	12 (6.9)	63 (36.2)	36 (20.7)	61 (35.1)
Preference of practitioner(s) for non-surgical treatments (+)	1 (a0.6)	10 (5.7)	66 (37.9)	33 (19.0)	64 (36.8)
The orthopaedic surgeon asked about previously received treatments (+)	10 (5.7)	7 (4.0)	40 (23.0)	29 (16.7)	88 (50.6)
Because of the good contact with my treating practitioner(s), I was able to carry on with non-surgical treatments (+)	10 (5.7)	4 (2.3)	75 (43.1)	25 (14.4)	60 (34.5)
Explanation of drawbacks of the surgery (+)	8 (4.6)	11 (6.3)	42 (24.1)	24 (13.8)	89 (51.1)
Preference of practitioner for surgery (-)	11 (6.3)	5 (2.9)	38 (21.8)	55 (31.6)	65 (37.4)
Mainly the benefits of a surgery were discussed (-)	11 (6.3)	14 (8.0)	29 (16.7)	34 (19.5)	86 (49.4)
Lack of information provision about the use of acetaminophen (-)	21 (12.1)	6 (3.4)	15 (8.6)	19 (10.9)	113 (64.9)
Lack of information provision about the use of injections (-)	19 (10.9)	2 (1.1)	15 (8.6)	19 (10.9)	119 (68.4)
Lack of information provision about physical therapy (-)	16 (9.2)	6 (3.4)	14 (8.0)	18 (10.3)	120 (69.0)
The practitioner did not think physical therapy was necessary (-)	12 (6.9)	4 (2.3)	14 (8.0)	18 (10.3)	126 (72.4)

Barriers and facilitators	Not important n (%)	A little bit important n (%)	Important n (%)	Very important n (%)	Not applicable n (%)
Lack of information provision about the use of NSAIDs (-)	16 (9.2)	8 (4.6)	11 (6.3)	13 (7.5)	126 (72.4)
Lack of information provision by my practitioner (-)	15 (8.6)	11 (6.3)	20 (11.5)	10 (5.7)	118 (67.8)
Lack of empathy of the practitioner (-)	20 (11.5)	8 (4.6)	13 (7.5)	8 (4.6)	125 (71.8)
Lack of guidance with weight loss (-)	19 (10.9)	2 (1.1)	9 (5.2)	7 (4.0)	137 (78.7)
Patient					
Important to exercise/ to keep on moving at home (+)	1 (0.6)	6 (3.4)	58 (33.3)	88 (50.6)	21 (12.1)
Surgery was the last treatment option (+)	8 (4.6)	10 (5.7)	42 (24.1)	49 (28.2)	65 (37.4)
Too much loss of cartilage to use non-surgical treatments (-)	13 (7.5)	11 (6.3)	39 (22.4)	52 (29.9)	59 (33.9)
Too much pain (-)	16 (9.2)	12 (6.9)	39 (22.4)	43 (24.7)	64 (36.8)
I prefer not to use medication (-)	15 (8.6)	9 (5.2)	38 (21.8)	38 (21.8)	74 (42.5)
I cannot do anything to prevent/slow the development of OA (-)	21 (12.1)	11 (6.3)	26 (14.9)	33 (19.0)	83 (47.7)
Comorbidities (-)	14 (8.0)	4 (2.3)	9 (5.2)	14 (8.0)	134 (76.4)
Dissatisfaction with physical therapy (-)	22 (12.6)	3 (1.7)	9 (5.2)	10 (5.7)	130 (74.7)
Negative attitude towards exercises (-)	28 (16.1)	5 (2.9)	16 (9.2)	10 (5.7)	115 (66.1)
Lack of trust in non-surgical treatments (-)	19 (10.9)	8 (4.6)	16 (9.2)	9 (5.2)	122 (70.1)
Social context					
Advice of people in my environment to keep on moving (+)	12 (6.9)	12 (6.9)	52 (29.9)	38 (21.8)	60 (34.5)
Good collaboration between the practitioners (+)	6 (3.4)	14 (8.0)	57 (32.8)	20 (11.5)	77 (44.3)
People in my environment had positive experiences with surgery (-)	10 (5.7)	9 (5.2)	46 (26.4)	46 (26.4)	63 (36.2)

Barriers and facilitators	Not important n (%)	A little bit important n (%)	Important n (%)	Very important n (%)	Not applicable n (%)
Organizational context					
Sufficient time of the practitioner(s) to explain everything (+)	2 (1.1)	8 (4.6)	76 (43.7)	55 (31.6)	33 (19.0)
Economic and political context					
Additional payment for physical therapy not (fully) covered by insurance (-)	18 (10.3)	3 (1.7)	5 (2.9)	14 (8.0)	134 (77.0)

(+) Mentioned as facilitator in the interviews, asked as facilitator in the questionnaire
(-) Mentioned as barrier in the interviews, asked as barrier in the questionnaire

Table 2. The influence of barriers and facilitators reported by patients for non-surgical treatment use (univariate analyses)

	Education about OA OR (95% CI)	Education about different treatment options OR (95% CI)	Lifestyle advice OR (95% CI)	(Referral to) dietary therapy OR (95% CI)	Physical therapy OR (95% CI)	Acetaminophen OR (95% CI)	NSAIDs OR (95% CI)
Innovation							
-							
Individual professional							
Guidance by the physical therapist (+)	**2.34 (1.10-4.99)**	**2.39 (1.24-4.63)**	**3.76 (1.94-7.32)**	1.90 (0.65-5.54)	**24.00 (10.00-57-58)**	1.85 (0.93-3.68)	1.30 (0.68-2.50)
The practitioner(s) took my problem serious (+)	1.93 (0.91-4.07)	**2.22 (1.17-4.41)**	**3.47 (1.83-6.59)**	2.61 (0.90-7.56)	**3.57 (1.77-7.20)**	1.54 (0.79-3.00)	1.654 (0.88-3.10)
Sufficient information about non-surgical treatments (+)	**2.75 (1.28-5.91)**	**3.05 (1.59-5.84)**	**3.39 (1.79-6.41)**	**3.04 (1.05-8.79)**	**7.39 (3.41-16.00)**	1.24 (0.64-2.41)	**2.00 (1.07-3.75)**
Preference of practitioner(s) for non-surgical treatments (+)	**2.36 (1.11-5.04)**	**3.41 (1.77-6.56)**	**3.39 (1.79-6.41)f**	**2.93 (1.01-1.42)**	**8.67 (3.91-19.19)**	1.24 (0.64-2.41)	**2.22 (1.18-4.17)**
The orthopaedic surgeon asked about previously received treatments (+)	**2.64 (1.12-6.22)**	**2.30 (1.16-4.54)**	**1.99 (1.04-3.79)**	**3.02 (1.18-7.75)**	**4.51 (1.95-10.40)**	**2.99 (1.40-6.38)**	1.90 (0.97-3.66)
Because of the good contact with my treating practitioner(s), I was able to carry on with non-surgical treatments (+)	1.81 (0.86-3.83)	1.85 (0.98-3.50)	**3.18 (1.69-6.01)**	**4.17 (1.33-13.07)**	**5.68 (2.71-11.93)**	1.62 (0.83-3.14)	1.384 (0.74-2.58)
Explanation of drawbacks of the surgery (+)	**2.42 (1.03-5.70**	1.63 (0.84-3.18)	**3.58 (1.78-7.21)**	**4.51 (1.70-11.95)**	**4.10 (1.77-9.46)**	**3.17 (1.45-6.90)**	1.70 (0.88-3.28)
Lack of information provision about the use of acetaminophen (-)	1.59 (0.56-4.44)	1.09 (0.49-2.43)	0.65 (0.30-1.37)	1.45 (0.51-4.11)	**0.44 (0.20-0.97)**	1.35 (0.56-3.22)	1.46 (0.65-3.30)

	Education about OA OR (95% CI)	Education about different treatment options OR (95% CI)	Lifestyle advice OR (95% CI)	(Referral to) dietary therapy OR (95% CI)	Physical therapy OR (95% CI)	Acetaminophen OR (95% CI)	NSAIDs OR (95% CI)
The practitioner did not think physical therapy was necessary (-)	2.81 (0.40-9.84)	0.83 (0.37-1.83)	0.90 (0.41-1.96)	**4.65 (1.68-12.87)**	0.55 (0.24-1.23)	1.50 (0.60-3.74)	1.31 (0.58-2.98)
Lack of information provision by my practitioner (-)	2.57 (0.73-9.03)	1.51 (0.63-3.63)	0.93 (0.42-2.07)	2.91 (0.95-7.61)	1.26 (0.50-3.18)	1.35 (0.54-3.39)	**2.62 (1.01-6.81)**
Lack of empathy of the practitioner (-)	5.71 (0.74-44.13)	1.03 (0.39-2.71)	1.29 (0.49-3.38)	1.46 (0.37-5.77)	**8.60 (1.12-65.99)**	4.21 (0.94-18.82)	1.48 (0.55-4.04)
Lack of guidance with weight loss (-)	4.11 (0.52-32.25)	1.60 (0.49-5.20)	2.95 (0.81-10.77)	**5.41 (1.73-16.99)**	6.16 (0.79-48.01)	6.55 (0.84-50.97)	1.79 (0.55-5.80)
Patient							
Important to exercise/ to keep on moving at home (+)	1.10 (0.41-4.96)	1.88 (0.83-4.28)	**6.52 (2.59-16.43)**	5.06 (0.64-5.06)	**5.98 (2.53-14.10)**	1.84 (0.79-4.28)	1.66 (0.74-3.77)
Surgery was the last treatment option (+)	**3.49 (1.56-7.83)**	**2.82 (1.47-5.40)**	**3.71 (1.95-7.08)**	**3.23 (1.18-8.83)**	**5.57 (2.59-11.98)**	1.51 (0.78-2.94)	**2.23 (1.19-4.19)**
I cannot do anything to prevent/ slow the development of OA (-)	1.96 (0.83-4.63)	1.26 (0.64-2.47)	1.69 (0.87-3.29)	1.97 (0.79-4.91)	0.68 (0.34-1.35)	**2.15 (1.01-4.61)**	1.67 (0.60-2.25)
Negative attitude towards exercises (-)	1.07 (0.37-30.7)	0.79 (0.34-1.87)	1.22 (0.51-2.91)	**2.91 (1.02-8.31)**	0.68 (0.34-1.35)	1.37 (0.51-3.63)	1.65 (0.60-2.25)
Lack of trust in non-surgical treatments (-)	0.77 (0.28-2.09)	**0.34 (0.14-0.81)**	0.93 (0.37-2.1)	1.29 (0.39-4.23)	1.20 (0.45-3.22)	3.28 (0.93-11.50)	1.55 (0.61-3.94)

	Education about OA OR (95% CI)	Education about different treatment options OR (95% CI)	Lifestyle advice OR (95% CI)	(Referral to) dietary therapy OR (95% CI)	Physical therapy OR (95% CI)	Acetaminophen OR (95% CI)	NSAIDs OR (95% CI)
Social context							
Advice of people in my environment to keep on moving (+)	1.56 (0.74-3.30)	1.30 (0.69-2.43)	**4.45 (2.30-8.58)**	**12.91 (2.88-57.82)**	1.47 (0.75-2.89)	1.64 (0.84-3.20)	**1.94 (1.04-3.63)**
Good collaboration between the practitioners (+)	1.97 (0.90-4.34)	1.54 (0.81-2.93)	**2.99 (1.56-5.75)**	**5.80 (2.00-16.81)**	**5.80 (2.51-13.39)**	1.74 (0.88-3.45)	**2.04 (1.07-3.87)**
People in my environment had positive experiences with surgery (-)	**3.60 (1.60-8.06)**	1.71 (0.91-3.22)	1.15 (0.62-2.12)	1.91 (0.75-4.88)	0.61 (0.31-1.21)	1.56 (0.80-3.04)	1.03 (0.56-1.92)
Organizational context							
Sufficient time of the practitioner(s) to explain everything (+)	1.29 (0.56-2.95)	1.80 (0.89-3.65)	**4.40 (2.12-9.14)**	**8.97 (1.16-69.50)**	**3.86 (1.85-8.05)**	1.32 (0.63-2.79)	1.78 (0.88-3.59)
Economic and political context							
-							

In bold: P-values ≤ 0.05
Only barriers and facilitators with a significant association with at least one non-surgical treatment are reported

Table 3. The independent effect of barriers and facilitators reported by patients for non-surgical treatment use (multivariable analyses)

Non-surgical treatment	Used, yes (%)	Barrier (B) or facilitator (F)	Odds ratio (95% Confidence interval)	p-value
Education about OA	80	People in my environment had positive experiences with surgery (-)	3.42 (1.48-7.09)	0.004
Education about different treatment options	66	Lack of trust in non-surgical treatments (-)	0.28 (0.11-0.71)	0.008
Lifestyle advice	61	Advice of people in my environment to keep on moving (+)	3.11 (1.43-6.74)	0.004
(Referral to) dietary therapy (when indicated, n=130)	18	Advice of people in my environment to keep on moving (+)	11.56 (1.90-70.22)	0.008
		Good collaboration between the practitioners (+)	12.12 (1.22-120.73)	0.033
(Referral to) physical therapy	73	Guidance by the physical therapist (+)	20.52 (5.56-75.79)	<0.001
		Lack of information provision about the use of acetaminophen (-)	0.22 (0.06-0.75)	0.016
Acetaminophen	72	-	-	-
NSAIDs	64	-	-	-

Only barriers and facilitators with P-values ≤ 0.05 are shown in the table

Barriers and facilitators among orthopaedic surgeons for prescription of non-surgical treatments

Table 4 shows all barriers (-) and facilitators (+) in the survey for each level of the framework of Grol and Wensing [4] and whether orthopaedic surgeons considered these barriers and facilitators as important for the prescription of non-surgical treatments. Facilitators that influenced the prescription of non-surgical treatment to a large extent according to orthopaedic surgeons were: “Important to follow guidelines” (49.4%), “Important to try non-surgical treatments first” (49.4%) and “Acetaminophen has only a few side effects” (48.8%) (table 4). Barriers reported by most orthopedic surgeons were “Glucocorticoid injections is a symptomatic treatment” (14.0%), “No effect of physical therapy when there is an obvious loss of cartilage” (9.9%) and “Physical therapy for hip OA is not effective” (6.4%).

Table 5 shows that the prescription of acetaminophen, dietary therapy and physical therapy were associated with the largest numbers of barriers and facilitators e.g. a

Table 4. The degree of influence of barriers and facilitators reported by orthopaedic surgeons for prescription of non-surgical treatments

Barriers and facilitators	Not at all n (%)	A little bit n (%)	To a reasonable extent n (%)	To a large extent n (%)
Innovation				
Clear referral criteria/ guideline (+)	7 (4.1)	10 (5.8)	96 (55.8)	59 (34.3)
The guideline is outdated (-)	69 (40.1)	74 (43.0)	21 (12.2)	8 (4.7)
Lack of guidance in guideline (-)	54 (31.4)	83 (48.3)	32 (18.6)	3 (1.7)
The guideline is unclear about NSAID dosage (-)	73 (42.4)	64 (37.2)	32 (18.6)	3 (1.7)
Individual professional				
Important to follow guidelines (+)	5 (2.9)	3 (1.7)	79 (45.9)	85 (49.4)
Important to try non-surgical treatments first (+)	5 (2.9)	10 (5.8)	72 (41.9)	85 (49.4)
Acetaminophen has only a few side effects (+)	9 (5.2)	20 (11.6)	59 (34.3)	84 (48.8)
Only few drawbacks for the use of non-surgical treatments (+)	2 (1.2)	10 (5.8)	83 (48.3)	77 (44.8)
Patients benefit from weight loss (+)	3 (1.7)	25 (14.5)	82 (47.7)	62 (36.0)
Non-surgical treatments motivate patients to do things themselves (+)	3 (1.7)	44 (25.6)	86 (50.0)	39 (22.7)
Good results of physical therapy (+)	6 (3.5)	57 (33.1)	84 (48.8)	25 (14.5)
Patients benefit from Acetaminophen (+)	6 (3.5)	55 (32.0)	87 (50.6)	24 (14.0)
Important to delay a surgery as long as possible (+)	6 (3.5)	55 (32.0)	87 (50.6)	24 (14.0)
Patients benefit from Glucocorticoid injections (+)[a]	7 (4.1)	62 (36.0)	84 (48.8)	19 (11.0)
Patients benefit from NSAIDs (+)	3 (1.7)	43 (25.0)	109 (63.4)	17 (9.9)
Surgery has many disadvantages/ complications/ risks (+)	17 (9.9)	97 (56.4)	48 (27.9)	10 (5.8)
Total knee arthroplasty leads to little results (+)	91 (52.9)	63 (36.6)	16 (9.3)	2 (1.2)
Glucocorticoid injections is a symptomatic treatment (-)[a]	64 (37.2)	53 (30.8)	31 (18.0)	24 (14.0)
No effect of physical therapy when there is an obvious loss of cartilage (-)	50 (29.1)	59 (34.3)	46 (26.7)	17 (9.9)
Physical therapy for hip OA is not effective (-)	39 (22.7)	74 (43.0)	48 (27.9)	11 (6.4)

Barriers and facilitators	Not at all n (%)	A little bit n (%)	To a reasonable extent n (%)	To a large extent n (%)
Limited results of dietary advice/ weight loss (-)	30 (17.4)	91 (52.9)	40 (23.3)	11 (6.4)
Lack of knowledge about guideline (-)	83 (48.3)	63 (36.6)	21 (12.2)	5 (2.9)
Disagreement with (part of) the guideline (-)	73 (42.4)	79 (45.9)	16 (9.3)	4 (2.3)
Side effects/ contraindications NDAIDs (-)	26 (15.1)	91 (52.9)	53 (30.8)	2 (1.2)
Side effects/ complications of Glucocorticoid injections (-)	57 (33.1)	89 (51.7)	25 (14.5)	1 (0.6)
Reduced success rate of TKA/ THA when surgery is delayed (-)	115 (66.9)	41 (23.8)	15 (8.7)	1 (0.6)
Preference for surgery (-)	161 (93.6)	9 (5.2)	1 (0.6)	1 (0.6)
Patient				
Patient cannot afford absenteeism at work (-)	35 (20.3)	82 (47.7)	44 (25.6)	11 (6.4)
Negative attitude of patients towards lifestyle adjustments (-)	61 (35.5)	74 (43.0)	31 (18.0)	6 (3.5)
Losing weight is a sensitive topic (-)	74 (43.0)	61 (35.5)	31 (18.0)	6 (3.5)
Patients do not want to take pills (-)	51 (29.7)	83 (48.3)	33 (19.2)	5 (2.9)
Patient does not want physical therapy (-)	55 (32.0)	87 (50.6)	26 (15.1)	4 (2.3)
Pressure by patient for surgery (-)	35 (20.3)	94 (54.7)	40 (23.3)	3 (1.7)
The decision to perform surgery is more easily made in elderly patients (-)	63 (36.6)	66 (38.4)	41 (23.8)	2 (1.2)
Social context				
Agreements with colleagues about the content of the care trajectory (+)	7 (4.1)	43 (25.0)	90 (52.3)	32 (18.6)
Peer review / audit of professional association (+)	17 (9.9)	38 (22.1)	85 (49.4)	32 (18.6)
Positive attitudes of colleagues about non-surgical treatments (+)	13 (7.6)	59 (34.3)	89 (51.7)	11 (6.4)
Trained to be reluctant with Glucocorticoid injections (-)[a]	91 (52.9)	58 (33.7)	15 (8.7)	8 (4.7)
Social pressure of environment patient (-)	74 (43.0)	71 (41.3)	26 (15.1)	1 (0.6)
Lack of feedback between different disciplines (-)	75 (43.6)	65 (37.8)	27 (15.7)	5 (2.9)

Barriers and facilitators	Not at all n (%)	A little bit n (%)	To a reasonable extent n (%)	To a large extent n (%)
Organizational context				
Clarity on what the patient has done at the physical therapist (+)	16 (9.3)	31 (18.8)	95 (55.2)	30 (17.4)
Agreements/ deliberations with primary care (GP, physical therapist, dietician) (+)	18 (10.5)	58 (33.7)	75 (43.6)	21 (12.2)
Presence of an obesity clinic (+)	81 (47.1)	66 (38.4)	22 (12.8)	3 (1.7)
A multidisciplinary meeting (+)	90 (52.3)	63 (36.6)	16 (9.3)	3 (1.7)
Easy communication with a dietician (+)	110 (64)	49 (28.5)	10 (5.8)	3 (1.7)
Lack of visibility into physical therapies (-)	64 (37.2)	75 (43.6)	23 (13.4)	10 (5.8)
Non-surgical treatments take a lot of time (-)	78 (45.3)	69 (40.1)	18 (10.5)	7 (4.1)
Lack of referral structure to dietician (-)	104 (60.5)	49 (28.5)	14 (8.1)	5 (2.9)
Non-surgical treatments belong to primary care (-)	105 (61.0)	46 (26.7)	17 (9.9)	4 (2.3)
Quick patients flow with surgery (-)	131 (76.2)	28 (16.3)	11 (6.4)	2 (1.2)
Pressure for production (-)	148 (86.0)	20 (11.6)	2 (1.2)	2 (1.2)
Lack of referral structure to physical therapist (-)	131 (76.2)	32 (18.6)	8 (4.7)	1 (0.6)
Indication for surgery depends on the length of the waiting list (-)	161 (93.6)	9 (5.2)	1 (0.6)	1 (0.6)
Economic and political context				
Availability of non-surgical treatments (+)	6 (3.5)	23 (13.4)	100 (58.1)	43 (25.0)
Physical therapy is not (fully) covered by insurance (-)	69 (40.1)	54 (31.4)	40 (23.3)	9 (5.2)
A consult at a dietician is not covered by insurance (-)	107 (62.2)	41 (23.8)	21 (12.2)	3 (1.7)
Availability of surgeries in other hospitals in the area (-)	128 (74.4)	37 (21.5)	4 (2.3)	3 (1.7)
Financial interest in surgery (-)	157 (91.3)	11 (6.4)	2 (1.2)	2 (1.2)

(+) Mentioned as facilitator in the interviews, asked as facilitator in the questionnaire
(-) Mentioned as barriers in the interviews, asked as barrier in the questionnaire
aOnly for patients with knee OA

Table 5. Influence of barriers and facilitators reported by orthopaedic surgeons for prescription of non-surgical treatments

	Education about OA	**Education about different treatment options**	**Lifestyle advice**	**(Referral to) dietary therapy**	**Physical therapy**	**Acetaminophen**	**NSAIDs**	**Glucocorticoid injectiona**
Innovation								
Clear referral criteria/ guideline	*r*=0.10 P=0.20	*r*=0.12 P=0.12	*r*=0.09 P=0.24	***r*=0.25** **P<0.01**	***r*=0.15** **P=0.05**	***r*=0.29** **P<0.01**	*r*=0.10 P=0.18	*r*=0.05 P=0.50
The guideline is outdated	*r*=-0.05 P=0.51	*r*=-0.06 P=0.46	*r*=0.02 P=0.83	*r*=0.06 P=0.48	*r*=0.05 P=0.51	*r*=-0.06 P=0.43	***r*=0.16** **P=0.04**	*r*=0.10 P=0.20
Lack of guidance in guideline	*r*=-0.03 P=0.69	*r*=-0.06 P=0.46	*r*=-0.02 P=0.85	*r*=-0.01 P=0.82	*r*=-0.04 P=0.62	*r*=-0.07 P=0.39	*r*=0.13 P=0.09	*r*=0.16 P=0.03
Individual professional								
Important to try non-surgical treatments first	***r*=0.21** **P<0.01**	*r*=0.14 P=0.08	*r*=0.12 P=0.13	***r*=0.17** **P=0.02**	*r*=0.08 P=0.28	***r*=0.25** **P<0.01**	*r*=0.12 P=0.13	*r*=0.05 P=0.56
Acetaminophen has only a few side effects	*r*=0.14 P=0.06	***r*=0.19** **P=0.01**	***r*=0.28** **P<0.01**	***r*=0.18** **P=0.02**	*r*=0.08 P=0.31	***r*=0.48** **P<0.0**	*r*=0.09 P=0.24	*r*=0.10 P=0.21
Only few drawbacks for the use of non-surgical treatments	*r*=0.09 P=0.24	*r*=0.10 P=0.21	***r*=0.21** **P<0.01**	***r*=0.21** **P<0.01**	*r*=0.12 P=0.12	***r*=0.23** **P<0.01**	*r*=-0.03 P=0.66	*r*=0.06 P=0.47
Patients benefit from weight loss	*r*=0.03 P=0.69	*r*=0.10 P=0.19	***r*=0.21** **P<0.01**	***r*=0.43** **P<0.01**	*r*=0.03 P=0.66	*r*=0.11 P=0.16	*r*=0.06 P=0.44	*r*<-0.01 P=0.9
Non-surgical treatments motivate patients to do things themselves	*r*=0.14 P=0.08	*r*=0.13 P=0.08	***r*=0.23** **P<0.01**	*r*=0.13 P=0.09	*r*=0.12 P=0.11	***r*=0.17** **P=0.02**	*r*=-0.01 P=0.86	*r*=-0.09 P=0.26
Good results of physical therapy	*r*=-0.02 P=0.84	*r*=-0.02 P=0.76	*r*=0.12 P=0.11	***r*=0.16** **P=0.03**	*r*=0.53 P<0.01	***r*=0.22** **P<0.01**	*r*=0.11 P=0.17	*r*<-0.01 P=0.95
Patients benefit from Acetaminophen	*r*=0.02 P=0.79	*r*=-0.05 P=0.53	*r*=0.03 P=0.66	***r*=0.22** **P<0.01**	*r*=0.10 P=0.19	***r*=0.50** **P<0.01**	***r*=0.20** **P<0.01**	*r*=0.07 P=0.36

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	Education about OA	**Education about different treatment options**	**Lifestyle advice**	**(Referral to) dietary therapy**	**Physical therapy**	**Acetaminophen**	**NSAIDs**	**Glucocorticoid injectiona**
Important to delay a surgery as long as possible	***r*=0.18** **P=0.02**	***r*=0.18** **P=0.02**	*r*=0.09 P=0.27	*r*=0.04 P=0.62	*r*=-0.03 P=0.75	*r*=0.15 P=0.05	*r*=-0.03 P=0.73	*r*=0.05 P=0.50
Patients benefit from Glucocorticoid injectionsa	*r*=-0.02 P=0.80	*r*=0.03 P=0.69	*r*=-0.07 P=0.39	r<0.01 P=0.97	*r*=-0.01 P=0.92	***r*=0.16** **P=0.04**	*r*=0.14 P=0.06	***r*=0.49** **P<0.01**
Patients benefit from NSAIDs	*r*=0.08 P=0.33	*r*=0.07 P=0.34	*r*=0.08 P=0.29	*r*=0.15 P=0.06	*r*=0.05 P=0.53	***r*=0.20** **P=0.01**	***r*=0.37** **P<0.01**	*r*=0.03 P=0.72
Surgery has many disadvantages/ complications/ risks	*r*=0.06 P=0.44	*r*=0.01 P=0.93	*r*=0.05 P=0.55	*r*=0.06 P=0.46	*r*=0.06 P=0.42	***r*=0.21** **P<0.01**	*r*=-0.02 P=0.85	*r*=-0.01 P=0.90
Glucocorticoid injections is a symptomatic treatmenta	*r*=-0.04 P=0.61	*r*=-0.10 P=0.20	*r*=0.09 P=0.26	*r*=0.12 P=0.11	*r*=0.08 P=0.30	*r*=-0.05 P=0.53	*r*=0.01 P=0.87	***r*=-0.25** **P<0.01**
No effect of physical therapy when there is an obvious loss of cartilage	*r*=0.02 P=0.85	*r*=0.02 P=0.79	***r*=-0.19** **P=0.02**	*r*=-0.09 P=0.23	***r*=-0.30** **P<0.01**	***r*=-0.21** **P<0.01**	*r*=-0.02 P=0.75	*r*=0.06 P=0.46
Physical therapy for hip OA is not effective	*r*=0.02 P=0.81	*r*=0.04 P=0.61	*r*=-0.10 P=0.21	*r*=-0.12 P=0.11	***r*=-0.29** **P<0.0**	*r*=-0.06 P=0.47	*r*=0.08 P=0.30	*r*=0.06 P=0.40
Lack of knowledge about guideline	*r*=-0.07 P=0.34	***r*=-0.21** **P<0.01**	***r*=-0.17** **P=0.03**	*r*=-0.07 P=0.35	*r*=-0.02 P=0.82	*r*=-0.05 P=0.51	*r*=-0.03 P=0.67	*r*=0.11 P=0.14
Patient								
Patient cannot afford absenteeism at work	*r*=0.14 P=0.06	***r*=0.15** **P=0.05**	*r*=0.10 P=0.2	*r*=-0.01 P=0.99	*r*=0.06 P=0.94	*r*=0.08 P=0.31	*r*=-0.02 P=0.81	*r*=0.03 P=0.68
Pressure by patient for surgery	*r*=0.12 P=0.1	*r*=-0.02 P=0.84	*r*<-0.01 P=0.97	*r*=0.14 P=0.08	*r*=-0.07 P=0.36	*r*=0.03 P=0.66	*r*=0.07 P=0.37	***r*=0.15** **P=0.05**

	Education about OA	Education about different treatment options	Lifestyle advice	(Referral to) dietary therapy	Physical therapy	Acetaminophen	NSAIDs	Glucocorticoid injectiona
Social context								
Trained to be reluctant with Glucocorticoid injections[a]	*r*=0.11 P=0.16	r<0.01 P=0.10	*r*=0.13 P=0.09	*r*=0.13 P=0.08	*r*=0.03 P=0.68	*r*=0.12 P=0.12	*r*=0.05 P=0.53	***r*=-0.30** **P<0.01**
Organizational context								
Clarity on what the patient has done at the physical therapist	*r*=0.02 P=0.80	*r*=0.10 P=0.20	***r*=0.17** **P=0.03**	*r*=0.14 P=0.06	***r*=0.30** **P<0.01**	***r*=0.25** **P=0.01**	*r*=0.04 P=0.60	*r*=-0.02 P=0.81
Agreements/ deliberations with primary care (GP, physical therapist, dietician)	*r*=0.08 P=0.33	*r*=-0.04 P=0.65	*r*=0.03 P=0.68	***r*=0.184** **P=0.02**	***r*=0.20** **P<0.01**	*r*=0.11 P=0.16	*r*=0.12 P=0.13	***r*=0.17** **P=0.02**
Presence of an obesity clinic	*r*=0.06 P=0.42	*r*=0.06 P=0.42	*r*=0.14 P=0.06	***r*=0.36** **P<0.01**	***r*=0.20** **P=0.01**	***r*=0.17** **P=0.02**	***r*=0.16** **P=0.03**	*r*=0.02 P=0.77
Easy communication with a dietician	*r*=-0.06 P=0.47	*r*=-0.03 P=0.72	*r*=0.05 P=0.55	***r*=0.29** **P<0.01**	*r*=0.09 P=0.27	*r*=0.13 P=0.09	*r*=0.09 P=0.24	*r*=0.02 P=0.79
Non-surgical treatments belong to primary care	*r*=-0.01 P=0.93	*r*=-0.04 P=0.58	*r*=0.01 P=0.94	*r*=-0.06 P=0.4	***r*=-0.23** **P<0.01**	*r*=0.02 P=0.84	*r*=0.10 P=0.21	*r*=-0.05 P=0.53
Lack of referral structure to physical therapist	*r*=-0.07 P=0.37	*r*=-0.02 P=0.83	*r*=-0.09 P=0.24	*r*=0.01 P=0.87	***r*=-0.20** **P=0.01**	*r*=0.01 P=0.92	***r*=0.17** **P=0.03**	*r*=-0.01 P=0.91
Economic and political context								
Availability of non-surgical treatments	*r*=0.06 P=0.45	*r*=0.15 P=0.06	*r*=0.14 P=0.06	***r*=0.20** **P=0.0**	***r*=0.16** **P=0.04**	*r*=0.14 P=0.06	r<-0.01 P=0.97	*r*=0.02 P=0.80
A consult at a dietician is not covered by insurance	*r*=0.01 P=0.87	*r*=0.05 P=0.54	*r*=0.07 P=0.36	*r*=0.02 P=0.83	*r*=-0.01 P=0.87	*r*=0.13 P=0.10	***r*=0.19** **P=0.01**	*r*=0.10 P=0.19

r= Spearman rank correlation
In bold: P-values ≤ 0.05
aOnly for patients with knee OA

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higher use of acetaminophen was associated with the belief that acetaminophen has only a few side effects (*r*=0.48, P<0.01). A higher prescription of dietary therapy was associated with the presence of an obesity clinic (*r*=0.36, P<0.01). Lower prescription of physical therapy is associated with the belief that physical therapy for hip OA was not effective (*r*=-0.29, P<0.01).

Only a few of these barriers and facilitators were independently and significantly associated with prescription of non-surgical treatments in the multivariable logistic regression analysis (table 6). Lack of knowledge about the guideline was associated with a decreased prescription of lifestyle advice. Agreements/ deliberations with primary care (GP, physical therapist, dietician) and easy communication with a dietician were both associated with increased prescription of dietary therapy. For acetaminophen, NSAIDs, and glucocorticoid injections, the belief in the efficacy of these treatments was associated with increased prescription. On the other hand, the belief that physical therapy for hip OA is not effective and that there is no effect when there is an obvious loss of cartilage was associated with decreased prescription of physical therapy.

Table 6. The independent effect of barriers and facilitators reported by orthopaedic surgeons for prescription of non-surgical treatments (multivariable analyses)

Non-surgical treatment	Provided, yes (%)	Barrier (B) or facilitator (F)	Odds ratio (95% Confidence interval)	p-value
Education about OA	87	-	-	-
Education about different treatment options	95	-	-	-
Lifestyle advice	98	Lack of knowledge about guideline	0.03 (0.001-0.50)	0.015
(Referral to) dietary therapy	28	Easy communication with a dietician	6.21 (1.48-26.10)	0.013
		Agreements/ deliberations with primary care (GP, physical therapist, dietician)	2.41 (1.05-5.53)	0.037
Referral to) physical therapy	54	Presence of an obesity clinic	4.12 (1.42-11.96)	0.009
		Clarity on what the patient has done at the physical therapist	2.42 (1.07-5.47)	0.034
		Physical therapy for hip OA is not effective	0.43 (0.20-0.92)	0.029
		No effect of physical therapy when there is an obvious loss of cartilage	0.39 (0.18-0.82)	0.013

Non-surgical treatment	Provided, yes (%)	Barrier (B) or facilitator (F)	Odds ratio (95% Confidence interval)	p-value
Acetaminophen	64	Acetaminophen has only a few side effects	7.99 (2.16-29.64)	0.002
		Important to try non-surgical treatments first	5.15 (1.16-22.87)	0.031
		Patients benefit from Acetaminophen	5.14 (1.80-14.72)	0.002
		No effect of physical therapy when there is an obvious loss of cartilage	0.23 (0.09-0.58)	0.002
NSAIDs	59	Patients benefit from NSAIDs	5.96 (2.45-14.52)	<0.001
		Pressure by patient for surgery	3.92 (1.63-9.45)	0.002

Only barriers and facilitators with P-values ≤ 0.05 are shown in the table

DISCUSSION

This study revealed barriers and facilitators for non-surgical treatment use in patients with hip and knee OA in orthopaedic practice. Most of the identified facilitators and barriers reported by orthopaedic surgeons reflect views on the effectiveness of non-surgical treatments. For example the barriers “Physical therapy for hip OA is not effective” or “No effect of physical therapy when there is an obvious loss of cartilage” were associated with decreased prescription of physical therapy. The facilitators “Patients benefit from Acetaminophen, NSAIDs or Glucocorticoid injections” were associated with an increased prescription of Acetaminophen, NSAIDs and Glucocorticoid injections, respectively. This means that an intervention to improve non-surgical treatment use may be targeted at trying to change the beliefs regarding the efficacy of non-surgical treatments among orthopaedic surgeons.

In addition, most of the barriers and facilitators reported by patients that were associated with the use of non-surgical treatment use reflect the importance of their environment e.g. “People in my environment had positive experiences with surgery” and “Advice of people in my environment to keep on moving”. Another study found that “help by others” was a facilitator for the use of analgesics in patients with knee OA [10]. Thus it seems to be important to involve patients’ environment (e.g. partners or other family members) so that they all understand the importance of non-surgical treatments, such as exercises and losing weight, and support the patient in using these treatments.

Previous studies focused on patients’ characteristics or on a specific treatment, whereas the present study adds that the patients’ environment and the views of orthopaedic surgeons on the effectiveness of non-surgical treatments play an important role in the use of these treatments. This is consistent with the barrier reported by patients reflecting the view of their health care provider: “Lack of trust in non-surgical treatments”, “Preference of practitioner for surgery” and “Too much loss of cartilage to use non-surgical treatments”. Furthermore, in our previous study only 54% of the orthopaedic surgeons reported that they referred patients to a physical therapist if a patient did not have that before [13]. This could partly be explained by the barriers reported by orthopaedic surgeons that were significantly associated with a decreased prescription of physical therapy: “Physical therapy for hip OA is not effective” and “No effect of physical therapy when there is an obvious loss of cartilage”. This shows that orthopaedic surgeons do not always believe in the effectiveness of physical therapy, even though evidence based guidelines do advice this [28]. Orthopaedic surgeons also perceived many barriers and facilitators regarding communication with primary care. In addition, a good collaboration between health care providers was associated with reported increased use of dietary therapy, as reported by patients. Therefore, it seems that clear referral criteria are needed between primary and hospital care, and agreements about the organization of care, for example how the physical therapist treats a patient. Focusing on dietary therapy, it appeared that “Agreements/ deliberations with primary care (GP, physical therapist, dietician)” and “Easy communication with a dietician” may facilitate the prescription of this treatment. Therefore, strategies to improve the prescription of these non-surgical treatments should also focus on the communication between orthopaedic surgeons and other health care providers, clear referral criteria and agreement about the organization of care, apart from changing the beliefs of orthopedic surgeons regarding the effectiveness of these non-surgical treatments.

This study has some limitations. First, because of the retrospective nature of our study and the reliance on self-reported data, it is susceptible to recall bias. To reduce this influence we only included patients who had a TKA or THA no longer than 12 months ago, or scheduled for surgery within the next 3 months. Second, the use of an internet-based survey could have induced selection bias. It is possible that more elderly persons do not have internet or an email address compared to younger persons. Indeed, the average age of patients with OA is 68 years [29] whereas the average age of our population was slightly lower, i.e. 64 (SD 7.7) years. Furthermore, response bias may have occurred because orthopaedic surgeons with an interest in non-surgical treatments may be more motivated and willing to participate and may perceive other barriers or facilitators. However, our response rate is comparable or higher than found in other online surveys among orthopaedic surgeons regarding different subjects [30-32]. Given the equal spread of respondents across the Netherlands, we think we will have captured all regions and thereby a rather complete view of both barriers and facilitators. Another limitation is that patients could answer “not applicable to my situation” in our survey. Although we explained to patients to choose this option only when they did not visit for example an exercise therapist when referring to barriers and facilitators for visiting an exercise therapist, it seems that this has been misunderstood. Despite this explanation and a previous pilot test of the questionnaire, we feel that patients misinterpreted this category. Therefore, we assumed that a patient would have selected an item if the patient had felt strongly about that item and interpreted “not applicable” as “not important”. Treating the answers “not applicable” as missing gave similar results in the univariate analyses (data not shown), which confirms the robustness of our results.

Strength of this study is that barriers and facilitators in the survey were identified during interviews with patients and orthopaedic surgeons in regions with low and high surgery rates. This ensures that the survey does not test the authors’ personal hypothesis but represents a rather complete set of possible barriers and facilitators based on existing frameworks. Another strong point is the finding that barriers and facilitators are independently associated with the use of non-surgical treatments. This ensures that identified barriers and facilitators are relevant to optimize of the use of non-surgical treatments. Still, the results of these multivariable regression analyses should be interpreted carefully, since answering categories were dichotomized [33]. For proper interpretation of results, the percentage using each non-surgical treatment, association of each barrier and facilitator and the multivariable analyses should all be taken into account.

Insight into barriers and facilitators is essential to optimize the use and prescription of non-surgical treatments. Previous studies that tested implementation strategies all conclude that a prior inventory of barriers and facilitators to develop a tailored implementation strategy is useful and can confirm whether barriers differ between settings [34-36]. Such a prior inventory thereby reduces the number of costly trials evaluating different implementation strategies [34,37,38]. Although previous studies already explored barriers and facilitators for the use of non-surgical treatments, these studies were performed in other settings, did not include all barriers/ facilitators and their influence on different non-surgical treatments, and were mostly focused on the patient level thereby ignoring the influence of professionals and organizations. A different setting may result in another strategy given the results from the present study e.g. if the beliefs regarding the effectiveness of non-surgical treatments differ between primary care and orthopaedic practice. The next step will be the development of an implementation strategy based on all identified barriers and facilitators both on the patient, professional and organizational level, which will be presented to the Dutch Orthopaedic Association to be implemented in clinical practice. Future studies should show whether this strategy is effective in improving the use and prescription of non-surgical care as well as patient outcomes.

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Chapter 5

Designing an implementation strategy to improve interprofessional shared decision making in sciatica: study protocol of the DISC study

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Implementation Science 2012, 7:55

ABSTRACT

Background

Sciatica is a common condition worldwide that is characterized by radiating leg pain and regularly caused by a herniated disc with nerve root compression. Sciatica patients with persisting leg pain after six to eight weeks were found to have similar clinical outcomes and associated costs after prolonged conservative treatment or surgery at one year follow-up. Guidelines recommend that the team of professionals involved in sciatica care and patients jointly decide about treatment options, so-called interprofessional shared decision making (SDM). However, there are strong indications that SDM for sciatica patients is not integrated in daily practice. We designed a study aiming to explore the barriers and facilitators associated with the everyday embedding of SDM for sciatica patients. All related relevant professionals and patients are involved to develop a tailored strategy to implement SDM for sciatica patients.

Methods

The study consists of two phases: identification of barriers and facilitators and development of an implementation strategy. First, barriers and facilitators are explored using semi-structured interviews among eight professionals of each (para) medical discipline involved in sciatica care (general practitioners, physical therapists, neurologists, neurosurgeons, and orthopedic surgeons). In addition, three focus groups will be conducted among patients. Second, the identified barriers and facilitators will be ranked using a questionnaire among a representative Dutch sample of 200 GPs, 200 physical therapists, 200 neurologists, all 124 neurosurgeons, 200 orthopedic surgeons, and 100 patients. A tailored team-based implementation strategy will be developed based on the results of the first phase using the principles of intervention mapping and an expert panel.

Discussion

Little is known about effective strategies to increase the uptake of SDM. Most implementation strategies only target a single discipline, whereas multiple disciplines are involved in SDM among sciatica patients. The results of this study can be used as an example for implementing SDM in other patient groups receiving multidisciplinary complex care (e.g., elderly) and can be generalized to other countries with similar context, thereby contributing to a worldwide increase of SDM in preference sensitive choices.

BACKGROUND

Sciatica, more accurately called lumbosacral radicular syndrome, is a form of radiating back pain, mostly caused by a herniated disc with nerve root compression. It is characterized by radiating leg pain in combination with dermatomal motor, sensory, or tendon reflex abnormalities. Sciatica is a common condition worldwide. In Western countries 5 to 10 per 1,000 persons annually develop sciatica, with variable pain intensities and disease course [1]. In the Netherlands, sciatica patients are initially diagnosed by general practitioners (GPs) and advised to continue daily activities with or without physical therapy (conservative treatment). After a period of six to eight weeks, the leg pain diminishes in 70% of the patients [2]. The remainder of the patients is usually referred to a neurologist for further investigation, often involving an MRI. If the MRI confirms a herniated disc, compatible with the radicular symptoms, the patient can be referred to the neurosurgeon or orthopedic surgeon to consider surgery [3,4]. In general, surgery leads to more rapid relief than prolonged conservative treatment in patients suffering radiating leg pain for more than eight weeks, but with smaller risks for prolonged conservative treatment, and both treatments have similar outcomes and societal costs at one year follow-up [5-7]. Therefore, the Dutch multidisciplinary guideline recommends that the team of professionals involved in sciatica care and patients jointly decide about treatment after this six to eight week period, i.e., surgery or prolonged conservative treatment, based on the evidence regarding associated risks and benefits and preference of the patient [8]. After all, both treatment options have equivalent results and the choice thus can be considered preference sensitive. This situation is optimally suited for interprofessional shared decision making (SDM) [9].

SDM enables patients to make an informed choice in collaboration with the professionals involved, and is important for providing care consistent with patient preferences. The Dutch government tries to make healthcare more patient-orientated, for example, by enabling free choice of insurance company, and a law that obligates professionals to discuss consequences and risks of each treatment option [10]. Despite these efforts to deliver patient-centered care, and the sciatica guideline recommendation, there are strong indications that SDM for sciatica patients is not yet widely used. Recently, a comparison between regions in the Netherlands showed considerable variation in the number of patients that undergo surgery, ranging from 31 to 140 per 100,000 inhabitants [11]. In addition, Dutch surgery rates for sciatica patients are four times higher than those in the UK and two times higher than in Sweden [11]. Only the United States have a 40% higher surgery rate than The Netherlands [12]. This is remarkable, because the guidelines in the United States and the UK show similarities, and both suggest referring patients to a specialist when they do not respond to standard noninvasive treatment or suffer from neurological deficits [13, 14]. It is very unlikely that this (inter)national variation is only caused by case mix and patient preferences. Research has shown that patients prefer a shared approach over a physician-dominated one, and are more likely to favor conservative treatments over surgery after patients' decision aid (DA) exposure [15, 16]. Furthermore, it has been shown that Dutch patients are used to delegate treatment decisions to their professionals, so that professional preferences dominate treatment decisions [17]. Thus, it is far more likely that noncompliance with the evidence-based back pain guidelines, specifically the lack of applying SDM, combined with surgeon preferences are responsible for the varying surgery rates. SDM may diminish this variation, prevent underuse and overuse of surgery [18], and thereby improve quality of care., and thereby improve quality of care.

Objective

The DISC study (the Dutch Implementation Study of interprofessional Shared Decision Making in Sciatica) aims to explore the barriers and facilitators associated with the everyday embedding of SDM for sciatica patients in the Dutch healthcare context, among all involved professionals and patients, and to develop a tailored, team-based, strategy for SDM implementation among sciatica patients.

METHODS

The study consists of two phases (table 1).

Table 1. Study phases and time schedule

	Planning (months)
Phase A. Identification of barriers and facilitators	
i. Barriers and facilitators are explored for SDM implementation	
Literature study and preparation interviews/ focus groups	1 to 3
Interviews and focus groups	3 to 10
ii. Identified barriers and facilitators are ranked by importance in a representative sample	
Survey among professionals and patients	11 to 13
Phase B. The development of an implementation strategy based on phase A	
Development of the implementation strategy and expert panel	13 to 15
Writing report	16

Identification of barriers and facilitators.

i. Barriers and facilitators are explored for SDM implementation

Study design

Barriers and facilitators among relevant stakeholders are explored in an interview study among professionals and in a focus group study among patients. The semi-structured interviews and focus groups are based on the framework developed by Grol and Wensing [19] in combination with the Normalization Process Model (NPM) [20]. The framework of Grol and Wensing [19] describes barriers and facilitators at the levels of the innovation, the professional, the patient, the social context, the organizational context, and the external environment (political and economic factors). However, the organizational context of their framework does not cover all relevant aspects for the implementation of SDM in practice. Therefore, we additionally use the NPM, which includes more details with respect to the organizational context [20] than the framework of Grol and Wensing. Normalization in the NPM is defined as the routine embedding of a complex intervention in healthcare, and this model thus offers a robust structure for investigating the collective work that leads to this embedding (or not), including:

1. Endogenous factors
    a. Interactional workability: influence of SDM on interactions between people and practices.
    b. Relational integration: relationship of SDM to existing knowledge and relationships.
2. Exogenous factors
    a. Skill set workability: influence of SDM on current division of labor.
    b. Contextual integration: relationship of SDM to the organizational setting.

The combination of the two frameworks thus ensures that all relevant aspects affecting implementation of SDM will be covered. The semi-structured interviews will be conducted among all professionals involved in the diagnosis and treatment of sciatica patients (GPs, physical therapists (PTs), neurologists, neurosurgeons, and orthopedic surgeons).

The focus group procedures of Morgan et al. will be used in preparing and conducting the focus group sessions [21]. A moderator and an observer will guide the focus groups. A group will consist of six to eight participants. When information saturation is not reached after this initial round, the focus groups will be extended in specific groups.

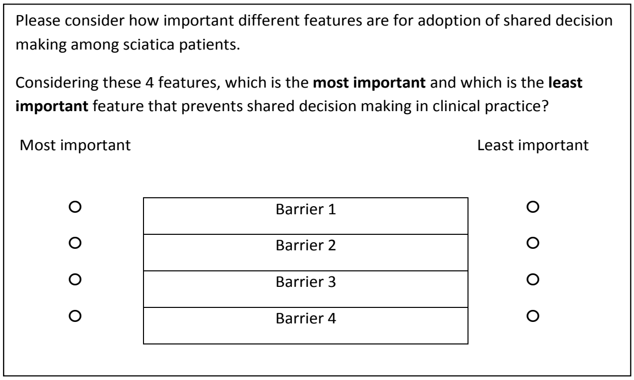

Figure 1. Hypothetical example of MaxDiff task.

Study population

We anticipate interviewing eight professionals in each of the target groups (GPs, PTs, neurologists, neurosurgeons, and orthopedic surgeons). In each group of professionals, we will continue until data saturation is reached, defined as three consecutive interviews without new ideas emerging (stopping criterion) [22]. To obtain contrasting views on barriers and facilitators, we select professionals from specific regions with either high surgery rates (most likely to raise barriers for SDM) or low surgery rates (most likely to raise facilitators for SDM) based on published reports [11, 23]. In addition, we ensure diversity of gender and hospital type (public hospital and private treatment centers), because this may influence the experienced barriers and facilitators.

We anticipate organizing three focus groups, with six to eight patients in each group [24]. To create homogeneous groups, one focus group will include patients who have had surgery, one will include patients who have had conservative treatment, and one focus group will include patients that still have to decide on treatment. Patients will be recruited through advertisements in the local newspapers. When needed, additional patients will be recruited via the patient registries of GPs, neurologists, neurosurgeons, and orthopedic surgeons coordinated by the Spine Intervention Prognostic Study (SIPS) Group.

Inclusion criteria for patients are: age ≥18 years, a doctor's diagnosis of sciatica no longer than 12 months ago, and a written informed consent. Patients with an inability to understand written and oral Dutch instructions or with active diseases likely to interfere with the purpose of this study, such as a terminal illness or severe psychiatric diseases, will be excluded from the study.

Analysis

The semi-structured interviews and focus group interviews will be audio-taped and transcribed in full. They will be qualitatively analyzed using thematic framework analysis [25] to classify and organize data according to key themes, concepts and predefined categories. The predefined categories of the framework of Grol and Wensing will be used [19] regarding the level of the innovation, the professional, the patient, the social context, the organizational context, and the external environment (political and economic factors). We will compare the barriers and facilitators, to look for differences that may explain lack of SDM implementation. We use Atlas.ti software for analysis.

Outcome measures

This study phase results in a list of identified barriers and facilitators for the implementation of SDM, grouped in a commonly used theoretical framework.

ii. Identified barriers and facilitators are ranked by importance in a representative sample

Study design

We will conduct an internet-based questionnaire study among professionals and patients, to rank the identified barriers and facilitators from the interviews and focus groups. A maximum difference scaling (MaxDiff) exercise with an orthogonal design will be included in this questionnaire [26]. MaxDiff is a method to rank multiple items in a more efficient manner, with the additional advantage of scale-free rating so that it prevents scale use bias [27]. With this method, respondents choose the most and least important item within a set of items (Figure 1), with different sets offered to respondents a number of times.

Each set thus provides more information than a number of pairwise comparisons and forces tradeoffs between items, thereby resulting in greater discrimination. A MaxDiff task is easy to complete for participants, and results in ratio-scaled scores of importance [26,28]. The order of items will be randomized between respondents, and each item will be equally represented, to avoid higher importance given to first mentioned items.

Study population

The survey will be sent to a representative sample of GPs (n = 200), PTs (n = 200), neurologists (n = 200), all neurosurgeons (n = 124), orthopedic surgeons (n = 200) and patients (n = 100).

The sample of professionals will be randomly selected from the Dutch medical address book and the membership lists of the professional organizations. The neurosurgeons (n = 124) are included from the same sources. We will sample patients using the patient registries of GPs, PTs, neurologists, neurosurgeons, and orthopedic surgeons, and advertisements in local newspapers.

Analysis

Based on the choices made by respondents, importance scores will be estimated for each barrier and facilitator, for each individual respondent, using hierarchical Bayes estimation [29]. Differences between groups of respondents will be further analyzed in SPSS.

Outcome measures

A list of the 10 most important barriers and facilitators for implementation of SDM among sciatica patients.

B: Development of a tailored implementation strategy

Study design

The DISC study group will develop a tailored, team-based strategy to enhance the adoption of SDM. This strategy will focus on the 10 most important barriers and facilitators found in phase A. Because multifaceted strategies are more effective than single strategies [30,31] and our expectation that several barriers at different levels will be found, it is plausible that the developed implementation strategy will include several components directed at different levels. Furthermore, it is expected that the strategy components will include educational outreach, an interactive educational strategy, and/or patient-specific strategies, because these facets seem to be promising for implementation of SDM [31,32].

In the development process, the project team will use the intervention mapping approach of Bartholomew et al. [33]. This method begins with the creation of matrices, in which the performance objectives are set against the 10 most important barriers and facilitators. Subsequently, the project team will brainstorm about the strategy components needed to achieve the performance objective in the presence of the barrier or facilitator mentioned in the matrix. The cells of the matrices are then gradually filled with implementation strategy components [34]. Next, the project team will translate the formulated strategy components into practical strategies.

After the implementation strategy has been developed, an expert meeting will be held with a panel of GPs, PTs, neurologists, neurosurgeons, orthopedic surgeons, patient representatives of the Dutch back pain patients' association, and implementation experts (n = 10 to 20) to discuss the feasibility, to refine the developed implementation strategy, and to gain acceptance of relevant stakeholders with respect to SDM.

Analysis

The expert meeting will be audiotaped and summarized by two observers and compared until consensus is reached. The participants of the expert meeting receive a summary of the meeting and are asked whether this summary is consistent with the conclusions reached in the meeting.

Outcome measures

A tailored strategy likely to be effective to implement SDM among sciatica patients in daily practice.

Ethical approval

This study protocol has been presented to the Medical Ethical Committee of the Leiden University Medical Center. Ethical approval for this type of study is not required under Dutch law.

DISCUSSION

Implementation of SDM enables sciatica patients to make better informed decisions congruent with their preferences on whether to undergo prolonged conservative treatment or surgery. However, there are strong indications that SDM is not yet adopted in daily practice. Professional preferences seem to dominate treatment decisions, consistent with evidence that Dutch patients are used to delegate treatment decisions to their professionals [17]. Little is known about barriers and facilitators to SDM and effective strategies to increase the uptake of SDM [35]. For successful implementation of SDM in daily practice, a tailored strategy is needed focused on the barriers and facilitators of each domain influencing the adoption of SDM.

To facilitate implementation of SDM in the treatment of sciatica patients, an evidence-based guideline and a DA have already been developed. The goal of the DA was to inform sciatica patients about the two treatment options. However, this DA was not successful in stimulating SDM. This may be due to the fact that DAs are not primarily developed for use during the consultations, and thus do not necessarily stimulate SDM [18]. The extent to which the DA is used in clinical practice is unknown. Despite the Dutch multidisciplinary guideline for SDM and the availability of a DA, SDM has not been adopted in clinical practice so far. This emphasizes that barriers are likely to exist when it comes to guideline adherence and to adoption of SDM. We need to determine these barriers to develop an effective implementation strategy that is not only evidence-based, but also targets these barriers.

Known barriers to SDM reported in previous studies include time constraints and lack of applicability, due to patient characteristics or to the clinical situation [36]. However, these studies focused on implementation among one discipline only, whereas insight into barriers and facilitators for the implementation of interprofessional SDM is lacking [37], and particularly relevant for the multidisciplinary sciatica care. To our knowledge, our study will be the first to examine barriers and facilitators to interprofessional SDM. This will generate new knowledge that may also be applied among other types of patients, given that these barriers and facilitators may not be patient-specific but rather organization or context-specific.

Limitations of this study may be the selection of patients and professionals. It is possible that selection bias occurs, because professionals who are familiar with SDM in daily practice may be more motivated and willing to participate. Professionals who are not using SDM in their consultation may be less likely to participate, and may experience other barriers. To minimize the bias in the interviews, we will stratify our sampling by selecting participants from regions with respectively low and high surgery rates. Another measure taken to avoid participation bias and to yield all relevant barriers is to continue with the interviews until three consecutive interviews emerge without new ideas (stopping criterion) [22]. Similarly, selection bias may occur in the focus groups as patients with pain or other symptoms may be less likely to travel to Leiden to attend a focus group. We will minimize selection bias in the survey by sending multiple reminders to increase the response. In addition, we will test for differences between responders and non-responders in distribution of gender, hospital type, and the location of the hospital to assess whether we may generalize our findings to the total sample.

The generated knowledge and understanding of the implementation process can be used to implement SDM for sciatica patients in the Netherlands and in other countries with a similar context. Furthermore, our study can be used as an example for implementing SDM in other patient groups receiving multidisciplinary complex care such as elderly patients. Increased use of SDM may reduce referral, improve patient satisfaction [38], reduce overuse of one of the treatment options [16,18,39] and thus increase both quality and efficiency of healthcare [40,41].

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Chapter 6

Barriers and facilitators to implement shared decision making in multidisciplinary sciatica care: a qualitative study

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ABSTRACT

Background

The Dutch multidisciplinary sciatica guideline recommends that the team of professionals involved in sciatica care and the patient together decide on surgical or prolonged conservative treatment (shared decision making [SDM]). Despite this recommendation, SDM is not yet integrated in sciatica care. Existing literature concerning barriers and facilitators to SDM implementation mainly focuses on one discipline only, whereas multidisciplinary care may involve other barriers and facilitators, or make these more complex for both professionals and patients. Therefore, this qualitative study aims to identify barriers and facilitators perceived by patients and professionals for SDM implementation in multidisciplinary sciatica care.

Methods

We conducted 40 semi-structured interviews with professionals involved in sciatica care (general practitioners, physical therapists, neurologists, neurosurgeons, and orthopedic surgeons) and three focus groups among patients (six to eight per group). The interviews and focus groups were audiotaped and transcribed in full. Reported barriers and facilitators were classified according to the framework of Grol and Wensing. The software package Atlas.ti 7.0 was used for analysis.

Results

Professionals reported 53 barriers and 5 facilitators, and patients 35 barriers and 18 facilitators for SDM in sciatica care. Professionals perceived most barriers at the level of the organizational context, and facilitators at the level of the individual professional. Patients reported most barriers and facilitators at the level of the individual professional. Several barriers and facilitators correspond with barriers and facilitators found in the literature (e.g., lack of time, motivation) but also new barriers and facilitators were identified. Many of these new barriers mentioned by both professionals and patients were related to the multidisciplinary setting, such as lack of visibility, lack of trust in expertise of other disciplines, and lack of communication between disciplines.

Conclusions

This study identified barriers and facilitators for SDM in the multidisciplinary sciatica setting, by both professionals and patients. It is clear that more barriers than facilitators are perceived for implementation of SDM in sciatica care. Newly identified barriers and facilitators are related to the multidisciplinary care setting. Therefore, an effective implementation strategy of SDM in a multidisciplinary setting such as in sciatica care should focus on these barriers and facilitators.

BACKGROUND

Sciatica is a common disorder that is characterized by radiating leg pain in combination with dermatomal motor, sensory, or tendon reflex abnormalities. It is mostly caused by a herniated disc with compression of the nerve root. The prevalence of sciatica in the general population ranges from 1.2% to 43%, depending on its definition [1]. In the Netherlands, most sciatica patients are primarily diagnosed by general practitioners (GPs). A total of 90% of the patients with sciatica recover with conservative therapy [2], with 70% doing so in the first six to eight weeks [3]. Given this favorable outcome during this first period of time, the GP advises to continue daily activities, if necessary with physical therapy and/or pain medication (conservative treatment) when severe neurologic symptoms are lacking. Patients who still suffer from sciatica after six to eight weeks are usually referred to a neurologist for further investigation, including an MRI. If the MRI confirms a herniated disc, the neurologist and patient can consider prolonged conservative treatment or surgery. If they consider surgery, the neurologist can refer the patient to a neurosurgeon or an orthopedic surgeon for the final decision.

A recent randomized controlled trial has shown no significant difference in clinical outcome between conservative treatment and (early) surgery after one or two years [4]. This trial concludes that surgery is more costly but also leads to more rapid relief from the pain, whereas conservative treatment is less invasive [4] but takes patients longer to recover, so that surgery is cost-effective [5]. However this is the only trial that investigated this properly. Other trials are of low quality [4,6]. Because the literature is not convincing about the best treatment option, the choice can be considered preference sensitive [7]. Therefore, the Dutch multidisciplinary guideline recommends that patients and the team of professionals involved in sciatica care jointly decide about treatment (shared decision making [SDM]). In SDM, clinicians and patients make decisions jointly, weighing the evidence regarding different treatment options [8]. In sciatica care, this means that patients are encouraged to consider both treatment options, to communicate their preferences and help select the best treatment for their situation.

Despite the recommendation in the Dutch multidisciplinary sciatica guideline to integrate SDM in consultations [9], there are strong indications that SDM is not yet adopted in clinical practice. Within the Netherlands, surgery rates differ from 31 to 140 per 100,000 inhabitants per region [10]. It is unlikely that this variation is caused by patient preferences or case mix only. Additionally, it has been shown that Dutch patients are used to delegating treatment decisions to their professionals [11]. Part of the variation in surgery rates may thus be associated with preferences of professionals for particular treatment and with a lack of SDM. Given the multidisciplinary nature of sciatica care, SDM has to be integrated in consultations by different professionals at different points in the care process, which may be more difficult than in those cases in which professionals from only one discipline are involved.

To improve SDM implementation, more insight is needed into specific barriers and facilitators of SDM in sciatica care. Previous research concerning SDM implementation mainly focused on one discipline (uni-disciplinary). A systematic review outlines different studies towards barriers and facilitators in uni-disciplinary care [12,13]. Main barriers identified include time constraints and lack of applicability due to patient characteristics or the clinical situation [12]. Main facilitators include motivation of health professionals and the perception that SDM leads to improved patient outcomes and to improved healthcare processes [12]. However, an increasing number of health problems involve multiple disciplines (multidisciplinary care). SDM in multidisciplinary care utilizes the skills and experience of professionals from different disciplines, with each discipline approaching the patient from its own perspective. This mostly involves separate consultations with different professionals [14]. Despite the increase in multidisciplinary care delivery, research into barriers and facilitators for SDM in a multidisciplinary setting, as in sciatica patients, is limited. A previous study that explored barriers and facilitators to SDM focused on barriers and facilitators for integrating SDM in inter-professional (IP) teams, better known as inter-professional SDM (IP-SDM) [15]. Within an inter-professional approach, efforts are made to integrate and translate themes and schemes shared by several professionals [16]. It involves separate disciplines that integrate different approaches mostly into a single consultation [14]. Main barriers related to IP-SDM were an imbalance of power between health professionals of different disciplines, the existence of professional silos, and disagreement about roles and responsibilities between different disciplines [15]. Main facilitators related to IP-SDM were mutual knowledge and understanding of disciplinary roles, trust and respect between different disciplines. Part of these may also apply to multidisciplinary care. However, SDM in multidisciplinary sciatica care involves different disciplines in both primary care and hospital care working independently, who do not see the patient in one and the same consultation, but in several separate consultations [16]. This independent approach within different levels of healthcare may involve other (additional) barriers and facilitators than an inter-professional approach or healthcare that involves professionals working in the same organization. Therefore, the objective of this study is to explore and categorize all barriers and facilitators associated with the implementation of SDM in sciatica care perceived by professionals and patients.

METHODS/ DESIGN

To identify barriers and facilitators for SDM in sciatica care, we performed a semi-structured interview study among professionals and a focus group study among patients. Interviews and focus groups reach the parts that quantitative methods cannot reach, because people's knowledge and attitudes are not entirely encapsulated in reasoned responses to direct questions. This type of data collection can provide rich and in-depth information about the cognitions, motivations and experiences of individuals [17-20], which is well-suited for this type of study. The identification of similarities and differences in perceived barriers and facilitators between professionals and patients contributes to a further understanding of attitudes and beliefs. This is important for the prediction of whether professionals will use SDM, and enables us to develop a tailored-based implementation strategy, with the main goal of improving the use of SDM in daily practice.

Interviews among professionals

During the period of March 2012 to June 2012, we conducted 40 semi-structured interviews with professionals involved in sciatica care (GP's, physical therapists [PT], neurologists [NL], neurosurgeons [NS] and orthopedic surgeons [OS] [eight per discipline]) at a location of the participant's choice (workplace or at home). We applied purposive sampling for the selection of professionals. First, we selected professionals from regions in the Netherlands with high and low surgery rates [10,21], as SDM has been shown to lead to lower surgery rates [22], and we thus would obtain both barriers and facilitators. In addition, we selected professionals working in hospital care in such a way as to ensure diversity of hospital type (general hospitals, university medical centers, and private clinics). The selected professionals received an invitation by e-mail, followed by a telephone call. When professionals did not want to participate, we invited another professional from the same region. To reach the number of 8 professionals for each discipline, we had to approach 8 neurosurgeons (response rate 100%), 10 orthopedic surgeons (response rate 80%), 14 physical therapists (response rate 57%), 16 neurologists (response rate 50%), and 45 general practices (response rate 18%). The most common reasons why professionals did not want to participate were a lack of time or not seeing (many) patients with sciatica in their practice. During the interviews, a topic guide with open-ended questions was used (Additional file 1). The following explanation of SDM was given: 'In SDM, clinicians and patients make decisions jointly, weighting the evidence regarding different treatment options [8]. In sciatica care this means that patients are encouraged to consider both conservative and surgical treatment options, to communicate their preferences and help select the best treatment for their situation.' In addition, professionals were asked to give an example of SDM in daily practice to determine whether the explanation was clear enough. Participating professionals received a hundred euro gift card as an incentive. The average duration of an interview was one hour and all interviews were audiotaped and transcribed in full. Interviews were conducted by one of two trained interviewers (SH and MW). Both interviewers have a master's degree in health sciences. Their education included training in the conduct of interviews and focus groups. The interviewers had no involvement in patient care, and the participants had no personal background information on the interviewers.

We continued with interviews until data saturation was reached. Data saturation was reached when no ideas emerged during three consecutive interviews [23].

Focus groups

In June 2012, we performed three focus group interviews (six to eight patients per group [17]) at the Leiden University Medical Center with patients who had been diagnosed with sciatica within the previous two years. The focus group procedures of Morgan *et al*. [24] were used in preparing and conducting the focus group sessions. We created three homogeneous groups to move patients more quickly to a discussion [24]. One focus group included patients who had had surgery, one included patients who had had conservative treatment, and one focus group included patients who still had to decide on treatment. Patients were recruited via advertisements in local newspapers. Participants ≥18 years, and with a written informed consent were included in the study. Patients with an inability to understand written and oral Dutch instructions were excluded. Patients received a twenty euro gift card as an incentive, and travel costs reimbursement.

Before the focus groups, participants received an information letter. They were asked to think about the decision making process for the treatment of their sciatica before attending the focus group. During the focus groups, a topic guide was used (Additional file 2). We explained the concept of SDM and gave an example of SDM in sciatica care. Participants were asked to write their positive and negative aspects about the decision making process on post-its, and posted these on separate boards. We used these post-its to stimulate discussions between participants. A trained moderator (SH) and an observer (MW) conducted the focus groups. The focus groups lasted two hours, including a 15-minute break. All focus-groups were audiotaped and transcribed in full.

Analysis

Directed content analysis was used to analyze the interviews and focus groups. This method is well suited for research that would benefit from further description and to extend conceptually a theory or framework [25]. We used the framework of Grol and Wensing [26]. This framework describes how barriers and facilitators can be identified, categorized, and used for the development of a tailored-based intervention strategy to facilitate desired change, in this study implementing SDM [26]. Based on several theoretical reflections on behavioral change, this framework categorizes barriers and facilitators into six levels: the innovation (in our case SDM), the individual professional, the patient, the social context, the organizational context, and the external environment (political and economic factors). We used predetermined barriers/ facilitators of the framework of Grol and Wensing [26] to ensure that we would find all barriers and facilitators for the implementation of SDM in sciatica care. New codes were created for text that could not be categorized within these predetermined barriers/ facilitators.

Two researchers (SH and MW) independently coded the interviews and focus groups. Discrepancies were discussed until consensus was reached. In the next step, reported barriers and facilitators were classified according to levels of the framework of Grol and Wensing. After classification of barriers and facilitators within the levels of the framework, three researchers (SH, PM, and LB) independently grouped the barriers and facilitators into themes for comparison between patients and professionals. Discrepancies were discussed until consensus was reached. Participants did not receive feedback on the findings. The software package Atlas.ti 7.0 [27] was used for analysis.

Ethical approval

This study protocol was presented to the Medical Ethical Committee of the Leiden University Medical Center. An exemption was obtained, as ethical approval for this type of study is not required under Dutch law.

RESULTS

Characteristics of the population

Table 1 shows the characteristics of the professionals who participated in the semi-structured interviews. The participating professionals covered a wide range with respect to age, experience and number of patients treated annually. Twenty-two patients participated in the focus groups. Eight patients per focus group were invited; two participants did not show up. Characteristics of the patients are described in Table 2. Participating patients covered a wide range with respect to age and time since diagnosis.

Barriers and facilitators

We identified 53 barriers and 5 facilitators perceived by professionals (Additional file 3: Table S1) for the implementation of SDM in sciatica patients. These barriers and facilitators could be grouped into 15 themes (Table 3). Professionals perceived most barriers at the level of the organizational context, and facilitators at the level of the individual professional (Additional file 3: Table S1). During the focus groups, 35 barriers and 18 facilitators for SDM on 15 themes (Table 3) were reported by patients regarding their decision making for sciatica treatment (Additional file 4: Table S2). Patients mentioned most barriers and facilitators at the level of the individual professional (Additional file 4: Table S2). Table 3 shows the themes influencing SDM in sciatica care for both professionals and patients. It is clear that more barriers than facilitators were mentioned, particularly by professionals. We will discuss each theme, and which specific barriers and facilitators that were mentioned within these themes.

Table 1. Characteristics of interviewed professionals

Discipline	n	Average age, years (range)	Male (%)	Average work experience, years (range)	Average no. of sciatica patients treated per year (range)
Physical therapist	8	47 (30-58)	4 (50)	23 (8-33)	56 (6-240)
General practitioner	8	49 (32-63)	5 (63)	17 (1-34)	20 (3-52)
Neurologist	8	49 (37-62)	6 (75)	11 (3.5-22)	311 (52-780)
Neurosurgeon	8	50 (38-62)	6 (75)	16 (5-27)	692 (300-1,404)
Orthopedic surgeon	8	52 (40-67)	8 (100)	16 (4-27)	444 (3-1,300)

Table 2. Characteristics of patients in focus groups

Focus group	n	Average age, years (range)	Male (%)	Average time since diagnosis, months (range)
1. Surgery	8	51 (19-81)	2 (25)	6 (1-18)
2. Conservative therapy	8	56 (19-75)	3 (38)	9 (1-24)
3. Still had to decide	6	51 (33-75)	2 (33)	9 (3-24)

Innovation (SDM)

Professionals mentioned the unclear concept of SDM as a theme. The lack of clarity of the concept of SDM was regarded as a barrier for SDM. With respect to the definition of SDM, many professionals thought they were using SDM. However, when discussing SDM they wondered whether they really met all the conditions (e.g., information provision of both treatments' options, ask patient's preferences) for a decision to be a shared decision. (OS3: 'Which conditions do you have to meet before you can say this is decision that has been taken jointly? That is not clear to me'.)

Individual professional

Both professionals and patients mentioned the three themes at this level of the framework: (poor) professional-patient relationship, professional's attitude/ behavior towards SDM, and lack of knowledge about SDM/ treatment options of professional. In addition, patients mentioned lack of information provision/ explanation by the professional as a theme.

Table 3. Themes influencing SDM in sciatica care according professionals and patients

Level	Theme (Professionals)	B	F	Theme (Patients)	B	F
Innovation (SDM)	Unclear concept of SDM	X				
Individual professional	Poor professional-patient relationship	X		Professional- patient relationship	X	X
	Negative (B)/ positive (F) professional's attitude/ behavior toward SDM	X	X	Negative (B)/ positive (F) professional's attitude/ behavior towards SDM	X	X
	Lack of knowledge of the professional about SDM/ treatment options	X		Lack of knowledge of the professional about SDM/ treatment options	X	
				Lack of (B)/ sufficient (F) information provision/ explanation	X	X
Patient	Negative patient's attitude towards SDM	X		Negative (B)/ positive (F) patient's attitude towards SDM	X	X
	Lack of patient's capabilities to decide	X		Lack of (B)/ sufficient (F) patient's capabilities to decide	X	
	Pressure by patient toward professional	X		Lack of knowledge of patient about treatment options	X	
Social context	Lack of inter-professional collaboration	X		Lack of (B)/ sufficient (F) inter-professional collaboration	X	X
	Social influences of third parties	X		Social influences of third parties	X	
Organizational context	Lack of tools to facilitate SDM	X		Lack of (B)/ sufficient (F) tools to facilitate SDM	X	X
	Situational factors (e.g., lack of time)	X		Situational factors (e.g., lack of time)	X	
	Long waiting list influences decision process	X		Long (B)/ short (F) waiting list influences decision process	X	X
	Poor logistics/ implementation			Conflicting information about treatment options	X	
External environment	Environmental influences on the decision process	X		Environmental influences on decision process	X	X
	Reimbursement in favor of surgery	X		Reimbursement in favor of surgery	X	

B barrier, F facilitator

Regarding the first theme, professionals said that a poor professional-patient relationship is a barrier for the SDM process. The relationship may be influenced by the multidisciplinary care patients receive, as they have superficial contacts with multiple professionals, instead of visiting one professional who really knows the patient. Especially professionals in primary care experience difficulties in applying SDM when they are not familiar with the background and personal situation of the patient or when they have a poor relationship with the patient. This may be due to how professionals in primary care in general have a better knowledge about the background and personal situation of most of their patients compared to professionals in hospital care. General practitioners said they have more and more patients in their practices, which makes it more difficult to really know their patients than before when practices were smaller. As a consequence, they experience more difficulties with applying SDM to patients they do not know, while professionals in hospital care are used to dealing with this lack of unfamiliarity. (NL3: 'You should really know the patient to respond better to the factors playing a role in deciding whether or not the patient needs a surgery. Who knows the patient nowadays?'). Patients also mentioned the importance of a patient-professional relationship, as a barrier and facilitator (bad versus good relationship). For example, they mentioned that some professionals had a lack of attention for their anxiety, personal situation, and preferences, while the elicitation of patient preferences is crucial to SDM. (P3: 'I had to impose my own will, and with a lot of difficulties the neurologist finally referred me to a surgeon, but I really had to push it through. The neurologist tried to stop me, whereas I had complaints for more than a year without any improvement').

Another theme is the attitude/ behavior towards SDM. Professionals felt it is important to express their own view about which treatment option to follow, and to determine the next step in the care trajectory, rather than the patient. (OS8: 'I am not a populist, I am not going to say "Oh this is what you want, you name it, we've got it"'). In addition, many professional had an explicit preference for conservative treatment or for surgery. This preference could influence SDM, if professionals push patients towards the treatment of their preference. (OS3: 'As long as there are no neurological symptoms, no cauda equina syndrome, then of course you do nothing. In those cases you try to convince patients of not having a surgery'). Patients confirmed that some professionals have a strong preference for one of the treatment options and mentioned that professionals tried to push them into the direction of their preference. (P6: 'My doctor insisted me to wait, to let my body recover by itself'). On the other hand, some professionals had a positive attitude towards SDM. For example, they said that SDM improves quality of care and patient outcomes, which may function as a facilitator for SDM.

The third theme is lack of knowledge of the professional about SDM/ treatment options. Patients felt that some professionals had a lack of knowledge about treatment options, especially in primary care. Professionals frequently told patients that there is only one treatment option. Again, this may be related to the complex structures in the multidisciplinary sciatica setting. Since many professionals are involved, professionals are likely to provide information regarding the treatment they can provide themselves, but have a lack of knowledge about other possible treatment options. (P6: 'I went to the PT and GP and they said: "Nowadays doctors do not perform sciatica surgeries anymore, you will just have to wait, because your body will recover your herniated disc itself"'). The sciatica guideline recommends that the patient and professional together decide on surgical or prolonged conservative treatment after considering the harms and benefits of each treatment option. This is impossible if not all the professionals are familiar with these options or with the sciatica guideline, and thus with the need for SDM in sciatica patients. (NS2: 'I am not really a guideline person').

A number of patients received the wrong diagnosis. Due to this wrong diagnosis, patients were suffering from sciatica for a long period of time. It sometimes took weeks or even months before they got the right diagnosis. As a result, the first six to eight weeks of conservative therapy had already passed, and they were referred to hospital care for surgery without given information about the care trajectory or alternative treatment options. The issue of not receiving SDM was thus a consequence of getting the wrong diagnosis. (P22: 'My GP though there was something with my Achilles tendon or muscles, but it appeared to be an herniated disc'). Furthermore, some professionals perceived a lack of education and skills for SDM, especially communicative skills. (NL4: 'You need some communication skills, and that is difficult. (…) Communication with the patient is the most important thing. Until now, there is not enough attention for communication skills').

Patients also mentioned the theme of information provision and explanation, and thought that there is room for improvement concerning this theme. They perceived a lack of information provision with regard to treatment options and potential harms and benefits. (P6: 'My doctor advised me to wait, and only told me about the disadvantages why I shouldn't have a surgery. In the end I needed a surgery, but the only thing I could think of were all the disadvantages of having a surgery'). Some patients received sparse information about one of the treatment options. Others did not mention one of the treatment options at all. They also mentioned a lack of explanation by professionals of the care trajectory. (P10: 'I went to the hospital, they gave me little explanation and no deliberation. They told me: you have a herniated disc, here you have morphine and you can go home now'). Besides these barriers, patients also mentioned facilitators regarding this theme. Most facilitators were in the opposite direction of the reported barriers (e.g., sufficient information provision, explanation about harms and benefits of each treatment option, and explanation of the care trajectory).

Patient

At the level of the patient, both professionals and patients mentioned the attitude/ capabilities of patients. Furthermore, professionals mentioned pressure by patients, and patients mentioned their own lack of knowledge about treatment options.

Regarding the first theme of negative attitude toward SDM/ patient's capabilities to decide, professionals stated that some patients preferred a professional-dominated over a shared approach. They think that patients do not want to decide together but want to leave the decision up to the professional. (NS7: 'Not everybody wants a shared decision. Some people want a decision made by the doctor'). In the focus groups, one patient preferred a physician-dominated decision. The other patients preferred a shared decision. (P2: 'I prefer to make the final decision, it is my body').

The second theme for professionals is pressure by patients toward professionals. Professionals mentioned that some patients are demanding. Demanding patients are not willing to wait, and put pressure on the GP's to refer early. Therefore, specialists are seeing patients during their first weeks with sciatica, and patients are demanding an MRI. In this first period, conservative treatment is recommended in the sciatica guideline. Often specialists order an MRI, but in the end, many patients recover during this first period, and the MRI at the hospital was unnecessary. (OS3: 'Nowadays, patients are not willing to wait for six weeks. Everybody wants an MRI as soon as possible').

The second theme for patients is their own lack of knowledge about treatment options. Patients said that they did not have enough knowledge to make the final decision. This reflects the information provision and explanation mentioned as barriers at the level of the individual professional, which was mentioned before. (P1: 'I did not tell my GP that I wanted surgery, because I did not know that was a possibility').

Social context

Themes mentioned by both patients and professionals at the level of the social context are (lack of) sufficient inter-professional collaboration and social influences of third parties. Most barriers mentioned are related to the multidisciplinary setting in sciatica care.

Regarding the (lack of) sufficient inter-professional collaboration, professionals found it difficult to get into contact and communicate with each other, especially medical and paramedical professionals. (PT2: 'Actually, we professionals are all doing our job on our own "island." We do not have direct contact with each other'). Some patients perceived a good communication between professionals, and said the information exchange between different disciplines made the decision making easier, so that it becomes a facilitator for SDM.

Other patients perceived a lack of communication between professionals. They visited multiple professionals during their care trajectory but had to tell their story many times. They thought it would help if professionals shared information with each other. (P9: 'If my PT sends a letter to the GP, she does not get an answer. There was also a lack of communication between the medical professionals I visited. It is annoying if you visit a medical professional and there has been no communication at all with the medical professional you have visited previously').

Besides the lack of communication, there is also a lack of trust in the expertise of other disciplines. Some professionals think that other (para)medical professionals do not have enough knowledge about sciatica or do not inform or treat patients in the right way. Therefore, some professionals do not refer patients, but give patients the treatment they can provide themselves. (NS3: 'Despite the fact that the neurologist says he informs the patient about conservative treatment, it always is a surprise for patients that natural recovery is a possibility in sciatica').

Within the theme social influences of third parties, a barrier perceived by professionals was the promotion of one of the treatment options by third parties (e.g., professional association). Patients perceived social pressure of family or friends, who sometimes have an outspoken opinion about which treatment the patient should follow.

Organizational context

Themes mentioned by both patients and professionals at the level of the organizational context were tools to facilitate SDM, situational factors and (long/ short) waiting lists that influence the decision process. In addition, professionals mentioned the poor logistics/ implementation, and patients mentioned conflicting information.

Tools to facilitate SDM were mentioned by both professionals and patients. Despite the availability of two decision aids, professionals mentioned a lack of tools to inform patients as a barrier. Patients mentioned conflicting information in leaflets as a barrier. Tools mentioned as facilitators were access to the professional if the patient wants to change treatment, and the possibility of having a telephone consultation.

The second theme concerns situational factors. Lack of time was mentioned by both professionals and patients. Many professionals perceived a high workload. The time of a consultation ranged from 10 minutes to 45 minutes in public and private hospitals. Professionals with little time said they did not have enough time to discuss everything with the patient, besides the diagnosis of sciatica. Patients also perceived this lack of time. (OS7: 'I think the factor time is the biggest bottleneck').

Financial interest is another example of a barrier mentioned by professionals within this theme. In some hospitals, specialists felt they could not apply SDM because they had to reach certain production rates. Some specialists also stated that sciatica surgery is interesting for hospitals because the costs of surgeries are lower than the reimbursement they receive. Therefore, hospitals sometimes reserve the operating rooms for sciatica surgeries. (OS4: 'For the hospital it is of financial interest that sciatica patients get surgery instead of conservative treatment, so hospitals prefer sciatica surgeries').

Another theme was the (long/ short) waiting lists that influence the decision making process. Short waiting lists were mentioned by patients as a facilitator. On the other hand, long waiting lists for a hospital visit or surgery was mentioned by both professionals and patients as a barrier. These waiting lists influence the decision making process; for example, some surgeons make the decision (surgery yes or no) based on the length of the waiting list. As a result, the patient is not presented with all options and thus will not have a shared decision. Other professionals already put the patient on the waiting list, just in case the patient should need a referral in the future, and thereby patients miss a step (referral or not) in the decision making process. This referral is not a shared decision, but the decision of the involved professional. (GP4: 'The neurologists in this region have an enormous waiting list. Sometimes that influences your way to get things done, for example you refer the patient early in the process, so that at least the appointment has already been made'). In addition, some patients said that once they had made the decision to have surgery, they had to wait for a long period of time, whereas the trajectory from primary to hospital care had already taken weeks, or sometimes months. Once the decision for surgery was made, they did not want to suffer pain any longer. (P6: 'I had to wait for five weeks until I could visit the neurologist, and then another eight to nine week for a surgery. (...) Ultimately you have your surgery, but you are exhausted and the healing process stagnates').

Professionals mentioned the theme of poor logistics/ implementation of SDM as a barrier. Especially in primary care, there is a lack of clear criteria for referral and/ or surgery, probably associated with multiple disciplines being involved. For instance, some professionals did not know when patients were eligible for surgery, and thus in which situations they can refer patients, offer patients different options for treatment, and can use SDM. (PT1: 'It would be great if I had clear criteria when to refer the patient to the GP because patients do not need a referral for physical therapy and some have not seen a GP'.)

Furthermore, there is a lack of visibility into what other disciplines can do in sciatica care. Professionals said that if they had more insight in what other disciplines can do, they can better explain all the options to the patient, and would be more open to referrals. (NS7: 'Sometimes anesthesiologists are saying, "you just perform surgeries, but one injection and the pain is gone," so to speak, but I do not know everything they can do, and that is inadequate').

Patients reported conflicting information given by different professionals as a barrier. Some patients said they did not know which option they had to choose, because of conflicting information from professionals. In one case, a specialist advised surgery, and another professional advised conservative treatment. In addition, sometimes advices given to patients during the conservative treatment are conflicting as well. (P9: 'My PT said that it was important to be active, while the GP said I should not move a lot').

External environment

With regard to the external environment, professionals and patients both mentioned the themes of reimbursement in favor of surgery and environmental influences on the decision process.

Persons in the Netherlands have a basic insurance package and have the option of purchasing supplementary insurance for additional healthcare. The first nine visits to the physical therapists are included in the basic insurance package. If a patient does not have an optional complementary insurance, they have to cover the cost for the other visits themselves. For some patients, this is a reason to quit their physical therapy and to look for other possibilities. In these cases, professionals referred patients earlier to hospital care, to get surgery.

(P2: 'I will quit physical therapy as soon as I have to pay for it.' PT8: 'I can imagine that patients rather have surgery when they do not have a complementary insurance and have to pay for physical therapy').

Unreliable and conflicting information on treatment options on the internet also hindered both professionals and patients in SDM. Patients read wrong information on the internet, which influenced their treatment or relationship with their caregiver. (P20: 'I read on the internet about a method in China, where they attach a pole to your back, so you can't move, but my PT didn't want to do that'). Professionals also found it time-consuming to talk with patients about all the incorrect information their patients read, while they are already struggling with the factor time. They also said patients would have more anxiety because of all the negative stories they read, which makes it more difficult for the patient to make a well-balanced decision. (GP3: 'The point is that especially doom diagnoses and complicated courses predominate on the internet and people cannot always correctly apply these to their personal situation'). Therefore, some patients suggested making one website with reliable information about sciatica.

DISCUSSION

This study addresses several gaps in the literature on SDM. It identifies a large number of barriers and facilitators related to SDM in sciatica treatment, and provides new insights, particularly for multidisciplinary care. To our knowledge, no previous study has focused on barriers and facilitators for SDM in multidisciplinary care trajectories that involve both primary care and hospital care. This multidisciplinary setting, with each discipline approaching the patient from its own perspective in different consultations, makes SDM more complex. We identified barriers and facilitators for SDM in multidisciplinary sciatica care perceived at different levels of the framework of Grol and Wensing [26]. Both professionals and patients reported more barriers than facilitators. Professionals perceived most barriers at the level of the organizational context, and perceived all facilitators at the level of the individual professional. Patients, on the other hand, reported most barriers and facilitators at the level of the individual professional. It is possible that patients hold the professionals responsible for the care they receive, including the use of SDM, while any barriers on the organizational context that may be important are not visible to them. The professional, on the other hand, is able to see and identify organizational factors as barriers from their perspective, but may also use them as excuses for not having to do anything themselves. This underlines the importance of including both the patient and the professional perspective to identify all barriers for SDM implementation in sciatica. All barriers and facilitators could be classified into a total of 18 themes. A total of 12 themes were the same for patients and professionals and were often related to each other. Patients perceived more facilitators than professionals. This may be due to the fact that professionals have to find a way to integrate SDM during their consultations and have to change their daily practice. Therefore, they may perceive more barriers and fewer facilitators as compared to patients. In addition, most reported facilitators were also reported as barriers, but in the opposite direction.

We found barriers and facilitators corresponding with the literature on uni-disciplinary settings (e.g., lack of applicability due to patient characteristics [12], insufficient provider training [28], lack of familiarity about SDM content [12], better patient adherence to treatment [29], motivation [12]). This suggests that barriers and facilitators in uni-disciplinary care also apply to the multidisciplinary setting. Barriers reported in the literature specific to an IP approach and also mentioned in our study are an imbalance of power between health professionals of different disciplines, the existence of professional silos, and disagreement about roles and responsibilities between different disciplines [15].

This study adds barriers and facilitators specifically related to the multidisciplinary context to the literature. These identified barriers and facilitators, include the themes of poor logistics/ implementation, (lack of) sufficient inter-professional collaboration, and reimbursement in favor of surgery. A specific barrier in the theme of poor logistics/implementation is for instance the conflicting information or advice received from different professionals, so that patients did not know which option to choose. Most patients had visited a GP, physical therapist, and neurologist by the time they visited a surgeon. All of these disciplines have different backgrounds and education, and focus on different aspects of sciatica care, but still it is important that they provide unambiguous information. Regarding lack of inter-professional collaboration, professionals mentioned lack of visibility into what other disciplines can do, and lack of trust in the expertise of other medical disciplines. These barriers cause professionals to talk only about the treatment option they can provide themselves. This may conflict with information given by others. A (better) collaboration and communication between disciplines, and a structure in the information process is necessary (i.e., Which professional explains what in which phase of the care trajectory?). To prevent professionals from wasting their time by repeating information from the previously visited professional, it is important that they know what information has already been given to the patient, so that they will have time to integrate SDM in their consultation. As in other studies [12], lack of time was a frequently mentioned barrier for SDM [12]. Structuring the information process ensures that professionals provide sufficient information to the patient within a limited time frame. Furthermore, barriers related to reimbursement in favor of surgery hinder SDM implementation, e.g., lack of reimbursement for physical therapy, and financial compensation for sciatica surgery. The reimbursement for surgery is higher than the actual costs, and therefore of financial interest to hospitals. Some surgeons reported that they were encouraged by the hospital to perform surgeries, for example by reserving operating rooms for sciatica surgeries, or even allotting a small amount of money for every sciatica surgery doctors perform. In addition, many private clinics arise because of this reimbursement. These (perverse) incentives may influence the decision making in favor of surgery. On the other hand, physical therapists have a financial interest as well, because they are paid for each treatment. This may cause physical therapists to keep treating the patient instead of referring him or her (back) to the GP. Further research is needed to determine the role of health insurance in SDM, and how the influence of reimbursement on SDM can be reduced. After all, the costs of sustained conservative treatment will be lower than the cost of surgery for insurance companies.

Besides these barriers related to multidisciplinary care, professionals also mentioned that not all patients are able or willing to decide on their care. However, the majority of patients that participated in the focus groups indicated that they do want to decide themselves. The establishment of patient's preference for his or her role in decision making [30] is an important part of the SDM process, and makes it clear what the patient and professional can expect from each other. Even if they decide jointly that the professional makes the final decision, it still is a shared decision.

A strength of this study is the use of purposive sampling to capture a broad range of perspectives reflecting a diversity of views. We applied purposive sampling by selecting participants from regions with respectively low and high surgery rates, and continued interviewing until data saturation was reached. The participating professionals covered a wide range with respect to age, experience, and number of patients treated annually, so that we can expect that most barriers and facilitators will have been captured by this group. A limitation of this study is the recruitment of patients. Patients were recruited in only one region responding to an advertisement; it is possible that this has caused over-reporting of barriers and facilitators because participating patients were motivated to give their opinion. In addition, patients in other regions, or patients who did not respond to the advertisement, may perceive other barriers or facilitators. On the other hand, participants of the focus groups differed in age, gender and ethnicity. They were also treated in different practices and (types of) hospitals, which ensures variety in perceived barriers and facilitators. A second limitation is the use of quantitative counts within this qualitative study. We reported all barriers and facilitators in tables, but only discuss those barriers and facilitators reported in at least eight interviews or two focus groups, without suggesting that other barriers or facilitators are less important. Based on this study, we cannot determine which barriers and facilitators are the most important barriers or facilitators for implementation of SDM, or how these are associated with characteristics of patients and professionals. Therefore, in the next phase of this study, we will carry out a quantitative study to determine which barriers and facilitators mentioned in this qualitative study are the most important for the adoption of SDM, and professionals' behavior towards SDM and differences in most important barriers and facilitators between these groups will be determined.

Despite these limitations, our study generated new knowledge that can be used to improve SDM implementation for sciatica patients in the Netherlands and in other countries with a similar context. Furthermore, our study can be used as an example for other patient groups receiving multidisciplinary complex care, given that most perceived barriers by professionals were organization-specific.

Conclusions

This study provides new insights into barriers and facilitators in a multidisciplinary setting, in primary and hospital care as perceived by both professionals and patients, which is also generalizable for other health problems with multiple disciplines involved. Insight into both barriers and facilitators is essential for the SDM implementation in a multidisciplinary setting. After all, we know from the literature that implementation strategies geared at barriers and facilitators are more effective [31]. Therefore, a multi-faceted strategy is more likely to improve care given to sciatica patients.

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Additional file 1. Topic list professionals

Topic list professionals

1. Introduction

Introduction interviewer
Background study
Information about the interview
Introduction participant: profession, years of experience, number patients with sciatica per year, way of working (concerning sciatica), preferences

2. Which factors influence the use of SDM in sciatica treatment?

Topics:
SDM
Prompts:
- Concept SDM – Do they know what SDM is?
- Explanation of SDM: In SDM, clinicians and patients make decisions jointly, weighting the evidence regarding different treatment options [8]. In sciatica care, this means that patients are encouraged to consider both conservative and surgical treatment options, to communicate their preferences and help select the best treatment for their situation.
- Can you give an example of SDM in daily practice?
- Attitude towards SDM in sciatica

Applicability of SDM in patients
Prompts:
- Attitude patient toward SDM
- Explanation scientific knowledge
- Questions patients ask
- Do patients want a more active role?

Requirements SDM
Prompt:
- Decision aid

Environment
Prompts:
- Role (other) professionals/ organization/ colleagues
- Multidisciplinary deliberation
- Factors/ policies at local/ national level

3. What are your recommendations for improving the implementation of SDM in sciatica treatment?

Additional file 2. Topic list focus groups

1. Introduction

    Introduction moderator and observer

    Background study

    Information about the focus group

    Introduction participant: when diagnosed with sciatica, their care trajectory

2. How was the decision for treatment made?

    Topics:

    Awareness of treatment options

    Information about treatment options

    Own preference

    Treatment of own preference?

3. Positive and negative experiences

- Explanation SDM: *In SDM, clinicians and patient make decisions jointly, weighting the evidence regarding different treatment options [8]. In sciatica care this means that patients are encouraged to consider both conservative and surgical treatment options, to communicate their preferences, and help select the best treatment for them.*

- Patients are asked to write their positive and negative aspects about the decision making process on post-its, and post their negative aspect on a 'negative' board and their positive aspect on a 'positive' board.

4. Questions and discussion based on the post-its

Additional table S1. Barriers for SDM according to professionals

Level	Barriers	Facilitators
Innovation (SDM)	Unclear concept of SDM **Definition of SDM unclear (when is it truly shared?)**	
Individual professional	Poor professional-patient relationship **Poor quality of professional-patient relationship** Negative professional's attitude/ behavior toward SDM Lack of interest in sciatica **Importance to express your own view** No place for SDM in routines/ habits No need for SDM **Preference for one of the treatment options*** Financial interest in one of the treatment options Lack of knowledge of professional about SDM/ treatment options **Lack of skills for SDM** **Lack of education on SDM** Lack of knowledge on SDM Lack of knowledge about treatment options **Lack of knowledge about the sciatica guideline** Different interpretations of scientific literature leading to different opinions	Positive professional's attitude/ behavior towards SDM Motivation (professionals also want a shared decision if they were suffering from sciatica) Importance of SDM SDM is essential for good healthcare SDM improves quality of care SDM leads to improved patient outcomes/ compliance
Patient	Negative patient's attitude toward SDM/ Lack of patient's capabilities to decide Inability of patient to make the decision about treatment Inability of patient to remember the information given during a visit Misinterpretation of information by patient **Patient's unwillingness to decide** Pressure by patient toward professional **Demanding patient** Pressure for quick recovery of patient Expectations of patient when visiting a sciatica pathway for having an MRI and surgery	

Level	Barriers	Facilitators
Social context	Lack of inter-professional collaboration Lack of communication with other medical disciplines **Lack of communication between medical professionals and paramedical professionals** Power struggle between professionals **Lack of trust in expertise other disciplines** Lack of interest in other disciplines Social influences of third parties Value of repeat consultations underestimated by colleagues Lack of encouragement from the professional group to apply SDM Promotion of one of the treatment options third parties*	
Organizational context	Lack of tools to facilitate SDM Lack of financial compensation for multidisciplinary deliberation Lack of financial compensation for SDM Lack of tools to inform patients Situational factors **Lack of time during consultation** Lack of opportunity for a repeat consultation **Financial interest practice/ hospital/ need for production** Lack of encouragement from the institution to apply SDM Long waiting list influences decision process **Long waiting list for a visit to hospital** A large/ small number of patients on the professional's waiting list / under treatment* Poor logistics/ implementation SDM is not my task **Lack of clear criteria for referral and/ or surgery** **Lack of visibility into what other disciplines can do** Lack of clear policy for PT's Lack of agreement about the content and the timing of information provision in the care trajectory	

External environment	Environmental influences on the decision process Preference for referral to private clinic/ clinic in another country Availability of treatment options in the area **Unreliable and contradictory information about treatment options on the internet** Reimbursement in favor of surgery **Additional payment for physical therapy not covered by insurance** Waiting list mediation by health insurer Agreements with health insurance Competition in Dutch healthcare	

Note. Barriers indicated in bold were reported in at least eight interviews.
* Two separate barriers

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Additional table S2. Barriers for SDM according to patients

Level	Barriers	Facilitators
Innovation (SDM)		
Individual professional	Professional-patient relationship Poor quality of professional-patient relationship Lack of empathy of the professional Lack of attention for patient's personal situation Lack of attention for patient's anxiety **Lack of attention for patient's preferences** Lack of confidence in the professional Negative professional's attitude/ behavior towards SDM PT keeps treating the patient without results because of belief in own treatment **Preference of professional for one of the treatment options*** Lack of guidance in conservative treatment by the professional Lack of information provision/ explanation Lack of explanation about the diagnosis sciatica by the professional **Lack of information provision about treatment options and potential harm and benefits** **Lack of explanation of the professional about the care trajectory** Lack of knowledge of the professional about SDM/ treatment options **Wrong diagnosis by professional** **Lack of knowledge of the professional**	Professional- patient relationship A good professional-patient relationship Attention for patient's preferences Attention for patient's personal situation GP knows patient's background Positive professional's attitude/ behavior toward SDM Guidance by the professional Monitoring recovery Sufficient information provision/ explanation Sufficient information provision of the professional Explanation about harms and benefits of each treatment Explanation of the MRI images Explanation of the care trajectory Openness of professional Explanation of outcomes scientific research
Patient	Negative patient's attitude toward SDM/ patient's capabilities to decide Difficulty to remember everything told during a visit Anxiety to express own preferences Lack of confidence in own choice Anxiety to contradict the professional Lack of knowledge of patient about treatment options **Lack of knowledge of patients about one of the treatment options***	Positive patient's attitude toward SDM/ patient's capabilities to decide **Motivation (important to decide about your own body)**
Social context	Lack of inter-professional collaboration **Lack of communication between professionals** Lack of trust between professionals Social influences of third parties Social pressure of family/ friends on patients	Sufficient inter-professional collaboration **Communication between professionals**

Organizational context	Lack of tools to facilitate SDM Conflicting information in leaflets Situational factors Lack of time during a consultation Lack of possibilities to discuss problems Long waiting list influences decision process **Long waiting list for a visit to the neurologist/ for surgery*** Conflicting information about treatment options **Conflicting information of the professionals**	Sufficient tools to facilitate SDM Accessibility of the professional to change treatment Telephonic consultation Short waiting list influences decision process Short waiting list/ quick referral
External environment	Environmental influences on the decision process Pressure of employer for quick recovery **Unreliable and contradictory information on the internet** Reimbursement in favor of surgery **Additional payment for physical therapy not covered by insurance** Individual mandate for a visit to a specialist	Environmental influences on decision process One reliable website about sciatica

Note. Barriers indicated in bold were reported in at least two focus groups.
* Two separate barriers

Chapter 7

Most important factors for the implementation of shared decision making in sciatica care: ranking among professionals and patients

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ABSTRACT

Introduction

Due to the increasing specialization of medical professionals, patients are treated by multiple disciplines. To ensure that delivered care is patient-centered, it is crucial that professionals and the patient together decide on treatment (shared decision making (SDM)). However, it is not known how SDM should be integrated in multidisciplinary practice. This study determines the most important factors for SDM implementation in sciatica care, as it is known that a prior inventory of factors is crucial to develop a successful implementation strategy.

Methods

246 professionals (general practitioners, physical therapists, neurologists, neurosurgeons, orthopedic surgeons) (30% response) and 155 patients (96% response) responded to an internet-based survey. Respondents ranked barriers and facilitators identified in previous interviews, on their importance using Maximum Difference Scaling. Feeding back the personal top 5 most important factors, each respondent indicated whether these factors were barriers or facilitators. Hierarchical Bayes estimation was used to estimate the relative importance (RI) of each factor.

Results

Professionals assigned the highest importance to: quality of professional-patient relationship (RI 4.87; CI 4.75-4.99); importance of quick recovery of patient (RI 4.83; CI 4.69-4.97); and knowledge about treatment options (RI 6.64; CI 4.53-4.74), which were reported as barrier and facilitator. Professionals working in primary care had a different ranking than those working in hospital care.

Patients assigned the highest importance to: correct diagnosis by professionals (barrier, RI 8.19; CI 7.99-8.38); information provision about treatment options and potential harm and benefits (RI 7.87; CI 7.65-8.08); and explanation of the professional about the care trajectory (RI 7.16; CI 6.94-7.38), which were reported as barrier and facilitator.

Conclusions

Knowledge, information provision and a good relationship are the most important conditions for SDM perceived by both patients and professionals. These conditions are not restricted to one specific disease or health care system, because they are mostly professional or patient dependent and require healthcare professional training.

INTRODUCTION

Sciatica is a common disorder with prevalence reported up to 43% [1]. It is mostly caused by a herniated disc with compression of the nerve root, which gives radiating leg pain. Seventy percent of patients with sciatica recover in the first 6-8 weeks with conservative treatment [2]. After 6-8 weeks it is possible to consider prolonged conservative treatment or surgery. Care to sciatica patients is given by various disciplines: the general practitioner, physical therapist, neurologist and neurosurgeon or orthopedic surgeon are frequently involved.

A large, randomized clinical trial showed no significant difference in clinical outcomes between conservative treatment and surgery after 1 and 2 years in patients with sciatica [3]. Other, low quality studies showed conflicting results [4]. As the literature is not consistent regarding the best treatment option [3,4], the choice can be considered preference sensitive. Therefore, the Dutch multidisciplinary sciatica guideline [5] recommends to integrate shared decision making (SDM) in consultations. In SDM, clinicians and the patient make decisions jointly, weighting the best available evidence regarding different treatment options [6]. Patients are encouraged to consider prolonged conservative treatment or surgery and the likely benefits and harm of each so that they communicate their preferences and help to select the best treatment for them. Only when professionals and the patient together decide on treatment (SDM), delivered care can be truly patient-centered.

Despite the recommendation to integrate SDM in consultations [5], there are strong indications that SDM is not yet adopted in clinical management of patients with sciatica. Recently, a comparison between regions in the Netherlands showed considerable variation in the number of sciatica patients that undergo surgery, ranging from 31 to 140 per 100,000 inhabitants [7]. In addition, Dutch surgery rates for sciatica patients are four times higher than in the United Kingdom and two times higher than in Sweden [7] while The United States have a 40% higher surgery rate than the Netherlands [8]. As enhancing the use of SDM was found to be associated with lower hospital admission rates through the prevention preference-sensitive surgeries [9], its use is likely to play a role in the variation in surgery, in addition to factors such as case mix.

Previous research concerning the barriers for implementation of SDM in clinical practice mainly focussed on one discipline (monodisciplinary) or on inter-professional (IP) teams [10-12]. An inter-professional approach involves separate disciplines that integrate different approaches mostly into a single consultation [13]. However, due to the increasing specialization of medical professionals, patients nowadays are treated by multiple disciplines in several separate consultations as for example in sciatica care were the general practitioner, physical therapist, neurologist and neurosurgeon or orthopedic surgeon are frequently involved. SDM in multidisciplinary care utilizes the skills and experience of professionals from different disciplines, with each discipline approaching the patient from their own perspective [13], so that different barriers and facilitators for SDM implementation may play a role and to a different extent than in a monodisciplinary setting or in an inter-professional team. This is currently unknown. Furthermore, most studies focus on professionals only, while patients are part of the SDM process and may perceive other barriers and facilitators which may be also important for the implementation of SDM. To our knowledge, this is the first quantitative study that focuses on barriers and facilitators of SDM perceived by professionals of different disciplines as well as patients.

In a previous qualitative study among patients and professionals we explored the full spectrum of barriers and facilitators related to the use of SDM in sciatica care, including those related to the multidisciplinary setting [14]. However, these qualitative data do not provide the importance of these barriers and facilitators for SDM implementation. This is needed to focus an implementation strategy towards the most important barriers and facilitators. Therefore this study aims to answer the following research questions:

1. Which factors are most important for SDM implementation in multidisciplinary sciatica care?
2. Are these factors mainly a barrier or a facilitator for SDM?

METHODS

Setting

In the Netherlands, the diagnosis sciatica is mostly made by general practitioners (GPs). The Dutch multidisciplinary guideline recommends conservative treatment during the first 6-8 weeks, provided when severe neurologic symptoms are lacking. After 6-8 weeks patients are usually referred to a neurologist for further investigation if symptoms continue. The neurologist evaluates the presence of a radicular pain syndrome and orders an MRI to visualize the affected spinal nerve(s) and to judge possible compression. If the MRI confirms a nerve compressing herniated disc, a surgical intervention can be considered, but it is also possible to choose prolonged conservative treatment. In case of surgery, the neurologist will refer the patient to a neurosurgeon or orthopedic surgeon for further surgical decision making.

Population

We randomly selected 200 general practitioners (GPs), 200 physical therapists (PTs), 200 neurologists and 200 orthopedic surgeons from the Dutch medical address book, which includes most professionals in The Netherlands. All Dutch neurosurgeons (n = 131) were invited to participate in the study. Patients were recruited via advertisements in local newspapers across the Netherlands. In addition, the professionals interviewed in our previous study were asked to recruit patients. We aimed to include at least 100 patients. We included sciatica patients diagnosed in the last 12 months, 18 years and older and able to understand written Dutch instructions. Questionnaires were sent in November 2012. Non-responders (professionals and patients) received two reminders, each within a period of 1.5 weeks. Participants who completed the questionnaire received a ten euro gift card as an incentive.

Survey development and deployment

We developed two different internet-based surveys, one for professionals and one for patients, as the barriers and facilitators identified in the previous qualitative study differed between these groups [14]. Each questionnaire consisted of two parts. In the first part we assessed professionals' and patients' preferences for decision making using the control preference scale (CPS) [15]. We asked professionals about their use of shared decision making in routine practice (self-reported), and which discipline should have the leading role in SDM in practice. Furthermore, we asked patients about their care trajectory and the decision making preferences and practice.

For the second part, barriers and facilitators identified in our previous qualitative study were translated into neutral statements. The questionnaire included 53 factors for professionals and 35 factors for patients, that were used in a best-worst scaling (Maximum Difference scaling (MaxDiff)) exercise following an orthogonal design [16]. MaxDiff is an efficient method to rank multiple items. It is easy to complete for respondents, because they only have to choose the most and least important factor within a set. The other factors are then known to be in between those factors. This is more efficient than using Paired Comparisons [17]. Furthermore, the MaxDiff is scale free, and therefore prevents scale-use bias [18]. In this study, respondents were presented with 6 factors at a time. This was repeated a number of times so that all factors were presented in different combinations. To avoid higher importance given to the first mentioned items, the order of items was randomized between respondents. Each item was presented twice [19], and we created 300 versions of the questionnaires to ensure variation in combination of items. At the end of the MaxDiff exercise, each respondent saw their own top five factors, considered as most important given their previous answers. Respondents were asked to indicate for each factor if they perceived it as a barrier or facilitator in their current situation (e.g., knowledge about treatment options can be perceived as a barrier if there is a lack of knowledge, and a facilitator if they have sufficient knowledge). We used Sawtooth Software's SSI Web 8.1 to construct the survey and the MaxDiff exercise.

Finally, we asked the following demographic information of all respondents: age, gender, region (north, middle, and south) and ethnicity. In addition we asked professionals in which setting they work (general hospital, university medical center, private clinic, teaching hospital), and patients educational level. We distinguished three educational level groups: basic education (no or only primary education), intermediate education (prevocational secondary education, senior secondary vocational training, senior secondary general education, preuniversity education), or high education (higher professional education or university (bachelor, master, or PhD degree)).

Analysis

Descriptive statistics were used for the general characteristics of the respondents. We compared the characteristics (age, gender, ethnicity, discipline and setting), and decision making style (preferences and behavior) of professionals who did and did not complete the questionnaire during the MaxDiff exercise. In addition we examined differences between professionals and patients regarding preferences and perceived practice of SDM use. For these comparisons we used independent T-test, Mann Whitney U, Fisher's exact or χ^2 tests, as appropriate. Hierarchical Bayes (HB) estimation was used to estimate relative importance scores (RI) for each factor for each respondent, based on the choices made by respondents in the MaxDiff exercise [20]. These scores can be derived even though respondents evaluate only a part of all possible combinations of items [16]. HB estimation uses an iterative process, along with information from other respondents, to estimate the utilities that best fit the choices of each subject. The sum of all RIs is 100 for each individual. Factors more often chosen as most important get a higher RI, whereas factors chosen as least important get a lower RI. Therefore, a high RI indicates that a factor is very important for this individual, whereas a low RI indicates that a factor is less important. To assess which factors on average are the most important factors for the use of SDM in clinical practice, we calculated the RI for each factor over all respondents with its 95% confidence interval. We checked for random responders using the root likelihood (RLH), excluding respondents with a root likelihood less than 208 [21]. The overall RLH was used as a measure of the goodness of fit. We examined differences in RI between primary care and hospital care professionals, as well as differences in decision making using χ^2 tests. We divided professionals in three groups: professionals who let the patient decide, professionals who make a shared decision, and professionals who decide themselves. Sawtooth Software 8.1 and SPSS 20.0 were used for analyses. Significance testing was done two-sided at $\alpha = 0.05$.

Ethical approval

This study protocol (P12.016) was presented to the Medical Ethical Committee of the Leiden University Medical Center. An exemption was obtained, as ethical approval for this type of study is not required under Dutch law.

RESULTS

Response

Figure 1 shows the inclusion and response of professionals after two reminders. A total of 246 professionals completed the questionnaire and were included. A total of 162 patients were invited for participation (91% via advertisement and 9% via professionals). One patient was excluded because he did not have sciatica. 155 patients (96%) completed the questionnaire.

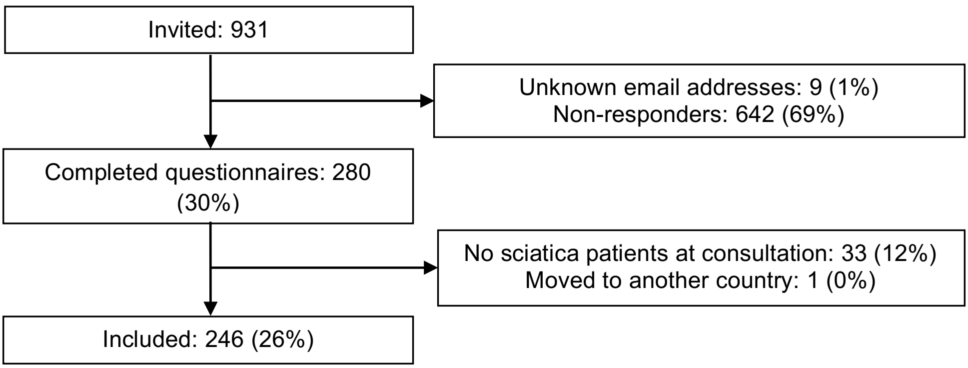

Figure 1. Inclusion and response of professionals

Characteristics of respondents

Among professionals GP's had the lowest response rate (15%) and neurosurgeons had the highest response rate (36%). Characteristics of professionals and patients who completed the questionnaire are described in table 1. Most professionals were male, and of Dutch origin. Responding and non-responding professionals did not differ in age, gender, ethnicity, discipline and setting (data not shown). Concerning the work area of professionals and residence of patients, respondents came from all regions in the Netherlands (table 1). The majority of patients had an intermediate level of education (table 1).

Current care and SDM

For 118 (76%) patients it was the first time they were diagnosed with sciatica. Of all the patients 120 (77%) had been referred to hospital care, 53 patients (34%) already had surgery, and 5 patients (3%) were on a waiting list for surgery. Visited disciplines were the PT (79%), GP (88%), neurologist (76%), neurosurgeon (47%), the orthopedic surgeon (12%) and others (20%; e.g., anesthesiologist (4%), other therapists (Caesar or mensendieck) (3%), or chiropractor (2%)).

Table 1. Characteristics of participating professionals and patients

Characteristics	Professionals (n=246)	Patients (n=155)
Age, years (mean, SD)	46 (10.0)	50 (13.2)
Sex, no. (%)		
Male	173 (70)	68 (44)
Education, no. (%)		
Basic	-	2 (1)
Intermediate	-	95 (61)
High	-	58 (37)
Ethnicity, no. (%)		
Dutch	198 (80)	149 (96)
Western (except Dutch)	37 (15)	6 (4)
Non-Western	11 (4)	0 (0)
Region, no. (%)	*Work area**	*Residence*
North	80 (33)	66 (43)
Middle	112 (46)	53 (34)
South	63 (26)	36 (23)
Discipline, no. (%)		
Physical therapist	63 (26)	-
General practitioner	29 (12)	-
Neurologist	58 (24)	-
Neurosurgeon	47 (19)	-
Orthopedic surgeon	49 (20)	-
Setting* (hospital care n=154), no. (%)		
General hospital	78 (51)	-
University medical center	39 (25)	-
Private clinic	9 (6)	-
Teaching hospital	61 (40)	-

* Multiple options possible

Figure 2 shows the preferences and practices of decision making in sciatica care according to professionals and patients. The majority of the professionals (61%) said that they prefer a shared decision, whereas 52% stated they actually use SDM in daily practice. Preferences of professionals for SDM and the actual use of SDM in their practice are associated ($p<0.001$). Fifty percent of the patients said they wanted the decision to be a shared decision. However, only 41% of the patients said they actually made the decision together with the professional in their own situation. These discrepancies between preference and actual use may be explained by different barriers and facilitators.

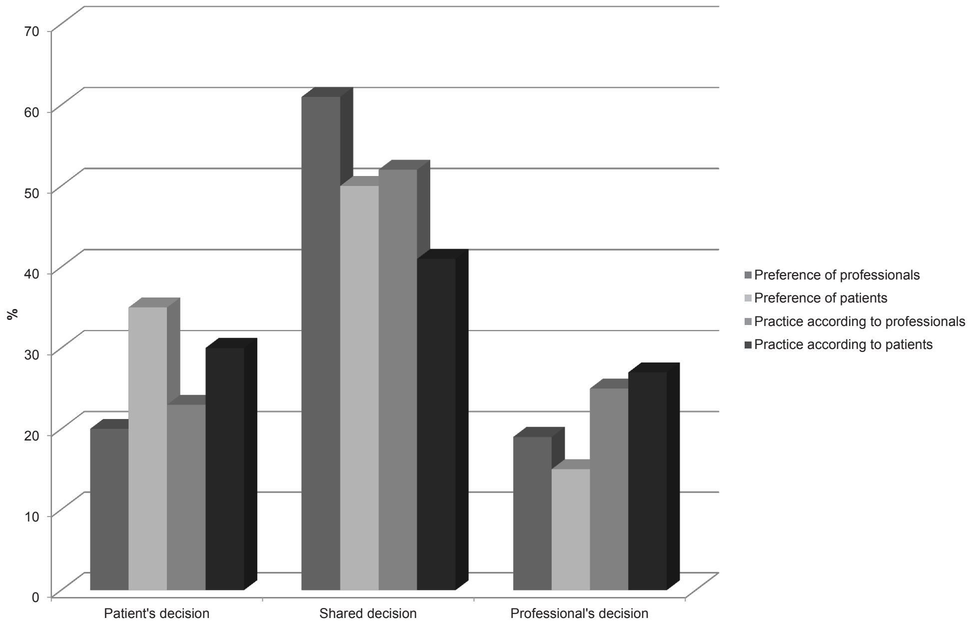

Figure 2. Preferences and practice of decision making in sciatica care according to professionals and patients
Patient's decision: Patient makes the final selection about treatment
Shared decision: the doctor and patient share responsibility for deciding which treatment is best for the patient
Professional's decision: the doctor makes the final decision about treatment

Barriers and facilitators for professionals

Table 2 presents the top 10 factors influencing SDM according to professionals. The factors in the tables are the factors presented to participants during the maximum difference exercise, translated from Dutch literally. Most important factors for professionals on average were: quality of professional-patient relationship, importance for quick recovery of patient, and knowledge about treatment options. The higher average RI of these factors means that more participants had this factor in their top 5. However, if there is a lot of variation between participants, for example if part of the respondents rank a factor as most important and another part as least important, the average RI will be lower even though a considerable amount of professionals mentioned this factor in their top 5. For example the factor "ability of patients to make the decision about treatment" has an RI of 4.48 (CI 4.33-4.63), despite the fact that 46% of the professionals mentioned this factor in their top 5, which is higher than the 38% for "knowledge about treatment options" with a slightly higher average RI (4.64 (CI 4.53-4.74) table 2).

Furthermore, table 2 shows that many factors are both barriers and facilitators, and that factors with the highest RI are also those most frequently mentioned as barriers and facilitators. For example 54% of the professionals reported “quality of professional-patient relationship” in their top 5. This factor represented 11% of all facilitators, and 11% of all barriers in the top 5’s. Overall in the top 5, more factors were perceived as facilitators than as barriers.

Table 2. Most important factors for SDM in sciatica care according to professionals

Factor	Relative importance score (mean, 95% CI)	% professional who reported factor in top 5	% of all top 5 facilitators (n=1080)	% of all top 5 barriers (n=150)
1. Quality of professional-patient relationship	4.87 (4.75-4.99)	54	11	11
2. Importance for quick recovery of patient	4.83 (4.69-4.97)	52	11	8
3. Knowledge about treatment options	4.64 (4.53-4.74)	38	7	10
4. Skills to apply SDM	4.53 (4.42-4.65)	36	7	6
5. Ability of patients to make the decision about treatment	4.48 (4.33-4.63)	46	10	7
6. Patients’ willingness to decide	4.46 (4.32-4.61)	42	8	11
7. Availability of scientific literature	4.25 (4.09-4.41)	36	8	5
8. Criteria for referral and/ or surgery	4.20 (4.05-4.35)	28	6	5
9. Interpretation of information by patients	3.92 (3.76-4.08)	22	4	7
10. Visibility into what other disciplines can do	3.77 (3.62-3.92)	13	2	4

We compared the ranking of factors for professionals working in primary (PT and GP) and hospital care (NL, NS and OS). Table 3 shows that the importance of factors from the overall top 10 depends on the work setting. For instance, professionals working in primary care considered “quick recovery of the patient” as more important compared to hospital care (RI 5.05 vs. 4.61) whereas professionals in hospital care found “skills to apply SDM” as more important (RI 4.73 vs. 4.28). Furthermore, professionals in primary care significantly more often considered “clarity of policy for PT’s in sciatica” (RI 3.97 vs. 0.82) and “communication between medical disciplines and paramedics” (RI 3.93 vs. 1.47) as important factors for SDM, which both are not in the overall top 10 of most important factors. Their top 10 did not contain the factors “availability of scientific literature” (RI 3.90), and “interpretation of information by patients” (RI 3.21).

Professionals in hospital care on the other hand, significantly more often considered “the need for SDM” (RI 4.31 vs. 2.57) as an important factor. Their top 10 also included the “the clarity of the concept SDM” (RI 4.10 vs. 3.19) but did not contain “criteria for referral and/ or surgery” (RI 3.64), and “visibility into what other disciplines can do” (RI 3.34).

Table 3. Most important factors for SDM in sciatica care, by work setting of professionals and decision making

Factors in general top 10	**Professional who reported factor in top 5 (%)**							
		Work setting			**Practices in decision making**			
	Overall (%)	**Primary care (%) (n=92)**	**Hospital care (%) (n=154)**	**P-value**	**Patient decide (%) (n=56)**	**SDM (%) (n=128)**	**Professional decide (%) (n=62)**	**P-value**
1. Quality of professional-patient relationship	54	46	60	0.032	55	54	55	0.981
2. Importance for quick recovery of patient	52	68	42	<0.001	54	47	61	0.170
3. Knowledge about treatment options	38	37	39	0.754	34	38	44	0.546
4. Skills to apply SDM	36	24	43	0.003	39	38	27	0.282
5. Ability of patients to make the decision about treatment	46	35	53	0.005	57	47	35	0.061
6. Patients’ willingness to decide	42	34	47	0.035	48	45	31	0.094
7. Availability of scientific literature	36	36	36	0.938	32	36	40	0.651
8. Criteria for referral and/ or surgery	28	48	16	<0.001	29	25	34	0.441
9. Interpretation of information by patients	22	13	27	0.012	29	16	26	0.116
10. Visibility into what other disciplines can do	13	20	9	0.018	13	14	11	0.861

In addition, we examined differences in decision making (self-reported) (table 3). Even though the differences were not statistically significant, it seemed that professionals who would let the patient decide, more often had the “ability of patients to make the decision about treatment” in the top 5 compared to professionals who decide themselves (p = 0.06, table 3). Furthermore, professionals who used SDM in their practice reported “clarity of the concept SDM” (RI 4.19) and “need for SDM” (RI 4.11) as important, whereas their top 10 did not include “interpretation of information by patients” (RI 3.74), and “visibility into what other disciplines can do” (RI 3.89). The top 10 of professionals who make the decision themselves, did not include “visibility into what other disciplines can do” (RI 3.21) but instead “knowledge about the sciatica guideline” (RI 3.97).

Barriers and facilitators for patients

Table 4 presents the top 10 factors influencing SDM according to patients. Patients on average perceived “correct diagnosis by the professional”, “information provision about treatment options and potential harm and benefits”, and “explanation of the professional

Table 4. Most important factors for SDM in sciatica care according to patients

Factor	Relative importance score (mean, 95% CI)	% patients who reported factor in top 5	% of all top 5 facilitators (n=671)	% of all top 5 barriers (n=104)
1. Correct diagnosis by professional	8.19 (7.99-8.38)	62	13	3
2. Information provision about treatment options and potential harm and benefits	7.87 (7.65-8.08)	53	10	12
3. Explanation of the professional about the care trajectory	7.16 (6.94-7.38)	37	7	10
4. Confidence in the professional	7.02 (6.82-7.23)	37	8	2
5. Knowledge of the professional	6.94 (6.68-7.20)	38	8	2
6. Guidance in conservative treatment by the professional	6.35 (6.09-6.61)	32	7	4
7. Explanation about the diagnosis sciatica by the professional	6.33 (6.05-6.62)	34	8	0
8. Attention for patient's personal situation	4.98 (4.54-5.43)	31	7	3
9. Attention for patient's preferences	4.71 (4.46-4.96)	17	3	5
10. Information materials about the diagnosis and treatment options and potential harms and benefits	4.24 (3.81-4.67)	17	3	3

about the care trajectory” as the most important factors, given the average RI. However, some factors may be perceived as important by a small group of patients, and thus will have a lower RI on average, which does not necessarily have to mean that these are not important barriers and facilitators. For example “contradictory information of the professionals”, “waiting list for surgery” and “waiting list for a visit to the neurologist” on average have a low importance (RI 1.16 (CI 1.45-1.77), RI 2.36 (CI 1.96-2.76) and RI 2.02 (CI 1.66-2.38), respectively) but relatively many of these patients perceived it as barriers and represented respectively 8%, 8% and 12% of all barriers. So these may be barriers for a smaller group of patients. As for professionals, more factors in the top 5 for patients were perceived as facilitators than as barriers.

DISCUSSION

This study shows which factors are most important for the implementation of SDM in sciatica care. Overall, more facilitators than barriers were perceived. For professionals the most important factors are “quality of professional-patient relationship”, “importance for quick recovery of patient”, and “knowledge about treatment options”. Patients perceived “correct diagnosis by professional”, “information provision about treatment options and potential harm and benefits”, and “explanation of the professional about the care trajectory” as the most important factors. In short: knowledge, information provision and a good relationship are perceived as important conditions for SDM by both patients and professionals.

Previous research concerning SDM implementation mainly focussed on one discipline (monodisciplinary). Main barriers mentioned in literature included time constraints, the lack of applicability due to patient characteristics or the clinical situation [10]. Main facilitators pertained to the motivation of health professionals, the perception that SDM leads to improved patient outcomes and to improved health care processes [10]. The lack of applicability due to patient characteristics as mentioned in the literature overlaps with some barriers mentioned in professionals top 10 in the current study (e.g., ability of patients to make the decision about treatment), but the other barriers and facilitators reported in the literature are not among the most important barriers and facilitators as reported in the present study. This may be due to the fact that available studies mainly assessed barriers and facilitators to implement SDM in a monodisciplinary setting, whereas sciatica care involves multiple disciplines. Barriers reported in a study related to interprofessional SDM were imbalance of power between health professionals of different disciplines, the existence of professional silos, and disagreement about roles and responsibilities between different disciplines. Main facilitators were mutual knowledge and understanding of disciplinary roles, trust and respect between different disciplines [12]. Visibility into what other disciplines can do and criteria for referral and/

or surgery are related to the barrier “disagreement about roles and responsibilities between different disciplines” and the facilitator “understanding of disciplinary roles”, but the other barriers and facilitators reported in this interprofessional SDM study are not among the most important barriers and facilitators as reported in the present study. Furthermore, many studies used qualitative methods [10,11] allowing an analysis of which barriers and facilitators play a role, but do not provide information on the importance of each barrier or facilitator. The barriers and facilitators most mentioned in our previous qualitative study [14], using interviews and focus groups were not always consistent with the highest ranked barriers or facilitators as seen in the present study. For example, during interviews professionals mentioned lack of knowledge about treatment options only a few times, whereas it was ranked as an important barrier for SDM. On the other hand lack of time during a consultation was mentioned often during interviews, and is also the most mentioned barrier for SDM in other studies [10]. In the present study, time during a consultation only took a 33th place, and did not occur in any of the professionals top 5. This emphasizes the importance of the ranking of barriers and facilitators after a qualitative study.

As professionals and patients mentioned different factors during (focus group) interviews, they therefore ranked different factors in the current study so that it is not possible to make an explicit comparison. However, many factors are related to each other. In view of the ranking of barriers and facilitators, there seems to be a need for more knowledge and information about sciatica and SDM, and skills to apply SDM. Therefore, healthcare professional training in knowledge regarding treatment options and SDM may improve SDM [22] and should be part of the implementation strategy. Another intervention may be the implementation of the existing decision aid for SDM in sciatica patients to facilitate information provision and SDM [22]. Furthermore, professionals working in primary or hospital care assigned a different importance to factors that may influence SDM, so that a multifaceted intervention is needed to integrate SDM in the complex multidisciplinary organization of sciatica care. For example who is responsible for which part of the information provision or guidance in which step of the care trajectory? Clear criteria are thus needed not only for (timing of) referral (especially important in primary care), but also regarding which part of the information on treatment is given by whom in which part of the care trajectory. The first mentioned intervention, training in knowledge and SDM will act on different factors. For example, professionals mentioned knowledge on treatment options, which is needed to provide information about both treatment options and potential harms and benefits to patients (which patients considered important). This training also gears at other important factors, such as skills to apply SDM, the importance for quick recovery of patient, and patients’ willingness to decide. For example when professionals use SDM in their consultations the patients will tell them whether they want to recover quickly or not, and to determine patients willingness to decide is part of the SDM process. The second mentioned intervention, the use of a decision aid, may improve the interpretation of information by patients and the ability of patients to make the decision about treatment. Additionally, research has shown that patients are more likely to favor conservative treatments over surgery after patients' decision aid (DA) exposure [23,24], which may lead to the reduction of preference-sensitive surgeries.

A strength of this study is the use of Maximum Difference scaling. MaxDiff is a relatively new method in health care research and was introduced by McIntosh and Louviere in 2002 [25]. As mentioned before, MaxDiff is scale free, and therefore prevents scale-use bias [18]. Furthermore, it is easy for respondents to complete, and results in ratio-scaled scores of importance [16,26]. Factors with the highest importance score on average are not always the most important barriers or facilitators for all participants. A factor with a lower importance score can be considered as an important barrier by a smaller group of people. Therefore, it is important to take both the importance score and percentage of the total barriers or facilitators into consideration. Furthermore, we see that some factors are classified as both facilitator and barrier. This may reflect a difference in experience, where it was mainly a facilitator for some participants and a barrier for others, as they were asked to indicate this for their current situation. Another interpretation may be that it was difficult to classify a factor as a facilitator or barrier, especially for patients, given the neutral formulation of each factor. However, regardless of the interpretation, the ranking clearly shows which factors are more important than others for SDM to be implemented. A limitation of this study pertains to the recruitment of patients and professionals. This study is limited by its low response rate. Regarding the recruitment of patients, the procedure does not allow for a calculation of a response rate. It is possible that selection bias occurred, because patients who responded to the advisements may perceive the importance of barriers and facilitators differently than patients who did not respond. For the professionals, the response rate was only 30% of which 26% was included. Although this rate is relatively low, it is comparable to the response seen in another online survey (25% response rate) on the management of sciatica among physicians [27]. In addition, the response rate of online surveys is often lower compared to traditional surveys, due to server rejection, spam filters, automated forwarding or out-of-office replies [28]. Overall there is a decline in response rates over the past decades [29]. Especially GPs were extremely difficult to reach over email (15% response), possibly explained by that they see only a few sciatica patients per year. A similar lower response rate among GPs (18%) was also found in a previous study [27]. We recommend that future studies consider other approaches to reach respondents in order to improve the response to surveys, especially the response of the GPs. A more effective approach may be the presentation of a survey in power point slide format during a meeting of the target group with the response recorded upon entering a choice on a remote controlled device, as Raja et al. [30] (response 96%). Furthermore, it is possible that selection bias has occurred if professionals who do not use SDM in their consultation were less likely to complete the questionnaire, and experience other barriers and facilitators or rank them differently. We analyzed differences in groups of professionals who did and did not use SDM, and observed large overlap in their rankings even though there were some differences. Therefore, we think that the response rate does not bias the results of this study.

CONCLUSIONS

This study showed the most important factors reported by patients and professionals for SDM implementation in sciatica care. Our study also demonstrates that the ranking of factors is an important step to determine which factors are the most important for which group of people, and thus on which factors an implementation strategy should be based. Several studies evaluated different interventions for an increase in the adoption of SDM among healthcare professionals, but there is a lack of evidence which type of intervention is the most effective [22]. Therefore, a multifaceted implementation strategy for SDM in sciatica care needs to be developed based on the most important factors as identified in this study. The effect of this strategy needs to be assessed to fill the gap between theories and clinical practice. This study focuses on SDM in sciatica care in the Netherlands, but the generated knowledge and understanding of the implementation process can also be used to implement SDM in other patients groups or other health care systems in which multiple disciplines are involved. Knowledge, information provision and a good relationship are the most important conditions for SDM perceived by both patients and professionals. These conditions are not restricted to one specific disease or health care system, because they are mostly professional or patient dependent and require healthcare professional training.

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7

Part 2

The optimization of surgical care in knee and hip osteoarthritis

Chapter 8

Indication criteria for total hip or knee arthroplasty in osteoarthritis: a state-of-the-science overview

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Submitted

ABSTRACT

Objective

To examine the evidence base of existing indication criteria for primary total hip and knee arthroplasty (THA/TKA) in osteoarthritis (OA), to provide a state-of-the-science overview to guide decision making on timing of surgery.

Methods

Websites of orthopaedic and arthritis organizations (English/Dutch language) were independently searched by two authors for THA/TKA guidelines for OA. Furthermore, a systematic search strategy in several databases through August 2014 was performed. Quality of the guidelines was assessed with the AGREE II instrument, which consists of 6 domains (maximum summed score of 6 indicating high quality). Also, the level of evidence of all included studies was assessed.

Results

We found 6 guidelines and 18 papers, out of 3065 references. The quality of the guidelines summed across 6 domains ranged from 0.46 to 4.78. In total, 12 THA, 10 TKA and 2 THA/TKA indication sets were found. Four studies stated that no evidence-based indication criteria are available. Indication criteria concerning THA/TKA consisted of the following domains: pain (in respectively 11 and 10 sets), function (12 and 7 sets), radiological changes (10 and 9 sets), failed conservative therapy (8 and 4 sets) and other indications (6 and 7 sets). Specific cut-off values or ranges were often not stated and the level of evidence was low.

Conclusion

The indication criteria for THA and TKA are based on limited evidence. Empirical research is needed, especially regarding domain specific cut-off values or ranges at which the best postoperative outcomes are achieved for patients, taking into account the limited lifespan of a prosthesis.

INTRODUCTION

Total hip and knee arthroplasty (THA/TKA) have been widely performed since the 1970s. In 2009 over a million of THA and TKA were carried out in the United States [1]. Osteoarthritis (OA) is the main clinical indication for which these procedures are performed [2]. Due to the ageing society as well as the obesity epidemic, the prevalence of OA is increasing [3]. As a result the procedure rates of THA and TKA are expected to rise, some estimates even indicate a quadruple demand by 2030 [4,5].

The rise in THA/TKA surgery has important implications for health care costs as well as capacity. In addition, a substantial part of the patients is unsatisfied after THA and TKA (10-30%), indicating that outcomes are less than expected [6]. Therefore, evidence-based indication criteria are warranted, so that these procedures are optimally timed to achieve the best possible patient outcomes, that revision surgery is prevented thereby reducing costs. The importance of such criteria is internationally acknowledged [7-12]

Guidelines concerning THA and TKA indications have been published and several studies regarding the appropriateness of THA and TKA have been conducted [3,7,13-15]. However, an overview of the evidence on which the proposed indication criteria are based is lacking, to guide decision making on timing of THA and TKA. In the present study the available guidelines and their indication sets for primary THA and TKA will be reviewed. In addition, we assess the quality of these guidelines and the evidence on which the indication sets are based. In the second part a systematic search is conducted of scientific publications containing proposed indication sets for primary THA and TKA in OA or expert opinion.

METHODS

Search strategy

Websites of orthopaedic and arthritis organizations (English or Dutch websites) were independently searched by two authors for guidelines concerning primary THA/TKA for OA. When these websites cross-linked to guidelines from other organizations these were also included. All available guidelines published since January 1, 2000 were included. A librarian-assisted search strategy was performed on August 3 2014 to retrieve additional publications on THA/TKA indications. The following databases were searched: Pubmed, MEDLINE, Embase, Web of Science, the COCHRANE Librabry, CENTRAL and CINAHL. Searches were limited to English, Dutch and German language papers published since January 1, 2000 (see Supplement 1).

Selection of publications

First titles and abstracts were independently screened by two authors (MG/SH).The full-text articles were reviewed by MG and were included when the following criteria were met: studies reporting about indication criteria and/or appropriateness of decision tools for primary THA/TKA in OA. Papers involving guidelines on unicompartimental replacements, resurfacing or revision of THA/TKA were excluded if no separate indications for primary THA/TKA were provided. Also papers on prioritizing tools to reduce waiting times were excluded.

The included papers where checked by a second author (SH). If disagreement existed the authors tried to reach consensus, when necessary a third author had the decisive vote (PM). When a guideline was also published as a scientific paper, only the guideline was included.

Data extraction

The following information was extracted from the guidelines by MG: orthopaedic or arthritis organization, publication date, indication criteria and the level of evidence on which indication criteria were based (see below). From the publications the following information was extracted: first author, publication date, country where the indication criteria were developed, organization(s) initiating development of the criteria, study type, indication criteria and the level of evidence on which indication criteria were based. Table 1 shows the criteria to score the level of evidence [3].

Data extraction and level of evidence score was checked by SH.

Table 1. Level of evidence

Level	Evidence
Ia	evidence from meta-analysis of randomized controlled trials
Ib	evidence from at least one randomized controlled trial
IIa	evidence from at least one controlled study without randomization
IIb	evidence from at least one well-designed quasi-experimental study
III	evidence from at least one non-experimental descriptive study, such as comparative studies, correlation studies, and case-control studies
IV	evidence from expert committee reports or opinions or clinical experience of respected authorities or both

Quality of the guidelines

Guideline quality was assessed with the validated AGREE-II instrument (Appraisal of Guidelines for Research and Evaluation, Dutch version)[16]. This instrument evaluates the process of practice guideline development and the quality of reporting. Two authors independently scored the guidelines according to the AGREE-II protocol (MG/SH). When large differences existed the authors tried to reach consensus, when necessary a third author had the decisive vote (PM).

AGREE-II consists of six quality domains: 1) scope and purpose, 2) stakeholder involvement, 3) rigour of development, 4) clarity of presentation, 5) applicability and 6) editorial independence. Each domain entails several questions which are rated from 1 (lowest score) to 7 (highest score), with 1 rated for items with no clear discussion or no specific information , 7 for exceptional reporting quality, 2–6 for items not fully meeting the AGREE-II criteria. Scaled domain scores were calculated using the following formula:

$$\frac{\text{(Obtained score – Minimum possible score)}}{\text{(Maximum possible score – Minimum possible score)}}$$

The scores will always lie between 0 and 1, with scores closer to 1 indicating higher quality. The scaled domain scores from the two authors were averaged to obtain one quality score for each domain. We summed the scaled domain scores across the 6 domains to obtain 1 overall guideline score. The maximum summed score was thus 6, indicating high quality.

RESULTS

Across guidelines and studies, 12 THA, 10 TKA and 2 THA/TKA indication sets were found.

Guidelines

We found six guidelines concerning THA, of which three specific OA guidelines (EULAR [14], NICE [17] and OARSI [3]). In addition, five guidelines concerning TKA were found, of which four OA specific guidelines (BOA [18], EULAR [13], NICE [17] and OARSI [3]) (Table 2).

Indication criteria concerning THA and TKA

Most indication criteria consisted of the following three domains: pain, function and radiological changes, with the prerequisite that pain could not be controlled by conservative therapy (Table 2). Specific cut-off values or ranges for pain and function were not reported. For radiological changes only the BOA TKA guideline reported a cut-off value (Kellgren Lawrence grade ≥ III). The evidence on which the indication criteria were based was rated as low quality evidence (level IV).

Table 2. Guidelines and their indication criteria concerning total hip arthroplasty and total knee arthroplasty

Guideline	Year of publication	OA specific	Evidence	Indication criteria				
				Pain	Function	Radiological changes	Failed or futile conservative therapy	Other criteria
Knee								
British Orthopedic Association [18]	2013	yes	level IV	moderate or severe pain		KL>III in at least one of the knee joints compartments	yes	Patients outside these criteria may still be considered for surgery but a second opinion/ recorded case discussion is advised. Cases focus on patients without pain (primary indication) but who present with: functional disability in the presence of end stage cartilage disease. Progressive deformity of the knee (varus/valgus) with functional disability.
Eular [13]	2003	yes	level IV	refractory pain	disability	radiological evidence of knee OA		
NZ [40]	?	no, but based on BOA guidelines which is OA specific	level IV	severe pain	disability	radiological changes	yes	Occasionally there may be an indication to replace a knee because of progressive deformity and/ or instability, and pain may not necessarily be the most significant factor. Where comorbidities exist risk benefit considerations may rule out the operation in an individual patient.
Hip								
British Orthopedic Association [41]	2013	no	level IV	inadequately controlled by medication	restriction in function	narrowing of the joint space	yes	Compromised quality of life

Guideline	Year of publication	OA specific	Evidence	Indication criteria				
				Pain	**Function**	**Radiological changes**	**Failed or futile conservative therapy**	**Other criteria**
NOV [42]	2010	no	level IV	pain	function loss	radiological changes	yes	Younger age and obesity are relative contraindications. Delay of surgery in high age is not advisable in view of reduced functional outcome and increased mortality. In addition when progressive loss of function (with or without contractures) predominates over pain, surgery should not be delayed in view of reduced postoperative functional outcome.
NZ [43]	?	no	level IV	significant pain	disability	radiological changes	yes	
Joint								
OARSI (hip-knee) [3]	2008	yes	level IV	no adequate pain relief	no adequate functional improvement		yes	
NICE [17]	2014	yes	level IV	pain	stiffness and reduced function		yes	substantial impact on quality of life

Quality of the guidelines

The quality of the guidelines differed considerably between the AGREE-II domains and the guidelines (Figure 1). The ranges of the scaled domain scores were: scope and purpose 0.06-0.81, stakeholder involvement 0.19-0.75, rigour of development 0.03-0.88, clarity of presentation 0.33-0.89, applicability 0-0.50, editorial independence 0-0.96. Low scores were frequently attained in the editorial independence domain due to no clear statement on the influence of the funding body and competing interests. In addition, low scores were often attained in the applicability domain, due to no clear statements on monitoring/auditing criteria of the guideline or facilitators and barriers to the application of the guideline. The OARSI and NOV guidelines attained the highest overall scores, 4.78 and 4.46 respectively. This is explained because both guidelines were developed according to the AGREE-II. The lowest scores were attained by the NZ guidelines, THA (0.84) and TKA (0.46). These guidelines primarily consisted of a, from the BOA guidelines derived, summary of statements concerning THA/TKA but limited information on the required 6 domains.

Although the process of guideline development and quality of reporting differed considerably between the guidelines, the given indication criteria for primary THA and TKA are similar across guidelines (pain, function, radiological changes). Hence, it seems that guideline quality did not influence the main domains included in the indication sets.

Publications

Our literature search yielded 3065 references (Figure 2), the full-text of 88 papers was assessed on eligibility. Of these 70 were excluded mainly because no indication criteria for THA/TKA in OA patients were reported. Finally, 18 papers were included (12 reviews/6 original studies).

Reviews

Only 2 systematic reviews were included (Table 3) [19,20]. Furthermore, only 2 reviews focussed on indications for THA/TKA as their main topic [21,22]. In addition, 1 review investigated the indications for THA/TKA referral [23]. Other topics on which the reviews focussed were management of THA/TKA [24-26], effectiveness of THA/TKA [20] and state of art overviews of THA/TKA [8,27,28].

Pain not responsive to conservative treatment, in patients who have functional limitations and radiographic evidence of joint degeneration was most often reported as THA/TKA indication (Table 3). No specific cut-off values were mentioned. It was often not stated if deviations in all these domains should be apparent, or which combinations should be apparent to indicate THA or TKA. Furthermore, the evidence behind all these indication criteria was very low (level IV). In 3 of the reviews the experts explicitly stated that no

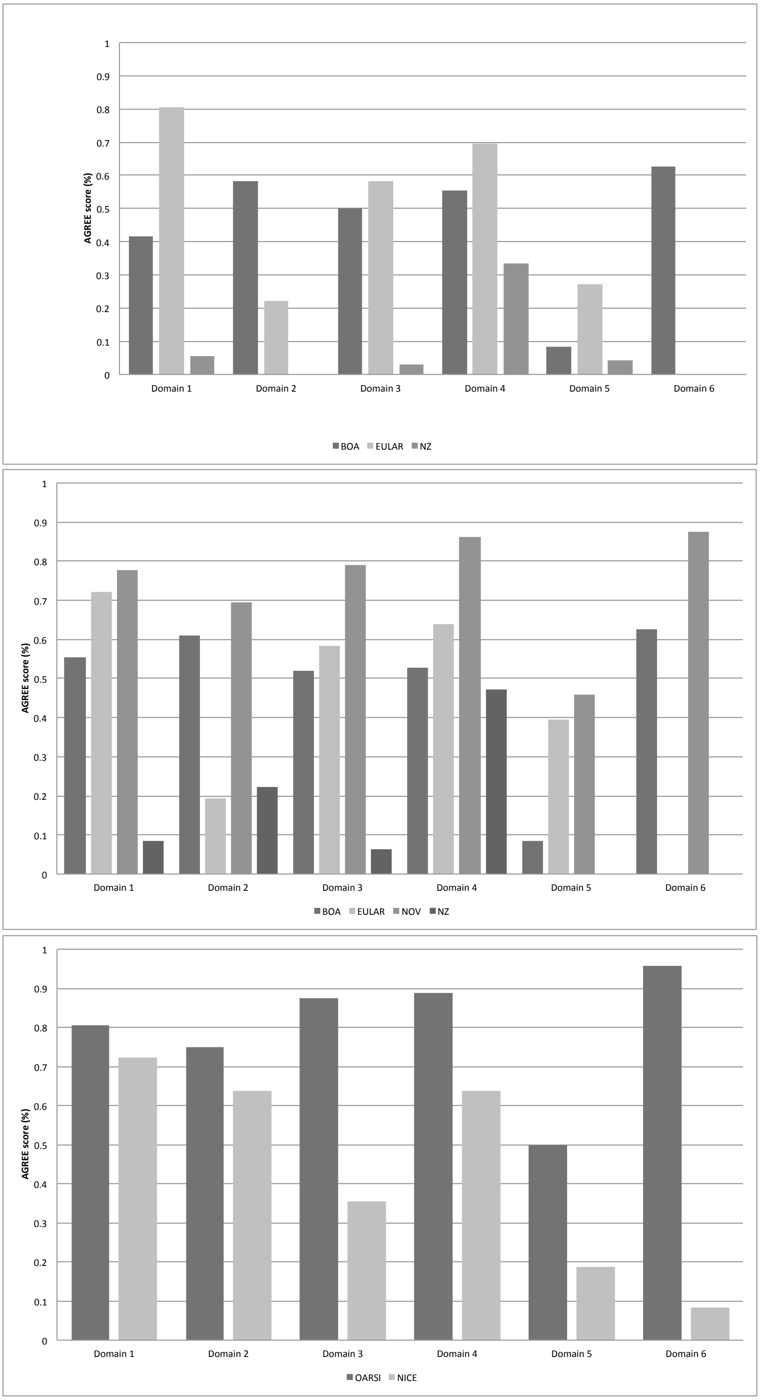

Figure 1. AGREE II guideline quality scores.
1 Panel A: AGREE II quality scores of the guidelines concerning hip replacement
1 Panel B: AGREE II quality scores of the guidelines concerning knee replacement
1 Panel C: AGREE II quality scores of the guidelines concerning joint replacement in osteoarthritis
Domain 1: scope and purpose, domain 2: stakeholder involvement, domain 3: rigour of development, domain 4: clarity of presentation, domain 5: applicability, domain 6: editorial independence.

Table 3. Reviews on indication criteria concerning total hip arthroplasty and total knee arthroplasty

Author	Year of publication	Study group region	Systematic review	Evidence	Indication criteria				
					Pain	Function	Radiological changes	Failed or futile conservative therapy	Other criteria
Knee									
Hanssen [28]	2000	USA	No	level IV					As the indications continue to expand, the decision to proceed with total knee arthroplasty in young, active patients' needs to be individualized after careful consideration of alternatives.
Kirschner [44]	2011	Germany	No	level IV	pain during activities or rest		radiologic evidence of arthritis		
van Manen [24]	2012	USA	No	level IV	severe, refractory knee pain, often at night	difficulty with activities of daily living; decreased mobility	Radiographic Evidence of Primary or Inflammatory Degenerative Joint Disease: Narrowed joint space; Osteophytes (spurring) and bone cysts; squaring of condyles; bone sclerosis.	failure to respond to conservative measures	Current healt status: Medically optimized for surgery; no evidence of infection; intact extensor mechanism; informed consent obtained.
Medical Advisory Secretariat [20]	2005	Canada	Yes	level IV	pain	functional ability			
Schneppenheim [22]	2001	Germany	No	level IV	debilitating pain	severe restrictions on the activities of the patients in daily life.	significant radiographic findings	yes	
Hip									
Kirschner [44]	2011	Germany	No	level IV	hip: pain during activities or rest	constricted range of motion	radiologic evidence of arthritis		
Lane [27]	2007	USA	No	level IV		substantial functional impairment			chronic discomfort
Levine [25]	2013	USA	No	level IV	pain refractory to nonsurgical management	functional impairment	Radiolographic findings (joint space narrowing, bone sclerosis, bone cysts femoral/ acetabular osteophytes	yes	physical exam findings (groin pain and decreased internal rotation), ruled out causes of referred pain including spine problems and bursitis

Author	Year of publication	Study group region	Systematic review	Evidence	Indication criteria				
					Pain	Function	Radiological changes	Failed or futile conservative therapy	Other criteria
Pivec [8]	2012	USA	No	level IV	pain	functional impairment	radiographic findings		initial course of conservative therapy should always be attempted with analgesia, activity modification, ambulatory aids, and weight loss.
Knee and Hip									
Altman [19]	2005	USA, France, Portugal, Belgium, Spain, Germany, Austria, Czech Republic, The Netherlands	Yes	level III					The criteria for when to perform such surgery are not clear.
Dowsey [21]	2014	Australia	No	level III					Selection of suitable candidates for TJR is critical but appropriate criteria are not clearly defined
Mandl [23]	2013	USA	No	level IV					There are no definitive recommendations for deciding which patients should be referred for TJA

*This study focusses on THA in older people (>65 years of age)
uni: unicompartmental excluded patello-femoral isolated; bi: unicompartmental plus patello-femoral; tri: tricompartmental

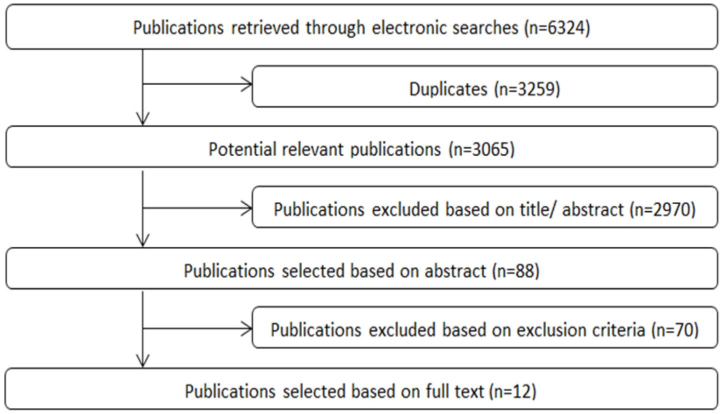

Figure 2. Flow diagram

appropriate indication sets are available for performing THA/TKA.

Original publications

Three original publications reported on TKA [29-31] and 3 on THA [32]. Yambabe et al. [29] considered severe cartilage defects as an optimal indication for TKA. In their discussion section they also included pain but no referral was made to any evidence or the way these indications were established. The other 5 included original studies investigated decision tools to assess the appropriateness of TKA (n=2) [30,31] or THA (n=3) [32-34] in OA patients.

TKA appropriateness

Two studies evaluated algorithms to assess TKA appropriateness [30,31]. The Escobar algorithm was established using the RAND/UCLA appropriateness method, in which expert opinion is combined with available scientific evidence [35]. The following variables where taken into account in different combinations: symptomatology, radiology, age, mobility and stability, previous surgical management and localization. Symptomatology and radiology were the largest contributors in explaining the variability of appropriateness in their model. Table 4 depicts various scenarios in which TKA was considered inappropriate, uncertain or appropriate [30]. However, appropriateness was rated uncertain in a high percentage of scenarios (24.5%). Another study showed that patients who were rated appropriate were more likely to achieve better health-related quality of life than patients rated as inappropriate [36].

Table 4. Different scenarios in which TKA is deemed appropriate, uncertain or inappropriate according to Escobar et al. [30]

Symptoms	Radiology	Age	Mobility	Localisation	Total knee arthroplasty
slight or moderate	Ahlbäck I-III				inappropriate
slight	Ahlbäck IV-V				inappropriate
moderate	Ahlbäck IV-V	<55			inappropriate
moderate	Ahlbäck IV-V	≥55		uni	inappropriate
moderate	Ahlbäck IV-V	≥55		bi-tri	appropriate
intense-severe	Ahlbäck I-III	<55		uni-bi	inappropriate
intense-severe	Ahlbäck I-III	<55		tri	uncertain
intense-severe	Ahlbäck I	≥55	normal		inappropriate
intense-severe	Ahlbäck II-III	≥55	normal		uncertain
intense-severe	Ahlbäck I	55-65	limited		uncertain
intense	Ahlbäck I	>65	limited		uncertain
severe	Ahlbäck I	>65	limited		appropriate
intense-severe	Ahlbäck II-III	≥55	limited		appropriate
intense-severe	Ahlbäck IV-V	<55		uni	uncertain
intense-severe	Ahlbäck IV-V	<55		bi-tri	appropriate
intense-severe	Ahlbäck IV-V	≥55			appropriate

Riddle et al. modified the Escobar algorithm to attain a decision tool for US patients [31]. They used the Kellgren Lawrence score rather than the Ahlbäck classification and quantified symptomatology using the Western Ontario and McMaster osteoarthritis index (WOMAC). In 21.7% of patients appropriateness of TKA was rated as uncertain.

THA appropriateness

Quintana et al. developed three THA appropriateness algorithms in OA patients [32-34]. Two were established using the RAND/UCLA appropriateness method. These algorithms took the following variables into account: age, surgical risk, previous nonsurgical treatments, pain and functional limitation. Table 5 depicts various scenarios in which THA was considered inappropriate, uncertain or appropriate [32]. In both algorithms, appropriateness was rated uncertain in a large part of patients, 46.2% and 32.4%. Both algorithms were validated in a population of OA patients scheduled for THA [32,34]. Patients rated appropriate THA candidates had better outcomes at 3 months on the WOMAC stiffness and functional limitation domains compared to inappropriate candidates.

The other algorithm was based on the WOMAC as they wanted to develop a tool based on a disease specific instrument rather than on expert opinion [33]. Surgical risk, pre-intervention pain and functional limitations were found to significantly predict changes in the WOMAC pain domain 6 months after THA and pre-intervention functional limitations

Table 5. Different scenarios in which THA is deemed appropriate, uncertain or inappropriate according to Quintana et al. [32]

Pain	Non-surgical procedure	Functional limitation	Surgical risk	Age	Total hip arthroplasty
severe	correctly	severe			appropriate
severe	correctly	minor or moderate			appropriate
severe	not done or not done correctly	severe			appropriate
mild or moderate	correctly	severe	low		appropriate
mild		minor			inappropriate
mild		moderate	high		inappropriate
mild		moderate	low		inappropriate
moderate or severe	not done or not done correctly			<50 years	inappropriate
moderate or severe	not done or not done correctly	minor		>50 years	inappropriate
mild or moderate	not done or not done correctly	severe	low		uncertain
mild or moderate	not done or not done correctly	severe	high		uncertain
mild or moderate	correctly	severe	high		uncertain
severe	not done or not done correctly	minor or moderate			uncertain
moderate	correctly	minor or moderate	high		uncertain
moderate	correctly	minor or moderate	low		uncertain
moderate	not done or not done correctly	moderate		>50	uncertain
mild	correctly	moderate	low		uncertain

predicted changes in the functional limitation domain [33]. In addition, by means of a classification and regression tree analysis a summary tree was constructed. THA was rated as appropriate when pain was qualified as severe (according to the pain and limitation short scales), when WOMAC pain pre-intervention score >60 or when WOMAC functional limitation pre-intervention >60 with pain pre-intervention >40. Surgical risk was not included in the decision tree. However, the authors stated that one should be aware that higher surgical risk often results in a worse outcome and that conservative treatment should always be performed before considering THA. Again this decision tool was validated in a THA cohort. They assessed sensitivity and specificity of being classified as appropriate compared with the appropriateness based on the minimal clinical important difference values (gain in WOMAC 6 months after THA, pain domain ≥30, function domain ≥25). A sensitivity of 95.0% and a specificity of 41.0% was found, suggesting that it seems difficult to identify the non-appropriate cases.

DISCUSSION

In this systematic review we examined the quality and evidence base of existing indication criteria and guidelines for primary THA and TKA in OA patients. Across guidelines and publications we found, 12 THA, 10 TKA and 2 THA/TKA indication sets. Only 6 guidelines included indication criteria for THA/TKA with differing quality. Overall quality of the guidelines summed across the 6 domains ranged from 0.46 to 4.78 Low scores were frequently attained in the editorial independence domain and the applicability domain. High scores were often attained in the clarity of presentation domain. In the additional12 reviews and 6 original publications most indication criteria included the following three domains: pain, function and radiological changes. Frequently a prerequisite was that conservative treatment had been insufficient in controlling pain. However, domain specific cut-off values or ranges, were mostly not reported. Also, it was often not stated if pain, functional disability and radiological changes should all exist, or which combinations of domain-specific deviations should be apparent to indicate THA or TKA. The level of evidence was low (level IV).

We were not able to discriminate between high en poor quality guidelines as the AGREE-II has not given a set of rules to define a high quality guideline. Given the low scores in the applicability and the editorial independence domains, we advise guideline developers to pay more attention in reporting these issues. A limitation of the current study may be that the scoring of guidelines according to the AGREE-II is not completely objective, even though the manual clearly articulates how each item should be scored including the criteria and considerations for each item. However, the weighting of criteria and considerations in the overall scoring of the item is not mentioned, which could introduce inter-observer variability. To cope with this, the AGREE-II proposes to use more than one observer, which is why the guidelines were scored independently by two investigators and compared to reach consensus (with or without a decisive vote of a third investigator). A such, we tried to minimalize subjectivity.

Irrespective of the quality of individual guidelines, the same domains concerning THA/TKA indications were reported across most guidelines. Based on the design of included studies, the highest level of evidence was reported by the OARSI and EULAR guidelines (only non-experimental studies, level III evidence). The evidence on which indication sets were based came from studies investigating the effectiveness and safety of THA/TKA, but these studies did not specifically address THA/TKA indication sets. Therefore the evidence from these guidelines was rated as level IV evidence, so that the evidence on which indication criteria are based, is low quality evidence.

Looking at other literature, most of the reviews also did not specifically focus on THA/TKA indications and none of the systematic reviews did. Moreover, in 2 of 3 reviews with

THA/TKA indication as main topic it was concluded that no conclusive evidence on THA/TKA indications are currently available. Furthermore, few original papers investigating THA/TKA indications were found, which may be partly due to the employed language restrictions, possibly resulting in language bias. Four of 5 original studies came from the same group and 4 were based on the RAND/UCLA method [30-32,34]. Although this is a respected approach , the limitation is that the indication set is mainly based on expert opinion if little research is available. Thus, even with an optimal composition of experts in the panel, the level of evidence will still be low. This is currently the case for THA/TKA indication sets. In addition, within the proposed THA/TKA decision tools, the appropriateness of surgery was rated as uncertain in many patients. This makes these decision tools difficult to use in daily practice, as uncertain rated patients may have similar improvements in health outcomes as patients rated as appropriate. Therefore, no evidence-based indications concerning THA/TKA are currently available which can be uniformly used in daily practice.

Nonetheless, when indications were reported, the same domains were included. Hence, although evidence based studies are lacking, expert opinion seems reasonably consistent. This is promising as these domains may give clues to the targets on which future research for THA/TKA indications should focus. It seems evident that pain, function, radiological changes and failed conservative therapy should be part of future studies on THA/TKA indications. The research of indication criteria is, however, difficult. One of the difficulties is that pain and function are relatively subjective measures both when reported by the patient or when judged by the physician. This is illustrated by the fact that although consensus on the indication domains seems to exist, disease severity greatly varies at the time of surgery across different centres in Europe and Australia [37,38]. This suggests no agreement on the cut-off values or ranges within these domains or between combinations of domains as an indication for surgery. Another difficulty is that it is not possible to conduct controlled trials with the timing of surgery randomized, so that other designs are needed. As a consequence the highest level of evidence is not likely to be obtained, but likely to be relatively low given mainly observational studies (level II and III). However, outcomes of observational studies can be valid and may provide similar results as RCTs. For instance, meta-analyses comparing RCTs and observational studies of treatment effects found no large systematic differences [39]. Furthermore, randomization will avoid confounding by indication but this can also be achieved with advanced statistical analyses and pseudo-randomization in observational studies. To obtain the best possible evidence, we should try to identify predictors for a (less than) good outcome after THA/TKA. With the identified predictors we might be able to simulate with mathematical modelling at which cut-off points surgery has the best postoperative outcomes, taking into account the limited lifespan of a prosthesis and the fact that revision surgery mostly has worse outcomes than primary surgery.

In conclusion, our current study gives an overview of the available evidence base of THA/TKA indication criteria in both guidelines and original studies. We showed that the currently available THA/TKA indication criteria are based on limited and low quality evidence. Hence, empirical research on this topic is needed, especially regarding domain specific cut-off values or ranges at which the best postoperative outcomes are achieved.

8

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SUPPLEMENT 1

The websites of several orthopaedic associations and arthritis organizations (with English or Dutch websites) were independently searched by two authors for guidelines concerning primary hip/knee replacement for OA : American Academy of Orthopaedic Surgeons, American College of Rheumatology, American Association of Orthopaedic Medicine, American Orthopaedic Association, Asia Pacific Orthopaedic Association, Asia Pacific League of Association for Rheumatology, Australian Orthopaedic Association, Australian Rheumatology Association, British Orthopaedic Association (BOA), British Society for Rheumatology, Canadian Orthopaedic association, Canadian Rheumatology Association, Dutch Society of Rheumatology, the European league against rheumatism (EULAR), European Federation of National Associations of Orthopaedics and Traumatology, European Orthopaedic Research Society, Irish Society of Orthopaedic Medicine, Irish Institute of Trauma and Orthopaedic Surgery, Irish Society for Rheumatology, Indian Rheumatology Association, Indian Orthopaedic Association, National Institute for Health Care Excellence, Netherlands Orthopaedic Association (NOV), New Zealand Orthopaedic Association (NZ), Nordic orthopaedic association, National Institute for Health and Care Excellence (NICE), New Zealand Rheumatology Association, Osteoarthritis Research Society International (OARSI), South African League Against Rheumatism and Arthritis Organization and South African Orthopaedic Association.

The search strategy for identification of publications on indications for THA and TKA is depicted in the table here below.

Databases	Search Strategy	Number unique references
PubMed	**(**("Arthroplasty, Replacement, Knee"[majr] OR "Knee Prosthesis"[majr] OR "knee replacement arthroplasty"[ti] OR "total knee arthroplasty"[ti] OR "total knee"[ti] OR tka[ti] OR "tkr"[ti] OR "total knee replacement"[ti] OR "knee prosthesis"[ti] OR "knee implantation"[ti] OR "knee implant"[ti] OR "knee implants"[ti] OR "knee prosthesis"[ti] OR "knee joint replacement"[ti] OR "knee joint arthroplasty"[ti] OR "Knee Replacement Arthroplasties"[ti] OR "Total Knee Replacements"[ti] OR "Knee Prostheses"[ti] OR "Knee endoprosthesis"[ti] OR "Knee endoprostheses"[ti] OR "Knee joint arthroplasty"[ti] OR "Knee joint arthroplasties"[ti] OR "knee joint prosthesis"[ti] OR "knee joint prostheses"[ti] OR "knee prosthetic"[ti] OR "Knee endoprosthetic"[ti] OR "knee joint prosthetic"[ti] OR "Knee joint endoprosthetic"[ti] OR "knee prosthetics"[ti] OR "Knee endoprosthetics"[ti] OR "knee joint prosthetics"[ti] OR "Knee joint endoprosthetics"[ti] OR "Knee replacement"[ti] OR "Knee replacements"[ti] OR "knee arthroplasty"[ti] OR "knee arthroplasties"[ti] **OR** "Arthroplasty, Replacement, Hip"[majr] OR "Hip Prosthesis"[majr] OR "hip replacement arthroplasty"[ti] OR "total hip arthroplasty"[ti] OR "total hip"[ti] OR tha[ti] OR "thr"[ti] OR "total hip replacement"[ti] OR "hip prosthesis"[ti] OR "hip implantation"[ti] OR "hip implant"[ti] OR "hip implants"[ti] OR "hip prosthesis"[ti] OR "hip joint replacement"[ti] OR "hip joint arthroplasty"[ti] OR "Hip Replacement Arthroplasties"[ti] OR "Total Hip Replacements"[ti] OR "Hip Prostheses"[ti] OR "Hip endoprosthesis"[ti] OR "Hip endoprostheses"[ti] OR "Hip joint arthroplasty"[ti] OR "Hip joint arthroplasties"[ti] OR "hip joint prosthesis"[ti] OR "hip joint prostheses"[ti] OR "hip prosthetic"[ti] OR "Hip endoprosthetic"[ti] OR "hip joint prosthetic"[ti] OR "Hip joint endoprosthetic"[ti] OR "hip prosthetics"[ti] OR "Hip endoprosthetics"[ti] OR "hip joint prosthetics"[ti] OR "Hip joint endoprosthetics"[ti] OR "Hip replacement"[ti] OR "Hip replacements"[ti] OR "hip arthroplasty"[ti] OR "hip arthroplasties"[ti] **OR (("total joint arthroplasty"[ti] OR "total joint replacement"[ti] OR "total joint prosthesis"[ti] OR "Arthroplasty, Replacement"[Majr:NoExp]**) NOT (shoulder*[ti] OR ankle*[ti]))) AND ((decision[ti] AND "to operate"[ti]) OR "decision to treat"[ti] OR "treatment decision"[ti] OR "operation decision"[ti] OR "surgery decision"[ti] OR "intervention decision"[ti] OR "treatment decisions"[ti] OR "operation decisions"[ti] OR "surgery decisions"[ti] OR "intervention decisions"[ti] OR "Patient Selection"[Mesh] OR "patient selection"[ti] OR "Patient Selections"[ti] OR "Selection for Treatment"[ti] OR "Selection for Treatments"[ti] OR "Selection of Subjects"[ti] OR "Subjects Selection"[ti] OR "Subjects Selections"[ti] OR "Selection Criteria"[ti] OR "priority tool"[ti] OR "priority tools"[ti] OR "priority criteria"[ti] OR "priority criterium"[ti] OR "indication set"[ti] OR "priority"[ti] OR "priorities"[ti] OR priorit*[ti] OR "indication"[ti] OR "indications"[ti] OR "**appropriateness criteria"[ti] OR ("evidence"[tw] AND ("indication"[tw] OR "indications"[tw])) OR (("Checklist"[Mesh] OR "checklist"[tw] OR "checklists"[tw]) AND ("indication"[tw] OR "indications"[tw])) OR "Guideline"[Publication Type] OR "Practice Guideline"[Publication Type] OR "Guidelines as Topic"[majr] OR "Practice Guidelines as Topic"[majr] OR (("guideline"[ti] OR "guidelines"[ti]) NOT "Guidelines for Authors"))) OR (**("Osteoarthritis"[Mesh] OR "Osteoarthritis"[tw] OR "Osteoarthritides"[tw] OR "Osteoarthrosis"[tw] OR "Osteoarthroses"[tw] OR "Degenerative Arthritides"[tw] OR "Degenerative Arthritis"[tw] OR OA[ti]) AND ("Arthroplasty, Replacement, Knee"[majr] OR "Knee Prosthesis"[majr] OR "knee replacement arthroplasty"[ti] OR "total knee arthroplasty"[ti] OR "total knee"[ti] OR tka[ti] OR "tkr"[ti] OR "total knee replacement"[ti] OR "knee prosthesis"[ti] OR "knee implantation"[ti] OR "knee implant"[ti] OR "knee 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"decision to treat"[tw] OR "treatment decision"[tw] OR "operation decision"[tw] OR "surgery decision"[tw] OR "intervention decision"[tw] OR "treatment decisions"[tw] OR "operation decisions"[tw] OR "surgery decisions"[tw] OR "intervention decisions"[tw] OR "Patient Selection"[Mesh] OR "patient selection"[tw] OR "Patient Selections"[tw] OR "Selection for Treatment"[tw] OR "Selection for Treatments"[tw] OR "Selection of Subjects"[tw] OR "Subjects Selection"[tw] OR "Subjects Selections"[tw] OR "Selection Criteria"[tw] OR "priority tool"[tw] OR "priority tools"[tw] OR "priority criteria"[tw] OR "priority criterium"[tw] OR "indication set"[tw] OR "priority"[tw] OR "priorities"[tw] OR priorit*[tw] OR "indication"[tw] OR "indications"[tw] OR "**appropriateness criteria"[tw] OR ("evidence"[tw] AND ("indication"[tw] OR "indications"[tw])) OR (("Checklist"[Mesh] OR "checklist"[tw] OR "checklists"[tw]) AND ("indication"[tw] OR "indications"[tw])) OR "Guideline"[Publication Type] OR "Practice Guideline"[Publication Type] OR "Guidelines as Topic"[Mesh] OR "Practice Guidelines as Topic"[Mesh] OR (("guideline"[tw] OR "guidelines"[tw]) NOT "Guidelines for Authors")))**	1516

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MEDLINE (OVID-version)	**(**(exp *Arthroplasty, Replacement, Knee/ OR exp *Knee Prosthesis/ OR "knee replacement arthroplasty".ti OR "total knee arthroplasty".ti OR "total knee".ti OR tka.ti OR "tkr".ti OR "total knee replacement".ti OR "knee prosthesis".ti OR "knee implantation".ti OR "knee implant".ti OR "knee implants".ti OR "knee prosthesis".ti OR "knee joint replacement".ti OR "knee joint arthroplasty".ti OR "Knee Replacement Arthroplasties".ti OR "Total Knee Replacements".ti OR "Knee Prostheses".ti OR "Knee endoprosthesis".ti OR "Knee endoprostheses".ti OR "Knee joint arthroplasty".ti OR "Knee joint arthroplasties".ti OR "knee joint prosthesis".ti OR "knee joint prostheses".ti OR "knee prosthetic".ti OR "Knee endoprosthetic".ti OR "knee joint prosthetic".ti OR "Knee joint endoprosthetic".ti OR "knee prosthetics".ti OR "Knee endoprosthetics".ti OR "knee joint prosthetics".ti OR "Knee joint endoprosthetics".ti OR "Knee replacement".ti OR "Knee replacements".ti OR "knee 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"guidelines".ti) NOT "guidelines for authors".mp))) OR (**(exp Osteoarthritis/ OR "Osteoarthritis".ti,ab OR "Osteoarthritides".ti,ab OR "Osteoarthrosis".ti,ab OR "Osteoarthroses".ti,ab OR "Degenerative Arthritides".ti,ab OR "Degenerative Arthritis".ti,ab OR OA.ti) AND (exp *Knee Arthroplasty/ OR exp *Knee Prosthesis/ OR "knee replacement arthroplasty".ti OR "total knee arthroplasty".ti OR "total knee".ti OR tka.ti OR "tkr".ti OR "total knee replacement".ti OR "knee prosthesis".ti OR "knee implantation".ti OR "knee implant".ti OR "knee implants".ti OR "knee prosthesis".ti OR "knee joint replacement".ti OR "knee joint arthroplasty".ti OR "Knee Replacement Arthroplasties".ti OR "Total Knee Replacements".ti OR "Knee Prostheses".ti OR "Knee endoprosthesis".ti OR "Knee endoprostheses".ti OR "Knee joint arthroplasty".ti OR "Knee joint arthroplasties".ti OR "knee joint prosthesis".ti OR "knee joint prostheses".ti OR "knee prosthetic".ti OR "Knee endoprosthetic".ti OR "knee joint prosthetic".ti 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Web of Science	**TI=(**(Knee Arthroplasty OR Knee Prosthesis OR "knee replacement arthroplasty" OR "total knee arthroplasty" OR "total knee" OR tka OR "tkr" OR "total knee replacement" OR "knee prosthesis" OR "knee implantation" OR "knee implant" OR "knee implants" OR "knee prosthesis" OR "knee joint replacement" OR "knee joint arthroplasty" OR "Knee Replacement Arthroplasties" OR "Total Knee Replacements" OR "Knee Prostheses" OR "Knee endoprosthesis" OR "Knee endoprostheses" OR "Knee joint arthroplasty" OR "Knee joint arthroplasties" OR "knee joint prosthesis" OR "knee joint prostheses" OR "knee prosthetic" OR "Knee endoprosthetic" OR "knee joint prosthetic" OR "Knee joint endoprosthetic" OR "knee prosthetics" OR "Knee endoprosthetics" OR "knee joint prosthetics" OR "Knee joint endoprosthetics" OR "Knee replacement" OR "Knee replacements" OR "knee arthroplasty" OR "knee arthroplasties" **OR** Hip Arthroplasty OR Hip Prosthesis OR "hip replacement arthroplasty" OR "total hip arthroplasty" OR "total hip" OR tha OR "thr" OR "total hip replacement" OR "hip prosthesis" OR "hip implantation" OR "hip implant" OR "hip implants" OR "hip prosthesis" OR "hip joint replacement" OR "hip joint arthroplasty" OR "Hip Replacement Arthroplasties" OR "Total Hip Replacements" OR "Hip Prostheses" OR "Hip endoprosthesis" OR "Hip endoprostheses" OR "Hip joint arthroplasty" OR "Hip joint arthroplasties" OR "hip joint prosthesis" OR "hip joint prostheses" OR "hip prosthetic" OR "Hip endoprosthetic" OR "hip joint prosthetic" OR "Hip joint endoprosthetic" OR "hip prosthetics" OR "Hip endoprosthetics" OR "hip joint prosthetics" OR "Hip joint endoprosthetics" OR "Hip replacement" OR "Hip replacements" OR "hip arthroplasty" OR "hip arthroplasties") AND ("decision to operate" OR "decision to treat" OR "treatment decision" OR "operation decision" OR "surgery decision" OR "intervention decision" OR "treatment decisions" OR "operation decisions" OR "surgery decisions" OR "intervention 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COCHRANE Library	title	123

((Knee Arthroplasty OR Knee Prosthesis OR "knee replacement arthroplasty" OR "total knee arthroplasty" OR "total knee" OR tka OR "tkr" OR "total knee replacement" OR "knee prosthesis" OR "knee implantation" OR "knee implant" OR "knee implants" OR "knee prosthesis" OR "knee joint replacement" OR "knee joint arthroplasty" OR "Knee Replacement Arthroplasties" OR "Total Knee Replacements" OR "Knee Prostheses" OR "Knee endoprosthesis" OR "Knee endoprostheses" OR "Knee joint arthroplasty" OR "Knee joint arthroplasties" OR "knee joint prosthesis" OR "knee joint prostheses" OR "knee prosthetic" OR "Knee endoprosthetic" OR "knee joint prosthetic" OR "Knee joint endoprosthetic" OR "knee prosthetics" OR "Knee endoprosthetics" OR "knee joint prosthetics" OR "Knee joint endoprosthetics" OR "Knee replacement" OR "Knee replacements" OR "knee arthroplasty" OR "knee arthroplasties" **OR** Hip Arthroplasty OR Hip Prosthesis OR "hip replacement arthroplasty" OR "total hip arthroplasty" OR "total hip" OR tha OR "thr" OR "total hip replacement" OR "hip prosthesis" OR "hip implantation" OR "hip implant" OR "hip implants" OR "hip prosthesis" OR "hip joint replacement" OR "hip joint arthroplasty" OR "Hip Replacement Arthroplasties" OR "Total Hip Replacements" OR "Hip Prostheses" OR "Hip endoprosthesis" OR "Hip endoprostheses" OR "Hip joint arthroplasty" OR "Hip joint arthroplasties" OR "hip joint prosthesis" OR "hip joint prostheses" OR "hip prosthetic" OR "Hip endoprosthetic" OR "hip joint prosthetic" OR "Hip joint endoprosthetic" OR "hip prosthetics" OR "Hip endoprosthetics" OR "hip joint prosthetics" OR "Hip joint endoprosthetics" OR "Hip replacement" OR "Hip replacements" OR "hip arthroplasty" OR "hip arthroplasties") AND ("decision to operate" OR "decision to treat" OR "treatment decision" OR "operation decision" OR "surgery decision" OR "intervention decision" OR "treatment decisions" OR "operation decisions" OR "surgery decisions" OR "intervention decisions" OR Patient Selection OR "patient selection" OR "Patient Selections" OR "Selection for Treatment" OR "Selection for Treatments" OR "Selection of Subjects" OR "Subjects Selection" OR "Subjects Selections" OR "Selection Criteria" OR "priority tool" OR "priority tools" OR "priority criteria" OR "priority criterium" OR "indication set" OR "priority" OR "priorities" OR priorit* OR "indication" OR "indications" OR * treatment indication OR "**appropriateness criteria" OR ("evidence" AND ("indication" OR "indications")) OR ((Checklist OR "checklist" OR "checklists") AND ("indication" OR "indications")) OR "guideline" OR "guidelines"))**

OR

title, abstract, keyword

((Osteoarthritis OR "Osteoarthritis" OR "Osteoarthritides" OR "Osteoarthrosis" OR "Osteoarthroses" OR "Degenerative Arthritides" OR "Degenerative Arthritis" OR OA) AND (Knee Arthroplasty OR Knee Prosthesis OR "knee replacement arthroplasty" OR "total knee arthroplasty" OR "total knee" OR tka OR "tkr" OR "total knee replacement" OR "knee prosthesis" OR "knee implantation" OR "knee implant" OR "knee implants" OR "knee prosthesis" OR "knee joint replacement" OR "knee joint arthroplasty" OR "Knee Replacement Arthroplasties" OR "Total Knee Replacements" OR "Knee Prostheses" OR "Knee endoprosthesis" OR "Knee endoprostheses" OR "Knee joint arthroplasty" OR "Knee joint arthroplasties" OR "knee joint prosthesis" OR "knee joint prostheses" OR "knee prosthetic" OR "Knee endoprosthetic" OR "knee joint prosthetic" OR "Knee joint endoprosthetic" OR "knee prosthetics" OR "Knee endoprosthetics" OR "knee joint prosthetics" OR "Knee joint endoprosthetics" OR "Knee replacement" OR "Knee replacements" OR "knee arthroplasty" OR "knee arthroplasties" **OR** Hip Arthroplasty OR Hip Prosthesis OR "hip replacement arthroplasty" OR "total hip arthroplasty" OR "total hip" OR tha OR "thr" OR "total hip replacement" OR "hip prosthesis" OR "hip implantation" OR "hip implant" OR "hip implants" OR "hip prosthesis" OR "hip joint replacement" OR "hip joint arthroplasty" OR "Hip Replacement Arthroplasties" OR "Total Hip Replacements" OR "Hip Prostheses" OR "Hip endoprosthesis" OR "Hip endoprostheses" OR "Hip joint arthroplasty" OR "Hip joint arthroplasties" OR "hip joint prosthesis" OR "hip joint prostheses" OR "hip prosthetic" OR "Hip endoprosthetic" OR "hip joint prosthetic" OR "Hip joint endoprosthetic" OR "hip prosthetics" OR "Hip endoprosthetics" OR "hip joint prosthetics" OR "Hip joint endoprosthetics" OR "Hip replacement" OR "Hip replacements" OR "hip arthroplasty" OR "hip arthroplasties") AND ("decision to operate" OR "decision to treat" OR "treatment decision" OR "operation decision" OR "surgery decision" OR "intervention decision" OR "treatment decisions" OR "operation decisions" OR "surgery decisions" OR "intervention decisions" OR Patient Selection OR "patient selection" OR "Patient Selections" OR "Selection for Treatment" OR "Selection for Treatments" OR "Selection of Subjects" OR "Subjects Selection" OR "Subjects Selections" OR "Selection Criteria" OR "priority tool" OR "priority tools" OR "priority criteria" OR "priority criterium" OR "indication set" OR "priority" OR "priorities" OR priorit* OR "indication" OR "indications" OR treatment indication OR "**appropriateness criteria" OR ("evidence" AND ("indication" OR "indications")) OR ((Checklist OR "checklist" OR "checklists") AND ("indication" OR "indications")) OR "guideline" OR "guidelines"))**

CENTRAL	title	7

(Knee Arthroplasty OR Knee Prosthesis OR "knee replacement arthroplasty" OR "total knee arthroplasty" OR "total knee" OR tka OR "tkr" OR "total knee replacement" OR "knee prosthesis" OR "knee implantation" OR "knee implant" OR "knee implants" OR "knee prosthesis" OR "knee joint replacement" OR "knee joint arthroplasty" OR "Knee Replacement Arthroplasties" OR "Total Knee Replacements" OR "Knee Prostheses" OR "Knee endoprosthesis" OR "Knee endoprostheses" OR "Knee joint arthroplasty" OR "Knee joint arthroplasties" OR "knee joint prosthesis" OR "knee joint prostheses" OR "knee prosthetic" OR "Knee endoprosthetic" OR "knee joint prosthetic" OR "Knee joint endoprosthetic" OR "knee prosthetics" OR "Knee endoprosthetics" OR "knee joint prosthetics" OR "Knee joint endoprosthetics" OR "Knee replacement" OR "Knee replacements" OR "knee arthroplasty" OR "knee arthroplasties" **OR** Hip Arthroplasty OR Hip Prosthesis OR "hip replacement arthroplasty" OR "total hip arthroplasty" OR "total hip" OR tha OR "thr" OR "total hip replacement" OR "hip prosthesis" OR "hip implantation" OR "hip implant" OR "hip implants" OR "hip prosthesis" OR "hip joint replacement" OR "hip joint arthroplasty" OR "Hip Replacement Arthroplasties" OR "Total Hip Replacements" OR "Hip Prostheses" OR "Hip endoprosthesis" OR "Hip endoprostheses" OR "Hip joint arthroplasty" OR "Hip joint arthroplasties" OR "hip joint prosthesis" OR "hip joint prostheses" OR "hip prosthetic" OR "Hip endoprosthetic" OR "hip joint prosthetic" OR "Hip joint endoprosthetic" OR "hip prosthetics" OR "Hip endoprosthetics" OR "hip joint prosthetics" OR "Hip joint endoprosthetics" OR "Hip replacement" OR "Hip replacements" OR "hip arthroplasty" OR "hip arthroplasties") AND ("decision to operate" OR "decision to treat" OR "treatment decision" OR "operation decision" OR "surgery decision" OR "intervention decision" OR "treatment decisions" OR "operation decisions" OR "surgery decisions" OR "intervention decisions" OR Patient Selection OR "patient selection" OR "Patient Selections" OR "Selection for Treatment" OR "Selection for Treatments" OR "Selection of Subjects" OR "Subjects Selection" OR "Subjects Selections" OR "Selection Criteria" OR "priority tool" OR "priority tools" OR "priority criteria" OR "priority criterium" OR "indication set" OR "priority" OR "priorities" OR priorit* OR "indication" OR "indications" OR treatment indication OR "**appropriateness criteria" OR ("evidence" AND ("indication" OR "indications")) OR ((Checklist OR "checklist" OR "checklists") AND ("indication" OR "indications")) OR "guideline" OR "guidelines")**

OR

title, abstract, keyword

((Osteoarthritis OR "Osteoarthritis" OR "Osteoarthritides" OR "Osteoarthrosis" OR "Osteoarthroses" OR "Degenerative Arthritides" OR "Degenerative Arthritis" OR OA) AND (Knee Arthroplasty OR Knee Prosthesis OR "knee replacement arthroplasty" OR "total knee arthroplasty" OR "total knee" OR tka OR "tkr" OR "total knee replacement" OR "knee prosthesis" OR "knee implantation" OR "knee implant" OR "knee implants" OR "knee prosthesis" OR "knee joint replacement" OR "knee joint arthroplasty" OR "Knee Replacement Arthroplasties" OR "Total Knee Replacements" OR "Knee Prostheses" OR "Knee endoprosthesis" OR "Knee endoprostheses" OR "Knee joint arthroplasty" OR "Knee joint arthroplasties" OR "knee joint prosthesis" OR "knee joint prostheses" OR "knee prosthetic" OR "Knee endoprosthetic" OR "knee joint prosthetic" OR "Knee joint endoprosthetic" OR "knee prosthetics" OR "Knee endoprosthetics" OR "knee joint prosthetics" OR "Knee joint endoprosthetics" OR "Knee replacement" OR "Knee replacements" OR "knee arthroplasty" OR "knee arthroplasties" **OR** Hip Arthroplasty OR Hip Prosthesis OR "hip replacement arthroplasty" OR "total hip arthroplasty" OR "total hip" OR tha OR "thr" OR "total hip replacement" OR "hip prosthesis" OR "hip implantation" OR "hip implant" OR "hip implants" OR "hip prosthesis" OR "hip joint replacement" OR "hip joint arthroplasty" OR "Hip Replacement Arthroplasties" OR "Total Hip Replacements" OR "Hip Prostheses" OR "Hip endoprosthesis" OR "Hip endoprostheses" OR "Hip joint arthroplasty" OR "Hip joint arthroplasties" OR "hip joint prosthesis" OR "hip joint prostheses" OR "hip prosthetic" OR "Hip endoprosthetic" OR "hip joint prosthetic" OR "Hip joint endoprosthetic" OR "hip prosthetics" OR "Hip endoprosthetics" OR "hip joint prosthetics" OR "Hip joint endoprosthetics" OR "Hip replacement" OR "Hip replacements" OR "hip arthroplasty" OR "hip arthroplasties") AND ("decision to operate" OR "decision to treat" OR "treatment decision" OR "operation decision" OR "surgery decision" OR "intervention decision" OR "treatment decisions" OR "operation decisions" OR "surgery decisions" OR "intervention decisions" OR Patient Selection OR "patient selection" OR "Patient Selections" OR "Selection for Treatment" OR "Selection for Treatments" OR "Selection of Subjects" OR "Subjects Selection" OR "Subjects Selections" OR "Selection Criteria" OR "priority tool" OR "priority tools" OR "priority criteria" OR "priority criterium" OR "indication set" OR "priority" OR "priorities" OR priorit* OR "indication" OR "indications" OR treatment indication OR "**appropriateness criteria" OR ("evidence" AND ("indication" OR "indications")) OR ((Checklist OR "checklist" OR "checklists") AND ("indication" OR "indications")) OR "guideline" OR "guidelines"))**

CINAHL	title	51
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Total		3065

8

Chapter 9

Preoperative predictors for outcomes after total hip replacement in patients with osteoarthritis: a systematic review

Stefanie N. Hofstede, Maaike G.J. Gademan, Thea P.M. Vliet Vlieland, Rob G.H.H. Nelissen, Perla J. Marang-van de Mheen

BMC Musculoskeletal Disorders. 2016; 14: 212

ABSTRACT

Background

This systematic review examines which patient related factors influence functional and clinical outcomes after total hip arthroplasty (THA) in patients with hip osteoarthritis (OA).

Methods

We performed a systematic review according to the PRISMA guidelines. We searched databases and trial registries for prospective studies including OA patients who underwent primary THA. Studies with preoperative measurements on predictors, with at least 1 year follow-up were included. Risk of bias and confounding was assessed for two domains: follow-up rate and looking at independent effects.

Results

Thirty-five studies were included (138,039 patients). Only nine studies (29 %) had low risk of bias for all domains thus suggesting an overall low quality of evidence. Studies were heterogeneous in the predictors tested and in the observed directions of the associations. Overall, preoperative function (13 studies (37 %), 2 with low risk of bias) and radiological OA (6 studies (17 %), 1 with low risk of bias) were predictors with the most consistent findings. Worse preoperative function and more severe radiological OA were associated with larger postoperative improvement. However, these patients never reached the level of postoperative functioning as patients with better preoperative function or less severe radiological OA. For age, gender, comorbidity, pain and quality of life the results of studies were conflicting. For BMI, some studies (n = 5, 2 with low risk of bias) found worse outcomes for patients with higher BMI. However, substantial improvement was still achieved regardless of their BMI.

Conclusion

There is not enough evidence to draw succinct conclusions on preoperative predictors for postoperative outcome in THA, as results of studies are conflicting and the methodological quality is low. Results suggest to focus on preoperative function and radiological osteoarthritis to decide when THA will be most effective. The present mapping of current evidence on the relationship between patient related factors and outcomes provides better information compared to individual studies and may help to set patient expectations before surgery. In addition, these findings may contribute to discussions on how to achieve the best possible postoperative outcome for specific patient groups.

BACKGROUND

Total Hip Arthroplasty (THA) is an effective treatment for most individuals who suffer from pain and loss of function due to end stage symptomatic hip osteoarthritis (OA). Parallel to the rising prevalence of hip OA, surgery rates are rising as well [1-4].

THA should not be given too early since the longevity of a prosthesis is limited [5] and outcomes after revision THA are generally worse compared to primary THA. Furthermore, about 10-15% of the patients is not satisfied after primary THA [6,7]. Therefore, defined criteria to assess when patients will benefit most from surgery are clearly warranted, as it may sometimes be better to first optimize the patient's preoperative condition. Current practice suggests that disease severity and timing of surgery vary largely among centers and countries [8,9]. The development of defined criteria to assess which patients will benefit most from surgery would preferably be based on the best available evidence. Previous reviews on which predictors determine outcome after THA were conducted some time ago or mainly focused on patient characteristics such as age, gender, socio economic status (SES)/ education and BMI [10,11]. Other patient related factors, such as preoperative function, pain and quality of life, were not included. Providing such an overview may contribute to discussions on how to achieve the best possible postoperative outcome for specific patient groups.

Therefore, aim of this study is to conduct a systematic review examining which preoperative patient related factors influence functional and clinical outcomes after THA in OA patients.

METHODS

We performed a systematic review according to the PRISMA guidelines. This systematic review was registered in Prospero, registration number RD42014009977.

Search strategy

A search strategy was composed together with a trained librarian (see Additional file 1). On PubMed, MEDLINE (Ovid version), EMBASE (Ovid version), Web of Science, The Cochrane Library, CENTRAL, and CINAHL articles were searched published up to August 8, 2014. The search strategy consisted of the AND combination of five concepts: osteoarthritis, hip replacement, predictive determinants, postoperative, and functional and clinical outcomes. All relevant keyword variations were used, not only those in the controlled vocabularies of the various databases, but the free text word variations of these concepts as well.

The search strategy was optimized for all databases, taking into account differences of the controlled vocabularies as well as database-specific technical variations (e.g., the use of quotation marks). Animal-only studies were excluded. Additional strategies were composed for PubMed to find (1) studies not focusing on OA, (2) studies on patient satisfaction or activities of daily living, and (3) studies with the word after instead of postoperative.

Inclusion of articles

We included prospective studies among primary hip OA patients who underwent primary THA, with preoperative and postoperative measurements on functional or clinical outcomes and a follow-up of at least one year. If studies included both THA and TKA patients, we only extracted the THA data. Thus the results after THA had to be described separately. We included predictors that could be determined using standard tests or questions used in clinical practice (i.e. patient characteristics, radiological images, questionnaires or physical exams). These variables could be the focus of the study, or included as confounder or covariate.

Articles were excluded with metal-on-metal prostheses, osteotomies before THA, only including bilateral surgeries, more than 5% of the patients had other diagnoses than primary OA (i.e. secondary OA or rheumatoid arthritis) or different diagnoses could not be stratified, or more than 5% of the population had received a revision and could not be stratified from primary THA. Furthermore, we excluded articles when results for hip and knee OA could not be stratified, data were collected retrospectively (i.e. preoperative status assessed after surgery) or if no full text was available online, via our library or after mailing the authors. In addition, studies were excluded when baseline scores were not reported, which is important to interpret the postoperative outcomes. Only for adverse outcomes such as loosening or complications, this was not applicable therefore these studies were included.

Selection of studies

Articles were selected in two steps. First, two researchers (SH and MG) independently excluded articles based on the title and/or the abstract. Second, one researcher (SH) excluded articles based on the full text. A second researcher (MG) checked whether selected articles met the inclusion criteria.

Assessment of risk of bias in included studies

Risk of bias was assessed by one author (SH) and checked by a second author (MG). It is unclear from the literature which elements causing risk of bias in observational studies should be assessed. Therefore, we tailored the risk of bias assessment to our research question, focusing on study design features that could potentially bias the association between exposure and outcome. Risk of bias was thus assessed for the following domains:

Follow-up rate: less than 20% loss to follow-up at 1 year was considered to represent low risk of bias [12,13]. For longer follow-up, we considered 10% loss to follow-up extra for each additional year as low risk of bias. Since reasons for loss to follow-up/ non-responders were often not reported, we counted all loss to follow-up regardless of the reason.

Looking at independent effects: e.g. the use of a multivariable model in etiological studies or a prediction model. For example when adjustments in analyses were made for confounding factors (at least one), it was considered as low risk of bias.

When no consensus between the two review authors was reached, a third review author (PM) was consulted for the final decision.

Data extraction

Data were extracted using a pre-defined data extraction form. Articles meeting the criteria were closely examined and data were extracted by one author (SH) and checked by a second author (MG). When no consensus could be reached, a third review author (PM) was consulted. We extracted the following information: sample size, gender, age, follow-up time, follow-up rate and adjustments in statistical analyses. Furthermore, we reported each predictor for all outcomes per study and their direction.

The following predictors were included:

- Patient characteristics: age, gender, SES/education, BMI
- Disease characteristics: radiological OA severity, comorbidities
- Patient expectations
- Pain
- Function
- Health related quality of life
- Mental well-being

All reported outcomes at different follow-up moments (≥1 year) for the above described predicting factors were extracted as reported in the included study. We examined both the change in outcome scores (postoperative score - preoperative score) and the level of the postoperative outcome, as patients with lower baseline scores are more likely to improve, but may not reach the same postoperative levels as patients with higher baseline scores.

Given the heterogeneity of predictors and outcomes, pooling of data using meta-analysis was not possible so that only descriptive analyses were conducted.

RESULTS

Search

The bibliographic databases yielded a total of 2,595 references and 46 additional studies in trial registers (figure 1). Full-text papers of 208 references were assessed for eligibility. We excluded 170 articles, mainly because more than 5% of the population had a diagnosis other than primary OA or a revision surgery. Thirty-five studies fulfilled our inclusion criteria.

Risk of bias

Table 1 shows that 14 studies (40%) had low risk of bias for the follow-up domain. Eight studies [14-21] had a high risk of bias on this domain. One study [22] had a loss to follow-up of >20% in the first and third year, but a low loss to follow-up at 5 and 7 years, so that risk of bias was unclear. Twelve studies had unclear risk of bias as the loss to follow-up was not described. Four of these studies were registry studies [23-26] and one study [27] was based on Medicare claims.

Most studies (n=28) adjusted for confounders or used a prediction model (low risk of bias), but differed from stratifying for one variable to multivariable adjustment (table 1). Seven studies [26,28-33] did not adjust for other factors in the analyses (high risk of bias).

Only nine studies (29%) had low risk of bias across both domains: Cushnaghan [34], Davis [35], Gandhi [36], Gordon [37,38], Fortin [39], Judge [40], McHugh [41], and

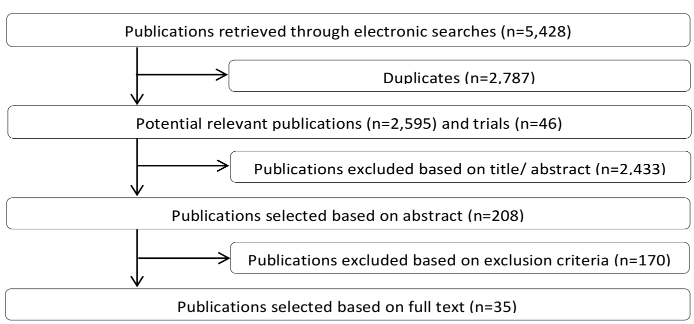

Figure 1. Flow diagram of included and excluded publications

Table 1. Risk of bias and confounding

First author, year	Follow-up (years)	Follow-up (% missing)	Looking at independent effects
Bethge, 2010 [14]	1	28.9	Age, gender and self-efficacy expectations
Clement, 2011 [43]	1	ND	Age
Clement, 2011 [47]	1	ND	Age, SF-12 scores and length of stay
Cushnaghan, 2007 [34]	Mean 8.8	48 cases 53 controls	Prediction model
Davis, 2011 [35]	5	HHS: 28 SF-36: 32	Age, gender, operating consultant, and a diagnosis of cancer, atherosclerotic disease, cardiac disease, diabetes mellitus, osteoporosis and phlebitis
Duivenvoorden, 2013 [15]	1	31	Age, gender, time spent on waiting list and unbalanced characteristics between study population and patients lost to follow-up
Gandhi, 2010 [36]	Mean 3.3	14 at 1 year follow-up	Age, gender, BMI, SF-36 Mental Health (MH) scores, method of fixation (cemented vs uncemented), and comorbidity
Gordon, 2014 [37]	1	8	Age, gender, Charnley classification, previous contralateral THR, and preoperative pain VAS
Gordon, 2014 [38]	1	8	Gender, previous contralateral hip surgery, pain, and Charnley classification
Greene, 2014 [16]	1	66.7	Bayesian model averaging with age, gender, Charnley classification, presence of comorbidities, whether the included hip was the first or second in the time interval, marital status, and education level
Fortin, 2002 [39]	2	25.7[a]	Age, gender, education, and comorbidity
Haverkamp, 2013 [28]	Mean 2.3	18.6[a]	No
Heiberg, 2013 [17]	1	27.3	Prediction model
Ieiri, 2013 [49]	1 and 3	ND	Canonical correlation analysis
Johansson, 2010 [29]	2	ND	No
Judge, 2014 [19]	1	30.8	Age, sex, SF-36 mental health, comorbidities, fixed flexion, analgesic use, college education, OA in other joints, expectation of less pain, radiological K&L grade, ASA grade, years of hip pain
Judge, 2013 [40]	each year up to 5	20 at 1 year, 30 at 5 year	Multivariable model
Judge, 2012 [48]	Mean 8	61.3[b]	Prediction model
Judge, 2011 [18]	1	31.6	Age, sex, school education, ASA grade, K&L grade, BMI, medication use
Katz, 2012 [27]	12	ND	Patient age, sex, race, Medicaid eligibility, comorbidity and hospital and surgeon annual THA volume
Kennedy, 2011 [44]	Up to 1.3	ND	Age, gender, body mass index
Keurentjes, 2013 [20]	1.5-6	54.1[a]	Age, sex, Charnley Comorbidity Classification and BMI
McHugh, 2013 [41]	1	11.7	Multivariable model

9

First author, year	Follow-up (years)	Follow-up (% missing)	Looking at independent effects
Meding, 2000 [22]	Mean 2.7	11.4 at 1 year, 37.2 at 3 years, 64.8 at 5 years and 84.3 at 7 years	Age and gender
Nikolajsen, 2006 [30]	1-1.5	6.4	No
Nilsdotter, 2003 [42]	Mean 3.6	9.6	Multivariable model
Nilsdotter, 2002 [32]	1	16.2	No
Nilsdotter, 2001 [31]	1	11.9	No
Röder, 2007 [24]	Mean 4.3	ND (registry study)	Gender, age, and follow-up year
Rolfson, 2009 [23]	1	ND (registry study)	Age, gender and comorbidity
Sadr Azodi, 2008 [25]	3	ND (registry study)	Age at the time of surgery, calendar period, and fixation principle
Sarasqueta, 2012 [21]	1	29	Prediction model
Stickles, 2001 [26]	1	ND (registry study)	No
Street, 2005 [33]	1 and 2	ND	No
Tanaka, 2010 [45]	1	ND	Age, sex, changes in the LLD, vertical ATD, femoral offset, and the horizontal and vertical position of the center of the femoral head, stage of hip OA (advanced or terminal); HHS, and the duration of OA

SF-12: 12-item Short Form Health Survey; HHS: Harris Hip Score; SF-36: 36-item Short Form Health Survey; BMI: Body Mass Index; MH: Mental Health; THR: Total Hip Replacement; VAS: Visual Analogue Scale; OA: OsteoArthritis; K&L grade: Kellgren-Lawrence; ASA: American Society of Anesthesiologists; LLD: Leg Length Discrepancy; ATD: Articulotrochanteric Distance
ND: not described or partly described
[a]For patients with THA and TKA, not separately described
[b]At six months

Nilsdotter [42], to which we will refer as low risk of bias studies. Thus most studies had unclear or high risk of bias for least one domain, to which we will refer as high risk of bias studies, suggesting overall low quality of evidence.

Study characteristics

The 35 included studies were all observational cohort studies. Table 2 shows that studies differ considerably in which factors predict outcomes after THA, given that only few significant associations were found per combination of a prognostic factor and outcome. Many studies assessed the effect of a prognostic factor on more than one outcome, as such it was possible to find a significant association for one outcome while no association with another outcome was found. As a result, a study may be described below both as a significant and a non-significant association. Most studies

Table 2. Number of reported outcomes for each prognostic factor

Prognostic factors	SF-36	EQ-5D	SF-12	WOMAC	OHS	HHS	Pain	Satisfaction	Walking distance	Revision	Dislocation	Other outcomes[a]
Age	5	1	1	3	2	-	-	1	1	1	-	Complications
Gender	3	3	-	-	-	-	1	2	1	1	-	
SES/education	-	1	-	1	1	-	1	1	-	-	-	
Comorbidities	4	3	-	1	1	-	1	1	-	-	2	
BMI	2	-	-	-	2	1	-	-	-	-	-	Superficial infection Ascending and descending stairs
Radiological OA severity	3	-	-	1	-	-	1	1	-	-	-	Gait improvement
Patient expectations	-	-	-	1	-	1	-	-	-	-	-	
Pain	3	-	-	4	-	1	1	-	-	-	-	
Function	3	-	-	6	1	1	-	-	4	-	-	Assistance from another person for ADL, flexion
Health related quality of life	4	3	1	2	1	-	1	1	-	-	-	
Mental well-being	2	1	-	-	1	-	1	2	-	-	-	HOOS

SF-36: 36-item short form health survey; EQ-5D: EuroQol 5 Dimensions; SF-12: 12-item short form health survey; WOMAC: Western Ontario & McMaster Universities Osteoarthritis Index; OHS: Oxford Hip Score; HHS: Harris Hip Score; HOOS: Hip disability and Osteoarthritis Outcome Score

[a]Reported in only one study

assessed outcomes through self-reported questionnaires and if the Harris Hip Score was used [29,33] it was often not described who performed the physical examination. Additional file 2 shows the number of patients in each included study, the gender and age distribution, follow-up time, and significant associations observed. A total of 138,039 patients were included with average age from 60-84 years. Four studies used registry data [23-26] and one study used Medicare claims data [27]. The follow-up time varied from 1 year to a mean of 12 years [27].

Prognostic factors

Age

Eleven studies (31%) reported that the outcome was significantly influenced by age (additional file 2), of which five studies had low risk of bias. Two of these low risk of bias studies found a nonlinear relationship with age. Gordon et al. [38] found that outcomes were fairly unaffected by age until patients were in their late sixties, after which age had a negative effect on the EQ-5D. Judge et al. [40] found a small, not clinically relevant, effect of patients aged 50-60 reaching better postoperative Oxford Hip Scores (OHS). The three other studies found that older patients had smaller improvements or worse outcomes, but most differences were small [34,36,42]. Furthermore, the study of Cushnaghan et al. [34] was one of the few studies with a longer follow-up (~8 years) and a control group. Although a higher age predicted smaller changes in the SF-36 (Physical Function (PF)) in this study, this difference was also found in the control group suggesting that the effect is explained by ageing. Most of the high risk of bias studies also found that older patients had smaller improvements or worse outcomes, but that most differences were small [17,32,43-45]. Furthermore, Clement et al. [43] found that patients aged ≤80 years had a greater, but not clinically relevant improvement on the SF-12. Despite smaller improvements for older patients (>80 years), they were more satisfied after THA. Another study found that older patients (>75 years) had a higher revision rate than younger patients (65-75 years) [27]. Eight studies tested the association between age and outcomes such as SF-12 MCS, OHS (pain), post-operative complications, walking distance, LEFS, SF-36, WOMAC, EQ-5D and gait improvement, but did not find significant effects [16,18,21,32,41,43-45]. One of these studies had low risk of bias [41].

Gender

Ten studies (29%) reported associations between gender and outcomes in different directions. Three studies had low risk of bias. Cushnaghan et al. [34] reported that females had smaller improvements on the SF-36 (PF) scale. However, this was found in both cases and controls regardless of arthroplasty. Gandhi et al. [36] on the other hand, reported worse outcomes for males on the SF-36 (PF) and Gordon et al. [37] reported higher EQ-5D scores for males. Of the other high risk of bias studies, Greene et al. and Rolfson et al. [16,23] found women were less satisfied. Heiberg et al. [17] found that males reached better scores of walking distance (on the 6-minute walk test (6MWT)) (60.3 meters more than women), which is a clinically relevant difference [46]. However, they did not use a control group and it may be that healthy male controls also reach better scores of walking distance compared to females. Furthermore, Katz et al. [27] found higher rates of revision in men than in women. Many studies investigated the association but did not find any significant associations of gender and various outcomes such as WOMAC, SF-36, pain, EQ VAS and gait improvement [16,18,21,23,31,32,36,37,41,42,45]. Four of these studies had low risk of bias [36,37,41,42].

SES/ education

Only three studies (9%) reported an association between socioeconomic status or education and outcomes. None of these studies had low risk of bias. The studies reported more favorable outcomes following surgery in patients with a higher education [16,18] or SES [47]. Sarasqueta et al. [21] did not find an association between education level and WOMAC.

Comorbidities

Comorbidities were associated with worse outcomes in 7 studies (20%), of which four studies had low risk of bias [34,36,37,40]. These low risk of bias studies found that patients with comorbidities had worse outcomes. However, the size of the effects varied from having a small effect for patients with comorbidities on the OHS [40] to a large effect for patients with diabetes on the SF-36 [34]. Gandhi et al. [36] found that patients with comorbidities scored worse on the WOMAC and the SF-36. Another low risk of bias study found that a higher Charnley comorbidity class was associated with worse outcomes on the EQ-5D [37]. The same results were also found in two high risk of bias studies [16,23]. In addition, Judge et al. [48] found an association between number of painful joint sites and worse outcomes on the SF-36. However, six studies did not find significant associations between different comorbidities and outcomes such as SF-36, revision, chronic hip pain and WOMAC [21,27,30,34,41,48]. Two of these studies had low risk of bias [34,41].

Body Mass Index

Five studies (14%) reported an association between BMI and postoperative outcomes. Two of these studies had low risk of bias [35,40] where the study of Davis et al. [35] reported the largest effect with morbidly obese patients (BMI ≥35 kg/m^2) having a 4.42 times higher dislocation rate than those with BMI <25 kg/m^2. The authors also found associations between higher BMI and more superficial infections, poorer HHS and lower SF-36 postoperative scores [35]. Judge et al. [40] reported that patients with higher BMI had smaller absolute improvement on the OHS. However, regardless of their BMI, patients achieved substantial improvement in the OHS which outweighs the small absolute difference in attained OHS. The same was found in a high risk of bias study [19]. Other high risk of bias studies found that overweight and obesity were associated with a 3.7 fold increased risk of implant dislocation [25], and with lower SF-36 postoperative scores [49]. Furthermore, eight studies did not find an association with BMI and different outcomes, such as 6MWT, LEFS, WOMAC, SF-36 and chronic hip pain [21,30,34,36,41,42,44,48]. Four of these studies had low risk of bias [34,36,41,42].

Radiological OA severity

Six studies (17%) reported significant associations between radiological OA severity and outcomes. Only one study had low risk of bias [34]. This study found that changes in physical functioning were markedly better in those with worse preoperative radiological OA grades. This was also found in two other high risk of bias studies [20,48]. However, these studies focused on changes and not on final outcomes. Patients with lower baseline scores are more likely to improve, but the question is whether they reach the same postoperative levels. Another high risk of bias study found that patients with less severe radiological change had better postoperative outcomes [18]. Furthermore, Tanaka et al. [45] showed that a worse radiological OA stage predicted worse gait improvements after surgery. On the other hand, Meding et al. [22] found that patients with a greater degree of preoperative cartilage space loss had less hip pain 1 year after surgery, but no association was found at 3 years after surgery. Nilsdotter et al. [31] found that patients with severe preoperative radiological OA did not differ in postoperative outcome compared with patients with only moderate preoperative radiological OA.

Patient expectations

Two included high risk of bias studies (6%) reported an association between patient expectations and outcomes. Bethge et al. [14] found that patients who expected an enduring illness and did not expect treatment to be helpful had worse postoperative scores on the HHS. Judge et al. [18] showed that patients with high expectations were more likely to improve on the WOMAC scale.

Pain

Six studies (17%) reported an effect of preoperative pain on outcomes. The results were conflicting. Two studies that had low risk of bias showed that pain was related to worse outcomes. Nilsdotter et al. [42] reported that a higher degree of pain predicted worse function at 3.6 years after surgery. McHugh et al. [41] found that worse pain at baseline was negatively associated with improvement. In other high risk of bias studies, patients with the worst pre-operative WOMAC pain scores and SF-36 (Bodily Pain) also performed worse at 1 year postoperatively [32]. On the other hand, Judge et al. [18] found that patients with worse baseline pain had a greater improvement post-surgery on pain.

Haverkamp et al. [28] showed that more preoperative pain at rest or at night resulted in more improvement on the WOMAC and VAS pain scale, but the patients maintained at a lower level at final follow up. Furthermore, Street et al. [33] looked at different pain areas and found that patients with knee pain showed less improvement (on HHS, WOMAC and SF-36) than those with hip or thigh pain. Röder et al. [24] concluded that pain relief was independent of the preoperative pain level. No significant associations were found in 5 other studies with outcomes such as pain, WOMAC and satisfaction [21,24,28,30,39]. One of these studies had low risk of bias [39].

Function

Several questionnaires were used to assess preoperative function and associations were found in 13 studies (37%). Two of these studies had low risk of bias [34,39]. One of these studies showed that patients with a worse preoperative function had a greater improvement [34], which was also found in other studies [18,43,48]. The other low risk of bias study showed that although patients with worse preoperative function had a greater improvement, they did not achieve the postoperative level of those with higher preoperative function [39]. This was also confirmed in other high risk of bias studies [17,24,29,32,40,44]. In most studies these observed differences were regarded as clinically relevant by the authors. Four studies did not find associations between function and various outcomes such as 6MWT, LEFS, ROM, deformity, HHS, SF-36 and gait improvement [17,29,44,45]. None of these studies had low risk of bias.

Health related quality of life

Ten studies (29%) reported significant associations between preoperative health related quality of life (HRQoL) and postoperative outcomes, three of these studies had low risk of bias [34,40,42]. In these low risk of bias studies, better preoperative quality of life was associated with better postoperative scores. Judge et al. [40] reported a small but statistically significant effect on the OHS. Nilsdotter [42] found an association with worse WOMAC scores. Cushnaghan [34] found that patients with a higher SF-36 score had less improvement postoperatively. This was also found in a high risk of bias study by Gordon et al. [38], in which the authors stated that patients with low preoperative scores had the highest gain, although they did not reach the same absolute levels as patients with high preoperative scores. No associations were found in eight studies that tested associations of different HRQoL scores on outcomes, such as WOMAC, pain, satisfaction, EQ-5D, SF-36 and WOMAC [14,16,18,21,23,32,36,42]. Two of these studies had low risk of bias [36,42].

Mental well-being

Five studies (14%) reported that mental well-being, such as anxiety and depressive symptoms, was associated with postoperative outcomes. Two of these studies had low risk of bias and found that worse mental well-being was associated low OHS [40] and less change in SF-36 PCS [41]. The three other high risk of bias studies also found that worse mental well-being was associated with various worse outcomes, such as pain relief, EQ-5D, satisfaction, SF-36 and Hip disability and Osteoarthritis Outcome Score (HOOS) [15,23,49].

DISCUSSION

We know that THA improves clinical and functional outcomes in most patients, and for some more than others. We also know that some patients achieve better postoperative levels of these outcomes than other patients. Hence it is relevant to assess which variables predict the outcome and the extent of improvement after THA. Therefore, we performed a systematic review in which multiple preoperative factors were included. Our review shows that the results on which predictors affect specific outcomes after THA were not consistent, even when looking only at low risk of bias studies. Some predictors were examined in many studies, but the results were conflicting as to whether an association was found (e.g. for age, comorbidity, pain and preoperative health related quality of life). Sometimes the associations could even go in different directions such as for gender. Other predictors were only reported in a few studies, such as SES/ education, patient expectations, and mental well-being. Consistent and clinically relevant effects on postoperative outcomes were only found for preoperative radiological OA severity and preoperative function. However, only one study that assessed radiological OA severity and two studies that assessed preoperative function had low risk of bias. Overall, even though greater improvements were found in patients with more severe radiological OA and lower function baseline scores, these patients did not reach the same postoperative levels in functioning as patients with less severe OA or higher baseline function scores. Moreover, these associations were not found in all studies [17,29,31,44,45] and these studies had a high risk of bias.

Even though BMI is often considered as a relevant predictor of postoperative outcome, our review shows that only 5 out of the 13 studies (2 low risk of bias studies) reported a significant association between BMI and outcomes. Furthermore, complication rates after surgery were higher for patients with a higher BMI, but the patient reported outcomes did not show clinically relevant differences depending on BMI in both low and high risk of bias studies. This may be explained partly because we focused on long term follow-up (≥1 year) and did not investigate short term complications, which more often occur in patients with a higher BMI. Patients achieved substantial improvement in the patient reported outcomes regardless of their BMI [19,35] so that patients should not be withheld from surgery only because of their high BMI. Furthermore, age was a major confounder in many studies, as with increasing age people tend to be for example less physically active and may have comorbidities as part of a physiological aging process which will bias the observed associations between other predictors and outcomes. As a result, some studies may have found smaller improvement in elderly people. However, it may be possible that elderly people are satisfied with a small improvement since their lifestyle may be less active as well. Since only one study compared the outcomes with a control group (without THA), it is difficult to conclude whether differences are based on the "prognostic" factor or that it is just the natural course of life.

An earlier systematic review on preoperative predictors on outcomes in THA [50] included studies until 2005. They concluded that THA resulted in pain relief, improved physical function and enhanced health-related quality of life regardless of patients' characteristics, type of operation or type of prosthesis. The only factor affecting patient outcomes was patients' poor preoperative function. Furthermore, the authors did not perform a risk of bias assessment. Most studies included in the present review were published after 2005 (31 of the 35). Still, we found similar results even when focusing on low risk of bias studies only. Furthermore, two reviews focused on patients' characteristics. Santaguida et al. [11] found in their systematic review that age and gender were associated with risk of revision and mortality after total hip and knee arthroplasty and that age was associated with function. However, they found that all patients benefited from total joint arthroplasty regardless of their age and gender. Waheeb et al. [10] also showed that high variability and conflicting findings were reported on the effect of age, gender and BMI on patient reported outcomes. While these reviews focused on patients' characteristics, our review adds how other factors such as radiological OA severity, preoperative quality of life and preoperative function affect postoperative outcomes.

Studies in our systematic review were heterogeneous and differed in follow-up time (beyond one year), prognostic factors and outcomes, which may explain the conflicting findings and make it difficult to compare studies. It also shows that there is no consensus in which outcomes should be used to assess the impact of surgery and which prognostic factors should be considered. Differences in reported associations may be partly explained by differences in the measurement of these predictors and outcomes (e.g. function is measured with HOOS, WOMAC, OHS etc.). The majority of the included studies assessed outcomes through self-reported questionnaires, which may bias results due to response shift [51]. Patients may report changes over time due to changes in their internal standards, values, or conceptualization of health related quality of life [51] so that it seems as if scores change, but this may not be reflected in objective measurements. In addition, radiological OA severity may vary due to inter- and intra-observer variability. Therefore, more uniformity is needed regarding types of measurements and questionnaires. Furthermore, some studies focused on improvements while other studies focused on the final outcome, so that regression to the mean should be taken into account.

Loss to follow-up was a problem in 18 studies, which is likely to bias the associations found. For instance, patients who are less satisfied or have poor outcome after a THA are less likely to further participate in a study and therefore be lost to follow-up. Hence, satisfied patients with good outcomes may be over-represented [52]. Another problem may be reporting bias. Although some authors described both significant associations and non-significant associations within a study, it is likely that the same associations were investigated by others, but not reported if results were non-significant. Since most studies examining these topics were observational studies, outcome reporting bias is possible as primary outcomes of observational studies are not documented in a trial register as for randomized controlled trials. Furthermore, predictors and outcomes were measured with questionnaires covering multiple domains. For example the SF-36 has eight domains and two summary scores (MCS and PCS). Studies using these questionnaires often did not correct for multiple testing so that it is possible that some associations were in fact chance findings (5%). Also some of the studies included overlapping cohorts, but most often did assess different prognostic variables on different outcomes. A strength of this review is the strict inclusion criteria concerning patients with primary OA who underwent a THA. This made the populations in the selected studies better comparable. This also led to exclusion of many studies that analyzed THA and TKA as one group or included other patient groups. Since THA and TKA are two different surgeries including these studies would have made results even more heterogeneous.

CONCLUSION

In this systematic review we synthesized information about multiple preoperative factors and their relation with postoperative outcomes. However, there is too little high quality evidence to draw firm conclusions on prognostics factors for specific outcomes after THA. Overall, preoperative function and radiological OA were predictors with the most consistent findings in studies with low risk of bias. Worse preoperative function and more severe radiological OA were associated with larger postoperative improvement. However, these patients did not reach the level of postoperative functioning as patients with better preoperative function or less severe radiological OA. The present mapping of current evidence on the relationship between patient related factors and outcomes provides better information compared to individual studies and may help to set patient expectations before surgery.

Implications for future research

Insight into preoperative patient related factors and their relation with postoperative outcomes brings us a step closer to the determination of the optimal timing of THA.

Procedures should not be performed too early, as the lifespan of a prosthesis is limited, and revision arthroplasty is less successful than primary TKA or THA [53]. A surgeon could possibly decide to postpone a THA by first optimizing preoperative function using different non-surgical treatments, if patients would then reach the same or better postoperative functional levels. Therefore, further research is needed to determine optimal preoperative (range of) cutoff points to recommend implant surgery, using a patients' lifetime perspective and our results on which preoperative factors determine the outcomes after THA. In addition, as we focused on patient related factors only, there are also many other factors that might influence the outcome, such as type of prosthesis (e.g. type of stem, head size, cemented/ uncemented), experience of the surgeon or hospital type. These factors should also be taken into account when determining the optimal timing of surgery.

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Additional file 1. Search Strategy

Databases	Search Strategy	Number of references	Number of unique references
PubMed	("Osteoarthritis"[mesh] OR "Osteoarthritis"[tw] OR osteoarthrit*[tw] OR "osteoarthrosis"[tw] OR "osteoarthroses"[tw] OR "Degenerative Arthritis"[all fields] OR "coxarthrosis"[tw] OR "gonarthrosis"[tw] OR "oa"[tw]) AND ((("Arthroplasty"[majr] OR "Joint Prosthesis"[majr] OR "Prostheses and Implants"[majr] OR arthroplast*[tiab] OR joint prosthe*[tiab] OR prosthe*[tiab]) AND ("Hip"[majr] OR "Hip Joint"[majr] OR hip[tiab] OR hips[tiab])) OR (("Arthroplasty, Replacement, Hip"[majr] OR "Hip Prosthesis"[majr] OR "hip prosthesis"[tiab] OR "hip prostheses"[tiab] OR "hip replacement"[tiab] OR "hip replacements"[tiab] OR "hip arthroplasty"[tiab] OR "hip arthroplasties"[tiab] OR (("tha"[tiab] OR "thr"[tiab] OR "thas"[tiab] OR "thrs"[tiab]) AND (hip[tiab] OR hips[tiab] OR replace*[tiab] OR replacement[tiab] OR replacing[tiab] OR replaced[tiab] OR arthroplast*[tiab] OR arthroplasty[tiab] OR arthroplastic[tiab] OR prosthe*[tiab] OR prosthesis[tiab] OR prostheses[tiab] OR prosthetic[tiab] OR endoprosthe*[tiab] OR implant*[tiab] OR implant[tiab] OR implants[tiab] OR implanted[tiab])) OR ((Hip[ti] OR Hips[ti] OR Hip*[ti]) AND (replace*[ti] OR replacement[ti] OR replacing[ti] OR replaced[ti] OR arthroplast*[ti] OR arthroplasty[ti] OR arthroplastic[ti] OR prosthe*[ti] OR prosthesis[ti] OR prostheses[ti] OR prosthetic[ti] OR endoprosthe*[ti] OR implant*[ti] OR implant[ti] OR implants[ti] OR implanted[ti]))))) AND ("determinant"[tw] OR "determinants"[tw] OR "predictor"[tw] OR "predictors"[tw] OR "predictive"[tw] OR "Predictive Value of Tests"[Mesh] OR "factor"[tw] OR "factors"[tw] OR "Epidemiologic Factors"[Mesh] OR "Risk Factors"[mesh] OR "associated"[tw] OR "association"[tw] OR "association"[mesh] OR "cause"[tw] OR "causal"[tw] OR "Causality"[Mesh] OR "causality"[tw] OR "attribute"[tw] OR "attributes"[tw] OR "Psychometrics"[Mesh] OR "psychometrics"[tw] OR psychometric*[tw] OR "prognostic"[tw] OR "Prognosis"[Mesh:noexp] OR "Prognosis"[tw] OR "timing"[tw] OR "Time Factors"[mesh] OR "non-surgical"[tw] OR "nonsurgical"[tw] OR "conservative"[tw]) AND ("postoperative"[tw] OR "post-operative"[tw] OR "Postoperative Period"[Mesh] OR "Postoperative Complications"[Mesh] OR "Postoperative Care"[Mesh] OR "postsurgical"[tw] OR "postsurgery"[tw] OR "post-surgical"[tw] OR "post-surgery"[tw]) AND ("QOL"[tw] OR "Quality of Life"[mesh] OR "quality of life"[tw] OR "Pain"[mesh] OR "pain"[tw] OR "Pain Measurement"[mesh] OR "function"[tw] OR functional[tw] OR "Range of Motion, Articular"[Mesh] OR "Mobility Limitation"[mesh] OR "Recovery of Function"[Mesh] OR "Musculoskeletal Physiological Phenomena"[Mesh] OR "adverse"[tw] OR "adverse effects" [Subheading] OR "Prosthesis Failure"[mesh] OR "mortality"[tw] OR "Mortality"[Mesh] OR "mortality"[Subheading] OR "revision"[tw] OR "Reoperation"[Mesh] OR "Reoperation"[tw] OR "outcome"[tw] OR "outcomes"[tw] OR "Outcome and Process Assessment (Health Care)"[Mesh] OR "clinical"[tw]) NOT ("Animals"[mesh] NOT "Humans"[mesh]) **Three additional strategies for PubMed only:** **1.** (hip[ti] OR hips[ti] OR tha[ti] OR thr[ti] OR (("total joint"[ti]) AND (hip[tw] OR hips[tw]))) AND (((("Arthroplasty"[majr] OR "Joint Prosthesis"[majr] OR "Prostheses and Implants"[majr] OR arthroplast*[ti] OR joint prosthe*[ti] OR prosthe*[ti]) AND ("Hip"[majr] OR "Hip Joint"[majr] OR hip[ti] OR hips[ti])) OR (("Arthroplasty, Replacement, Hip"[majr] OR "Hip Prosthesis"[majr] OR "hip prosthesis"[ti] OR "hip prostheses"[ti] OR "hip replacement"[ti] OR "hip replacements"[ti] OR "hip arthroplasty"[ti] OR "hip arthroplasties"[ti] OR (("tha"[ti] OR "thr"[ti] OR "thas"[ti] OR "thrs"[ti]) AND (hip[ti] OR hips[ti] OR replace*[ti] OR replacement[ti] OR replacing[ti] OR replaced[ti] OR arthroplast*[ti] OR arthroplasty[ti] OR arthroplastic[ti] OR prosthe*[ti] OR prosthesis[ti] OR prostheses[ti] OR prosthetic[ti] OR endoprosthe*[ti] OR implant*[ti] OR implant[ti] OR implants[ti] OR implanted[ti])) OR ((Hip[ti] OR Hips[ti] OR Hip*[ti]) AND (replace*[ti] OR 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Satisfaction"[majr] OR "Activities of Daily Living"[majr]) NOT ("Animals"[mesh] NOT "Humans"[mesh])) **3.** (("Osteoarthritis"[mesh] OR "Osteoarthritis"[tw] OR osteoarthrit*[tw] OR "osteoarthrosis"[tw] OR "osteoarthroses"[tw] OR "Degenerative Arthritis"[all fields] OR "coxarthrosis"[tw] OR "gonarthrosis"[tw] OR "oa"[tw]) AND ((("Arthroplasty"[majr] OR "Joint Prosthesis"[majr] OR "Prostheses and Implants"[majr] OR arthroplast*[tiab] OR joint prosthe*[tiab] OR prosthe*[tiab]) AND ("Hip"[majr] OR "Hip Joint"[majr] OR hip[tiab] OR hips[tiab])) OR (("Arthroplasty, Replacement, Hip"[majr] OR "Hip Prosthesis"[majr] OR "hip prosthesis"[tiab] OR "hip prostheses"[tiab] OR "hip replacement"[tiab] OR "hip replacements"[tiab] OR "hip arthroplasty"[tiab] OR "hip arthroplasties"[tiab] OR (("tha"[tiab] OR "thr"[tiab] OR "thas"[tiab] OR "thrs"[tiab]) AND (hip[tiab] OR hips[tiab] OR replace*[tiab] OR replacement[tiab] OR replacing[tiab] OR replaced[tiab] OR arthroplast*[tiab] OR arthroplasty[tiab] OR arthroplastic[tiab] OR prosthe*[tiab] OR prosthesis[tiab] OR prostheses[tiab] OR prosthetic[tiab] OR endoprosthe*[tiab] OR implant*[tiab] OR implant[tiab] OR implants[tiab] OR implanted[tiab])) OR ((Hip[ti] OR Hips[ti] OR Hip*[ti]) AND (replace*[ti] OR replacement[ti] OR replacing[ti] OR replaced[ti] OR arthroplast*[ti] OR arthroplasty[ti] OR arthroplastic[ti] OR prosthe*[ti] OR prosthesis[ti] OR prostheses[ti] OR prosthetic[ti] OR endoprosthe*[ti] OR implant*[ti] OR implant[ti] OR implants[ti] OR implanted[ti]))))) AND ("determinant"[tw] OR "determinants"[tw] OR "predictor"[tw] OR "predictors"[tw] OR "predictive"[tw] OR "Predictive Value of Tests"[Mesh] OR "factor"[tw] OR "factors"[tw] OR "Epidemiologic Factors"[Mesh] OR "Risk Factors"[mesh] OR "associated"[tw] OR "association"[tw] OR "association"[mesh] OR "cause"[tw] OR "causal"[tw] OR "Causality"[Mesh] OR "causality"[tw] OR "attribute"[tw] OR "attributes"[tw] OR "Psychometrics"[Mesh] OR "psychometrics"[tw] OR psychometric*[tw] OR "prognostic"[tw] OR "Prognosis"[Mesh:noexp] OR "Prognosis"[tw] OR "timing"[tw] OR "Time Factors"[mesh] OR "non-surgical"[tw] OR "nonsurgical"[tw] OR "conservative"[tw]) AND ("postoperative"[tw] OR "post-operative"[tw] OR "Postoperative Period"[Mesh] OR "Postoperative Complications"[Mesh] OR "Postoperative Care"[Mesh] OR "postsurgical"[tw] OR "postsurgery"[tw] OR "post-surgical"[tw] OR "post-surgery"[tw] OR "after"[tiab]) AND ("QOL"[tw] OR "Quality of Life"[mesh] OR "quality of life"[tw] OR "Pain"[mesh] OR "pain"[tw] OR "Pain Measurement"[mesh] OR "function"[tw] OR functional[tw] OR "Range of Motion, Articular"[Mesh] OR "Mobility Limitation"[mesh] OR "Recovery of Function"[Mesh] OR "Musculoskeletal Physiological Phenomena"[Mesh] OR "adverse"[tw] OR "adverse effects" [Subheading] OR "Prosthesis Failure"[mesh] OR "mortality"[tw] OR "Mortality"[Mesh] OR "mortality"[Subheading] OR "revision"[tw] OR "Reoperation"[Mesh] OR "Reoperation"[tw] OR "outcome"[tw] OR "outcomes"[tw] OR "Outcome and Process Assessment (Health Care)"[Mesh] OR "clinical"[tw]) NOT ("Animals"[mesh] NOT "Humans"[mesh]))	2.040	2.040

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MEDLINE (OVID-version)	(exp Osteoarthritis/ OR "Osteoarthritis".mp OR osteoarthrit*.mp OR "osteoarthrosis".mp OR "osteoarthroses".mp OR "Degenerative Arthritis".mp OR "coxarthrosis".mp OR "gonarthrosis".mp OR "oa".mp) AND (((exp *Arthroplasty/ OR exp *Joint Prosthesis/ OR exp *"Prostheses and Implants"/ OR arthroplast*.ti,ab OR joint prosthe*.ti,ab OR prosthe*.ti,ab) AND (exp *Hip/ OR exp *Hip Joint/ OR hip.ti,ab OR hips.ti,ab)) OR ((exp *"Arthroplasty, Replacement, Hip"/ OR exp *Hip Prosthesis/ OR "hip prosthesis".ti,ab OR "hip prostheses".ti,ab OR "hip replacement".ti,ab OR "hip replacements".ti,ab OR "hip arthroplasty".ti,ab OR "hip arthroplasties".ti,ab OR (("tha".ti,ab OR "thr".ti,ab OR "thas".ti,ab OR "thrs".ti,ab) AND (hip.ti,ab OR hips.ti,ab OR replace*.ti,ab OR replacement.ti,ab OR replacing.ti,ab OR replaced.ti,ab OR arthroplast*.ti,ab OR arthroplasty.ti,ab OR arthroplastic.ti,ab OR prosthe*.ti,ab OR prosthesis.ti,ab OR prostheses.ti,ab OR prosthetic.ti,ab OR endoprosthe*.ti,ab OR implant*.ti,ab OR implant.ti,ab OR implants.ti,ab OR implanted.ti,ab)) OR ((Hip.ti OR Hips.ti OR Hip*.ti) AND (replace*.ti OR replacement.ti OR replacing.ti OR replaced.ti OR arthroplast*.ti OR arthroplasty.ti OR arthroplastic.ti OR prosthe*.ti OR prosthesis.ti OR prostheses.ti OR prosthetic.ti OR endoprosthe*.ti OR implant*.ti OR implant.ti OR implants.ti OR implanted.ti))))) AND ("determinant".mp OR "determinants".mp OR "predictor".mp OR "predictors".mp OR "predictive".mp OR exp "Predictive Value of Tests"/ OR "factor".mp OR "factors".mp OR exp "Epidemiologic Factors"/ OR exp "Risk Factors"/ OR "associated".mp OR "association".mp OR exp "association"/ OR "cause".mp OR "causal".mp OR exp Causality/ OR "causality".mp OR "attribute".mp OR "attributes".mp OR exp Psychometrics/ OR "psychometrics".mp OR psychometric*.mp OR "prognostic".mp OR Prognosis/ OR "Prognosis".mp OR "timing".mp OR exp Time Factors/ OR "non-surgical".mp OR "nonsurgical".mp OR "conservative".mp) AND ("postoperative".mp OR "post-operative".mp OR exp Postoperative Period/ OR exp Postoperative Complications/ OR exp Postoperative Care/ OR "postsurgical".mp OR "postsurgery".mp OR "post-surgical".mp OR "post-surgery".mp OR "after surgery".mp OR "after total hip".mp OR "after hip".mp OR "after tha".mp OR "after thr".mp) AND ("QOL".mp OR exp "Quality of Life"/ OR "quality of life".mp OR exp Pain/ OR "pain".mp OR exp Pain Measurement/ OR "function".mp OR functional.mp OR exp "Range of Motion, Articular"/ OR exp Mobility Limitation/ OR exp "Recovery of Function"/ OR exp "Musculoskeletal Physiological Phenomena"/ OR "adverse".mp OR "adverse effects".fs OR exp "Prosthesis Failure"/ OR "mortality".mp OR exp Mortality/ OR "mortality".fs OR "revision".mp OR exp Reoperation/ OR "Reoperation".mp OR "outcome".mp OR "outcomes".mp OR exp "Outcome and Process Assessment (Health Care)"/ OR "clinical".mp) NOT (exp Animals/ NOT exp Humans/)	1.569	39
Embase (OVID-version)	(exp *Osteoarthritis/ OR "Osteoarthritis".ti,ab OR osteoarthrit*.ti,ab OR "osteoarthrosis".ti,ab OR "osteoarthroses".ti,ab OR "Degenerative Arthritis".ti,ab OR "coxarthrosis".ti,ab OR "gonarthrosis".ti,ab) AND (((exp *Arthroplasty/ OR exp *Joint Prosthesis/ OR exp * "orthopedic prosthesis and orthosis"/ OR exp *"orthopedic prostheses, orthoses and implants"/ OR arthroplast*.ti OR joint prosthe*.ti,ab OR prosthe*.ti) AND (exp *Hip/ OR hip.ti OR hips.ti)) OR ((exp *hip arthroplasty/ OR exp *Hip Prosthesis/ OR "hip prosthesis".ti,ab OR "hip prostheses".ti,ab OR "hip replacement".ti,ab OR "hip replacements".ti,ab OR "hip arthroplasty".ti,ab OR "hip arthroplasties".ti,ab OR (("tha".ti,ab OR "thr".ti,ab OR "thas".ti,ab OR "thrs".ti,ab) AND (hip.ti,ab OR hips.ti,ab OR replace*.ti,ab OR replacement.ti,ab OR replacing.ti,ab OR replaced.ti,ab OR arthroplast*.ti,ab OR arthroplasty.ti,ab OR arthroplastic.ti,ab OR prosthe*.ti,ab OR prosthesis.ti,ab OR prostheses.ti,ab OR prosthetic.ti,ab OR endoprosthe*.ti,ab OR implant*.ti,ab OR implant.ti,ab OR implants.ti,ab OR implanted.ti,ab)) OR ((Hip.ti OR Hips.ti OR Hip*.ti) AND (replace*.ti OR replacement.ti OR replacing.ti OR replaced.ti OR arthroplast*.ti OR arthroplasty.ti OR arthroplastic.ti OR prosthe*.ti OR prosthesis.ti OR prostheses.ti OR prosthetic.ti OR endoprosthe*.ti OR implant*.ti OR implant.ti OR implants.ti OR implanted.ti))))) AND ("determinant".mp OR "determinants".mp OR "predictor".mp OR "predictors".mp OR "predictive".mp OR exp predictor variable/ OR exp " prediction and forecasting"/ OR "factor".mp OR "factors".mp OR exp Epidemiology/ OR exp "Risk Factor"/ OR "associated".mp OR "association".mp OR exp association/ OR exp disease association/ OR "cause".mp OR "causal".mp OR exp Causality/ OR "causality".mp OR "attribute".mp OR "attributes".mp OR exp Psychometry/ OR "psychometrics".mp OR psychometr*.mp OR "prognostic".mp OR Prognosis/ OR "Prognosis".mp OR "timing".mp OR Time/ OR "non-surgical".mp OR "nonsurgical".mp OR "conservative".mp OR exp conservative treatment/) AND ("postoperative".mp OR "post-operative".mp OR exp Postoperative Period/ OR exp Postoperative Complication/ OR exp Postoperative Care/ OR "postsurgical".mp OR "postsurgery".mp OR "post-surgical".mp OR "post-surgery".mp OR "after surgery".mp OR "after total hip".mp OR "after hip".mp) AND ("QOL".mp OR exp "Quality of Life"/ OR "quality of life".mp OR exp Pain/ OR "pain".mp OR exp Pain Assessment/ OR "function".mp OR functional.mp OR exp "Range of Motion"/ OR exp walking difficulty/ OR exp convalescence/ OR exp musculoskeletal function/ OR "adverse".mp OR adverse outcome/ OR exp "Prosthesis Failure"/ OR "mortality".mp OR exp Mortality/ OR "mortality".fs OR "revision".mp OR exp Reoperation/ OR "Reoperation".mp OR "outcome".mp OR "outcomes".mp OR exp treatment outcome/) NOT (exp Animals/ NOT exp Humans/)	941	297
Web of Science	(TS=(Osteoarthritis OR "Osteoarthritis" OR osteoarthrit* OR "osteoarthrosis" OR "osteoarthroses" OR "Degenerative Arthritis" OR "coxarthrosis" OR "gonarthrosis" OR "oa") AND TI=(((Arthroplasty OR Joint Prosthesis OR arthroplast* OR joint prosthe* OR prosthe*) AND (Hip OR hip OR hips)) OR ((hip arthroplasty OR Hip Prosthesis OR "hip prosthesis" OR "hip prostheses" OR "hip replacement" OR "hip replacements" OR "hip arthroplasty" OR "hip arthroplasties" OR (("tha" OR "thr" OR "thas" OR "thrs") AND (hip OR hips OR replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)) OR ((Hip OR Hips OR Hip*) AND (replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)))))) AND TS=(("determinant" OR "determinants" OR "predictor" OR "predictors" OR "predictive" OR predictor variable OR " prediction and forecasting" OR "factor" OR "factors" OR Epidemiology OR "Risk Factor" OR "associated" OR "association" OR association OR disease association OR "cause" OR "causal" OR Causality OR "causality" OR "attribute" OR "attributes" OR Psychometry OR "psychometrics" OR psychometr* OR "prognostic" OR Prognosis OR "Prognosis" OR "timing" OR Time OR "non-surgical" OR "nonsurgical" OR "conservative" OR conservative treatment) AND ("postoperative" OR "post-operative" OR Postoperative Period OR Postoperative Complication OR Postoperative Care OR "postsurgical" OR "postsurgery" OR "post-surgical" OR "post-surgery" OR "after surgery" OR "after total hip" OR "after hip") AND ("QOL" OR "Quality of Life" OR "quality of life" OR Pain OR "pain" OR Pain Assessment OR "function" OR functional OR "Range of Motion" OR walking difficulty OR convalescence OR musculoskeletal function OR "adverse" OR adverse outcome OR "Prosthesis Failure" OR "mortality" OR Mortality OR "mortality" OR "revision" OR Reoperation OR "Reoperation" OR "outcome" OR "outcomes"))	391	131
COCHRANE Library	((Osteoarthritis OR "Osteoarthritis" OR osteoarthrit* OR "osteoarthrosis" OR "osteoarthroses" OR "Degenerative Arthritis" OR "coxarthrosis" OR "gonarthrosis" OR "oa") AND (((Arthroplasty OR Joint Prosthesis OR arthroplast* OR joint prosthe* OR prosthe*) AND (Hip OR hip OR hips)) OR ((hip arthroplasty OR Hip Prosthesis OR "hip prosthesis" OR "hip prostheses" OR "hip replacement" OR "hip replacements" OR "hip arthroplasty" OR "hip arthroplasties" OR (("tha" OR "thr" OR "thas" OR "thrs") AND (hip OR hips OR replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)) OR ((Hip OR Hips OR Hip*) AND (replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)))))) AND (("determinant" OR "determinants" OR "predictor" OR "predictors" OR "predictive" OR predictor variable OR " prediction and forecasting" OR "factor" OR "factors" OR Epidemiology OR "Risk Factor" OR "associated" OR "association" OR association OR disease association OR "cause" OR "causal" OR Causality OR "causality" OR "attribute" OR "attributes" OR Psychometry OR "psychometrics" OR psychometr* OR "prognostic" OR Prognosis OR "Prognosis" OR "timing" OR Time OR "non-surgical" OR "nonsurgical" OR "conservative" OR conservative treatment) AND ("postoperative" OR "post-operative" OR Postoperative Period OR Postoperative Complication OR Postoperative Care OR "postsurgical" OR "postsurgery" OR "post-surgical" OR "post-surgery" OR "after surgery" OR "after total hip" OR "after hip") AND ("QOL" OR "Quality of Life" OR "quality of life" OR Pain OR "pain" OR Pain Assessment OR "function" OR functional OR "Range of Motion" OR walking difficulty OR convalescence OR musculoskeletal function OR "adverse" OR adverse outcome OR "Prosthesis Failure" OR "mortality" OR Mortality OR "mortality" OR "revision" OR Reoperation OR "Reoperation" OR "outcome" OR "outcomes" OR treatment outcome OR "clinical"))	141	41

CENTRAL	((Osteoarthritis OR "Osteoarthritis" OR osteoarthrit* OR "osteoarthrosis" OR "osteoarthroses" OR "Degenerative Arthritis" OR "coxarthrosis" OR "gonarthrosis" OR "oa") AND (((Arthroplasty OR Joint Prosthesis OR arthroplast* OR joint prosthe* OR prosthe*) AND (Hip OR hip OR hips)) OR ((hip arthroplasty OR Hip Prosthesis OR "hip prosthesis" OR "hip prostheses" OR "hip replacement" OR "hip replacements" OR "hip arthroplasty" OR "hip arthroplasties" OR (("tha" OR "thr" OR "thas" OR "thrs") AND (hip OR hips OR replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)) OR ((Hip OR Hips OR Hip*) AND (replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)))))) AND (("determinant" OR "determinants" OR "predictor" OR "predictors" OR "predictive" OR predictor variable OR " prediction and forecasting" OR "factor" OR "factors" OR Epidemiology OR "Risk Factor" OR "associated" OR "association" OR association OR disease association OR "cause" OR "causal" OR Causality OR "causality" OR "attribute" OR "attributes" OR Psychometry OR "psychometrics" OR psychometr* OR "prognostic" OR Prognosis OR "Prognosis" OR "timing" OR Time OR "non-surgical" OR "nonsurgical" OR "conservative" OR conservative treatment) AND ("postoperative" OR "post-operative" OR Postoperative Period OR Postoperative Complication OR Postoperative Care OR "postsurgical" OR "postsurgery" OR "post-surgical" OR "post-surgery" OR "after surgery" OR "after total hip" OR "after hip") AND ("QOL" OR "Quality of Life" OR "quality of life" OR Pain OR "pain" OR Pain Assessment OR "function" OR functional OR "Range of Motion" OR walking difficulty OR convalescence OR musculoskeletal function OR "adverse" OR adverse outcome OR "Prosthesis Failure" OR "mortality" OR Mortality OR "mortality" OR "revision" OR Reoperation OR "Reoperation" OR "outcome" OR "outcomes" OR treatment outcome OR "clinical"))	143	11
CINAHL	((Osteoarthritis OR "Osteoarthritis" OR osteoarthrit* OR "osteoarthrosis" OR "osteoarthroses" OR "Degenerative Arthritis" OR "coxarthrosis" OR "gonarthrosis" OR "oa") AND (((Arthroplasty OR Joint Prosthesis OR arthroplast* OR joint prosthe* OR prosthe*) AND (Hip OR hip OR hips)) OR ((hip arthroplasty OR Hip Prosthesis OR "hip prosthesis" OR "hip prostheses" OR "hip replacement" OR "hip replacements" OR "hip arthroplasty" OR "hip arthroplasties" OR (("tha" OR "thr" OR "thas" OR "thrs") AND (hip OR hips OR replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)) OR ((Hip OR Hips OR Hip*) AND (replace* OR replacement OR replacing OR replaced OR arthroplast* OR arthroplasty OR arthroplastic OR prosthe* OR prosthesis OR prostheses OR prosthetic OR endoprosthe* OR implant* OR implant OR implants OR implanted)))))) AND (("determinant" OR "determinants" OR "predictor" OR "predictors" OR "predictive" OR predictor variable OR " prediction and forecasting" OR "factor" OR "factors" OR Epidemiology OR "Risk Factor" OR "associated" OR "association" OR association OR disease association OR "cause" OR "causal" OR Causality OR "causality" OR "attribute" OR "attributes" OR Psychometry OR "psychometrics" OR psychometr* OR "prognostic" OR Prognosis OR "Prognosis" OR "timing" OR Time OR "non-surgical" OR "nonsurgical" OR "conservative" OR conservative treatment) AND ("postoperative" OR "post-operative" OR Postoperative Period OR Postoperative Complication OR Postoperative Care OR "postsurgical" OR "postsurgery" OR "post-surgical" OR "post-surgery" OR "after surgery" OR "after total hip" OR "after hip") AND ("QOL" OR "Quality of Life" OR "quality of life" OR Pain OR "pain" OR Pain Assessment OR "function" OR functional OR "Range of Motion" OR walking difficulty OR convalescence OR musculoskeletal function OR "adverse" OR adverse outcome OR "Prosthesis Failure" OR "mortality" OR Mortality OR "mortality" OR "revision" OR Reoperation OR "Reoperation" OR "outcome" OR "outcomes" OR treatment outcome OR "clinical"))	157	36
Total			2.595
Trialregisters			
ClinicalTrials.gov http://clinicaltrials.gov/	(predictor OR predictors OR predictive OR predicting OR prediction OR predictions OR determinant OR determinants) AND (outcome OR outcomes) AND hip AND osteoarthritis	27	27
Multi-register http://www.controlled-trials.com/mrct/	(predictor OR predictors OR predictive OR predicting OR prediction OR predictions OR determinant OR determinants) AND (outcome OR outcomes) AND hip AND osteoarthritis	19	19

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Additional file 2. Reported predictors for outcomes

First author, year	n	Females (%)	Age (mean)	Follow-up (years) $	Significant associations: Prognostic factor	Outcome	Direction*
Studies with low risk of bias across both domains							
Cushnaghan, 2007 [34]	282	65	68	~8	Higher SF-36 (PF)	Change SF-36 (PF)	↓
					Female	Change SF-36 (PF)	↓
					Higher age	Change SF-36 (PF)	↓
					Diabetes	Change SF-36 (PF)	↓
					Higher radiological grade	Change SF-36 (PF)	↑
					Higher number of painful joint sites	Change SF-36 (PF)	↓
Davis, 2011 [35]	1,163	61	69	5	Higher BMI	Dislocation	↑
					Higher BMI	Superficial infection	↑
					Higher BMI	HHS	↓
					Higher BMI	SF-36 (except for the domains mental health and change in health)	↓
Fortin, 2002 [39]	84	59	65.7	2	Higher WOMAC (physical function)	WOMAC (physical function)	↑
					Higher WOMAC (physical function)	Assistance from another person for ADL	↑
Gandhi, 2010 [36]	636	54	63	Mean 3.3	Higher age	WOMAC	↑
					Comorbidities	WOMAC	↑
					Higher age	SF-36 (PF)	↓
					Comorbidities	SF-36 (PF)	↓
					Male	SF-36 (PF)	↓
					Higher age	SF-36 (RP)	↓
					Comorbidities	SF-36 (RP)	↓
Gordon, 2014 [37]	26,249	57	70 female 80 male	1	Female	EQ-5D	↓
					Charnley class C	EQ-5D	↓
Gordon, 2014 [38]	27,245	57	67	1	Higher age from 60 year	EQ-5D	↓
					Higher age from 60 year	EQ VAS	↓
					Lower EQ-5D	Improvement EQ-5D	↑
					Lower EQ VAS	Improvement EQ VAS	↑

First author, year	n	Females (%)	Age (mean)	Follow-up (years) §	Significant associations		
					Prognostic factor	Outcome	Direction*
Judge, 2013 [40]	1,375	62	70.0	each year up to 5	Age 50-60	OHS	↑
					Higher BMI	OHS	↓
					Comorbidities	OHS	↓
					Lower SF-36 (Mental Health)	OHS (pain/ function)	↓
					Lower OHS	OHS	↓
McHugh, 2013 [41]	206	57	66.3	1	Higher ESSI (social support)	SF-36 (MCS)	↑
					Previous joint replacement	Change in SF-36 (PCS)	↓
					Taking NSAIDs or COX-2 inhibitors	Change in SF-36 (PCS)	↑
					Higher HADS anxiety score	Change in SF-36 (PCS)	↓
					Higher HADS depression score	Change in SF-36 (PCS)	↓
					Higher WOMAC pain score	Change in SF-36 (PCS)	↓
Nilsdotter, 2003 [42]	198	54	71	Mean 3.6	Higher age	WOMAC function	↑
					Lower SF-36 (BP)	WOMAC function	↑
Studies with high/unclear risk of bias in at least one of the domains							
Bethge, 2010 [14]	135	66	72	1	Higher BIPQ (subscale Expecting an enduring illness)	HHS	↓
					Higher BIPQ (subscales expectation treatment is helpful)	HHS	↑
Clement, 2011 [43]	163 ≥80y 376 <80y	55 63	84 70	1	Lower age	SF-12 PCS	↑
					Higher age	Satisfaction	↑
					Lower age	OHS (function)	↑
					Higher age	Complications	↑
Clement, 2011 [47]	1,312	58	68	1	Higher OHS	OHS	↑
					Higher DEPCAT	OHS	↓
					Higher DEPCAT	Satisfaction	↓

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First author, year	n	Females (%)	Age (mean)	Follow-up (years) §	Significant associations		
					Prognostic factor	Outcome	Direction*
Duivenvoorden, 2013 [15]	140	64	68	1	Anxiety symptoms	HOOS (subscales pain, ADL, sports, QOL)	↓
					Anxiety symptoms	Satisfaction (overall, pain reduction, improvement ADL, improvement QOL)	↓
					Depressive symptoms	HOOS (subscales pain symptoms, ADL, QOL)	↓
					Depressive symptoms	Satisfaction (improvement QOL)	↓
Greene, 2014 [16]	11,464	64	54	1	High education	EQ-5D index	↑
					EQ-5D index	EQ-5D index	↑
					Charnley class B or C	EQ-5D index	↓
					Comorbidities	EQ-5D index	↓
					Male	EQ-5D index	↑
					High education	EQ VAS	↑
					EQ-5D index	EQ VAS	↑
					Second hip	EQ VAS	↓
					Charnley class B or C	EQ VAS	↓
					Comorbidities	EQ VAS	↓
					High education	Pain VAS	↓
					EQ-5D index	Pain VAS	↓
					Widow/ married	Pain VAS	↓
					Charnley class B or C	Pain VAS	↑
					High education	Satisfaction VAS	↓
					EQ-5D index	Satisfaction VAS	↓
					Second hip	Satisfaction VAS	↑
					Charnley class B or C	Satisfaction VAS	↑
					Females	Satisfaction VAS	↑
Haverkamp, 2013 [28]	155	71†	68.3†	Mean 2.3†	Pain at rest/ at night	Improvement WOMAC	↑
					Pain at rest/ at night	Improvement VAS pain	↑
Heiberg, 2013 [17]	64	52	65	1	Younger age	6MWT	↑
					Males	6MWT	↑
					Higher 6MWT	6MWT	↑
					ROM	6MWT	↑

First author, year	n	Females (%)	Age (mean)	Follow-up (years) $	Significant associations		
					Prognostic factor	**Outcome**	**Direction***
Ieiri, 2013 [49]	108	85	61.3	1	Contralateral hip OA	SF-36 (PF, RP, MH, RE, BP, VT, GH, SF)	↓
					Walking aids	SF-36 (PF, RP, MH, RE, BP, VT, GH, SF)	↓
					Lower contralateral hip ROM	SF-36 (PF, RP, MH, RE, BP, VT, GH, SF)	↓
					Lower affected hip ROM	SF-36 (PF, RP, MH, RE, BP, VT, GH, SF)	↓
				3	Higher age	SF-36 (PF, RP)	↓
					Walking aids	SF-36 (PF, RP)	↓
					Higher BMI	SF-36 (PF, RP)	↓
					Lower contralateral hip ROM	SF-36 (PF, RP)	↓
					Higher pre SF-36 mental health	SF-36 (MH, RP, GH, SF, VT, RE, BP)	↑
					Not living alone	SF-36 (MH, RP, GH, SF, VT, RE, BP)	↑
					Not working	SF-36 (MH, RP, GH, SF, VT, RE, BP)	↑
Johansson, 2010 [29]	75	48	67	2	HHS poor (vs good)	HHS	↓
					HHS poor (vs good)	WOMAC	↓
					HHS poor	SF-36	↓
Judge, 2014 [19]	4,413	62	68.5	1	Higher BMI	OHS	↓
Judge, 2012 [48]	249	64	67.2	Mean 8	Female	SF-36 (PF)	↓
					Higher age	SF-36 (PF)	↓
					Lower SF-36 (PF)	Improvement SF-36 (PF)	↑
					Previous hip injury	SF-36 (PF)	↓
					Greater number of painful joint sites	SF-36 (PF)	↓
					Worse radiological grades	Improvement SF-36 (PF)	↑
Judge, 2011 [18]	908	56	65.9	1	Higher expectations	Change WOMAC	↑
					High education	Change WOMAC	↑
					Worse baseline pain	Change WOMAC	↑
					Worse baseline function	Change WOMAC	↑
					Less severe radiological change	Change WOMAC	↑

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First author, year	n	Females (%)	Age (mean)	Follow-up (years) $	Significant associations		
					Prognostic factor	Outcome	Direction*
Katz, 2012 [27]	49,136	63	60% 65-75 y, 40% >75Y	12	Males	Revision	↑
					Younger patients	Revision	↑
Kennedy, 2011 [44]	75	43	61	Up to 1.3	Higher 6MWT distance	6MWT distance	↑
Keurentjes, 2013 [20]	445	63	66.6	1.5-6	Kellgren Grade 0-2 vs 3-4	SF-36 (PF)	↑
					Kellgren Grade 0-2 vs 3-4	Numeric Rating Scale Satisfaction	↑
Meding, 2000 [22]	1,015	55	67.2	Mean 2.7	Greater degree of cartilage space loss	Pain at 1 year	↓
Nikolajsen, 2006 [30]	1,048	ND	ND	1-1.5	Females	Daily, constant pain in hip and elsewhere	↑
Nilsdotter, 2002 [32]	124	56	71	1	Age >72 year	WOMAC (physical function)	↑
					Age >72 year	SF-36 all subscales except bodily pain	↓
					Lower WOMAC (physical function and pain)	WOMAC (physical function and pain)	↓
					Higher SF-36 (pain)	SF-36 (pain)	↑
Nilsdotter, 2001 [31]	74 (WOMAC)	53	71.2	1	Higher WOMAC (physical function)	WOMAC (physical function)	↑
					WOMAC (Pain)	WOMAC (Pain)	↑

First author, year	n	Females (%)	Age (mean)	Follow-up (years) §	Significant associations		
					Prognostic factor	**Outcome**	**Direction***
Röder, 2007 [24]	12,925	50	males 68.6 females 66,3	Mean 4.3	Better walking capacity	Walking capacity	↑
					Better Flexion	Flexion	↑
Rolfson, 2009 [23]	6,158	57	69	1	Charnley class C	Pain relief (VAS)	↓
					Anxiety/ depression (EQ-5D)	Pain relief (VAS)	↑
					Female	Satisfaction	↓
					Anxiety/ depression (EQ-5D)	Satisfaction	↓
					Charnley class C	Satisfaction	↓
					Female	EQ-5D	↓
					Anxiety/ depression (EQ5D) score 2 or 3	EQ-5D	↑
					Charnley class C	EQ-5D	↓
Sadr Azodi, 2008 [25]	2,106	0	30-54: 239, 55-59: 324, 60-64: 387, 65-69: 391, 70-74: 370, 75-79: 244, 80+: 151	3	Obesity	Dislocation	↑
Sarasqueta, 2012 [21]	166	47	67	1	Higher SF-12 (PC)	Function (WOMAC)	↓
					Function (WOMAC) ≥76.48	Function (WOMAC)	↑
Stickles, 2001 [26]	592	56	68.9	1	Higher BMI	Ascending and descending stairs	↓
Street, 2005 [33]	236	ND	67.1	1 and 2	Knee pain (vs hip and thigh pain)	HHS	↓
					Knee pain (vs hip pain)	WOMAC	↑
					Knee pain (vs hip and thigh pain)	SF-36 (physical function, vitality, social function and mental health at 1 and 2 year f-up and role physical at 2 year f-up	↓

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First author, year	n	Females (%)	Age (mean)	Follow-up (years) §	Significant associations Prognostic factor	 Outcome	Direction*
Tanaka, 2010 [45]	43	100	59.7	1	Severe stage hip OA (radiological)	Gait improvement	↓

BIPQ: The Brief Illness Perception Questionnaire; HHS: Harris Hip Score; SF-12: 12-item Short Form Health Survey; OHS: Oxford Hip Score; DEPCAT: Deprivation Categories; SF-36: 36-item Short Form Health Survey; PF: Physical Functioning; RP: Physical Role; BP: Bodily Pain; GH; General Health; VT: Vitality; SF: Social Functioning; RE: Role-Emotional; MH: Mental Health; MCS: Mental Component Summary score; PCS: Physical Component Summary score; BMI: Body Mass Index; HOOS: Hip disability and Osteoarthritis Outcome Score; ADL: Activities of Daily Living; QOL: Quality Of Life; EQ-5D: EuroQol 5 Dimensions WOMAC: Western Ontario & McMaster Universities Osteoarthritis Index; VAS: Visual Analogue Scale; 6MWT: 6 Minute Walk Test; ROM: Range Of Motion; ESSI: The ENRICHD Social Support Instrument; HADS: Hospital Anxiety and Depression Scale; OA: OsteoArthritis

§ Follow-up moments ≥1 year, when analyses were performed

† Based on both THA and TKA population

ND Not described

*Direction according to scale of the instrument (e.g. VAS pain, VAS Satisfaction, WOMAC: lower scores indicate better outcomes, SF-36, HOOS, HHS etc.: higher scores indicate better outcomes).

9

Chapter 10

The influence of preoperative variables on health related quality of life, functioning and pain after total knee and hip replacement in patients with osteoarthritis: pooled analysis of existing cohorts in the Netherlands

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Submitted

ABSTRACT

Background

Several studies have shown contradicting results preoperative variables that predict health related quality of life (QoL), functioning and pain after total knee or hip arthroplasty (TKA/THA) possibly due to lack of power and not adjusting for confounders. The present study aims to study the independent effect of these variables on postoperative QoL, functioning and pain.

Methods

We pooled individual patient data (n=1783 TKA and n=2400 THA) from 19 cohorts with osteoarthritis (OA) patients in the Netherlands. We examined the influence of age, gender, BMI and preoperative values of QoL, functioning and pain on postoperative status and total improvement. Linear mixed models were used to estimate the effect of each preoperative variable on a particular outcome for each cohort separately. These effects were pooled across cohorts using a random effects model.

Results

For each preoperative point in QoL, the postoperative QoL increased by 0.51 points in TKA and 0.37 points in THA. Similarly, each point in preoperative functioning, resulted in a higher postoperative functioning of 0.31 (TKA) and 0.21 (THA) points on the KOOS/HOOS-ADL scale. For pain this was 0.18 (TKA) and 0.15 (THA) points higher on the KOOS/HOOS-pain scale (higher means less pain). Even though patients with better preoperative values achieved better postoperative outcomes, their improvement was smaller. Both gender and BMI influenced pain after a TKA and THA. Age and BMI influenced QoL, function and pain after a THA.

Conclusion

Patients with a better preoperative QoL, functioning and pain have better outcomes, but also less improvement. Even though the independent effects may seem small, combined results of preoperative variables may result in larger effects on postoperative outcomes. This information may help orthopaedic surgeons to estimate how much a patient and will allow them to counsel patients about the possible outcomes of a joint replacement may improve if surgery is done now versus alternative scenarios.

INTRODUCTION

Total knee or hip arthroplasty (TKA/THA) is an effective treatment for most individuals who suffer from pain and loss of function due to end stage symptomatic hip osteoarthritis (OA). In 2010, 109 and 153 patients per 100,000 persons received a TKA or THA respectively in Europe [1]. The development and progression of OA is strongly influence by age and obesity and more common in women. Parallel to the rising prevalence of knee and hip OA, due to an ageing society and obesity, surgery rates are rising as well [2-4].

TKA and THA should not be given too early since revision rates are higher in younger patients and the length of life of a prosthesis is limited [5]. On the other hand performing a surgery earlier gives more years of productive quality-adjusted life years (QALY's). However, outcomes after revision surgery are generally worse compared to primary surgery. Current practice shows that preoperative disease severity varies largely among centers and countries [6,7], suggesting differences in timing. In addition, about 10-20% of the patients is not satisfied after primary TKA/THA [8-11], possibly caused by unmet expectations of patients due to suboptimal timing of surgery.

Previous research has identified preoperative variables that influence outcomes, but these differed between studies and had opposite directions. This may be due to lack of power so that some studies did not find any effect, while other studies did not adjust for confounders. Pooling the data from available cohort studies may provide more reliable evidence on which variables influence the outcome after TKA/THA because of the larger sample size.

Therefore, the present study aims to study the independent effect of several preoperative variables for outcomes after TKA or THA by pooling individual patient data from available prospective cohorts in the Netherlands.

MATERIALS AND METHODS

The ARGON-OPTIMA (Outcome Predictors for TIMing of ArthropLasty) study is part of the ARGON program (Arthritis Research Group Orthopaedics in The Netherlands). Within this study, we pooled individual patient data from all available prospective TKA/THA cohorts in the Netherlands. All orthopaedic clinics in The Netherlands were invited to participate and submit data. We included prospective studies among patients with primary OA who underwent TKA or THA, with at least one preoperative and one postoperative measurement on functional or clinical outcomes and a follow-up of at least one year. Studies regarding metal-on-metal (MoM) prostheses were excluded, since these are not recommended in current guidelines in The Netherlands.

The assessed preoperative variables were age, gender and BMI, since these were collected in each of the included cohorts. Only few cohorts had data on smoking, degree of radiological osteoarthritis, and comorbidities. Furthermore, we examined the influence of preoperative health related quality of life (QoL), functioning and pain. We studied the effect on the absolute level of the postoperative outcome, but also on the extent of improvement to assess which patients would benefit most from change in a preoperative variable.

Since different cohorts used different questionnaires, these were standardized to compare the same domains across different questionnaires. Furthermore, multiple questionnaires were sometimes used to measure the same domain within a cohort. As each patient should be included only once for each domain, we ordered questionnaires in their ability to measure each outcome reliably, determined by a group of experts within the ARGON consortium. Only the highest rated questionnaire in each dataset was included. The following ordering was used:

Health related quality of life: 1. Physical component summary scale of the SF-36/RAND-36 (36 items), 2. Physical component summary scale of the SF-12 (12 items), 3. EQ-5D (5 items)

Functioning: 1. HOOS/ KOOS subscale ADL (17 items), 2. WOMAC subscale Physical Function (17 items), 3. HOOS-PS/KOOS-PS (5 items) 4. OHS subscale function (6 items)/ OKS subscale function (5 items) according to Harris et al. [12,13]

Pain: 1. HOOS/ KOOS subscale Pain (10 items), 2. WOMAC subscale Pain (5 items), 3. OHS subscale Pain (6 items)/ OKS subscale Pain (7 items) according to Harris et al. [12,13], VAS pain scale

Standardization was performed according to (functioning as example):

Standardized Functioning score (at each time point) =

$$\frac{\text{(functioning score (at each time point) - preoperative mean of functioning)}}{\text{preoperative SD of functioning}}$$

Some questionnaires differed in the direction of the scale e.g. on the VAS pain scale, lower scores mean less pain whereas lower scores mean more pain on the HOOS/ KOOS subscale pain. The direction of all scales were recoded so that higher scores referred to better values).

Statistical analysis

Data of TKA and THA were analyzed separately. As a first step, linear mixed models (LMM) were used to estimate the influence of each preoperative variable on each major outcome for each cohort separately, adjusted for the other variables. As determinants were included in the fixed part of the LMM: the standardized preoperative score (QoL, functioning and pain), age, sex, BMI and follow-up time. Interaction terms were fitted between the variables and follow-up time. In the LMM the patients were specified as the subjects, with an unstructured covariance matrix. This was done for each standardized postoperative outcome. In the second step, the regression coefficients from all cohorts were pooled using a random effects model to obtain one pooled estimate for each preoperative variable and outcome. Given the pooled estimates of the impact of preoperative status on postoperative status, we can also determine the total improvement (postoperative minus the preoperative status). If patients would have the same amount of improvement, 1 point higher in preoperative status would result in a postoperative status of 1 point higher. So if the increase in postoperative status is < 1 (e.g. 0.4), this means that the improvement is 0.6 points smaller for every point increase in preoperative status.

Given that preoperative scores were standardized, the pooled regression coefficient should be interpreted as the number of standard deviations that an outcome will change, per point increase in the preoperative variable. For example looking at the effect of age on postoperative functioning with a standardized regression coefficient of 0.2 and the preoperative SD of functioning is 7, this means that one year increase in age is estimated to increase the postoperative functioning by: 0.2*7. To facilitate interpretation of the pooled standardized regression coefficients of age, BMI and gender, we transformed standardized regression coefficients back to a 0-100 scale (e.g. HOOS, SF-36), using the preoperative standard deviation (SD) of the most representative study. In addition, we will illustrate the potential size of the effects by describing scenarios.

SPSS 20 was used to perform the LLM and Stata 11.1 for the meta-analyses. A p-value of 0.05 was considered significant in all analyses.

Assessment of heterogeneity

The I2 statistic was used to test for heterogeneity between cohorts. This can be interpreted as the percentage of total variability in a set of effect sizes due to between-studies variability. We considered results as heterogeneous when I2 was 50% or greater [14].

Ethical approval

The Medical Ethical Committee of the Leiden University Medical Center (CME P15.043/

SH/sh) confirmed that ethical approval for this type of study is not required under Dutch law."

Source of funding

This research project is supported by a grant (ARGON) from The Dutch Arthritis Foundation (project number BP 12-3-401). The funder had no role in the investigation.

RESULTS

Twenty hospitals submitted data and 19 cohorts from 11 hospitals were included. Of these, 8 cohorts included 1783 knee OA patients undergoing primary TKA and 11 cohorts included 2400 hip OA patients undergoing primary THA. Table 1 shows the characteristics of patients per cohort. Table 2 shows the pooled estimates of the effect of age, gender and BMI on outcomes as well as the transformed values. Most effects were small and homogeneous. For TKA, only gender and BMI were significantly associated with pain. Women had more pain postoperatively than men (3.92 points lower on a 0-100 scale, where 100 is no pain). An increase in BMI with one point, resulted in more postoperative pain (0.47 points on a 0-100 scale). For THA, age and BMI were significantly associated with QoL, functioning and pain. One year increase in age decreased postoperative functioning by 0.33 point on a 0-100 scale. Furthermore, females perceived more pain postoperatively (2 points on a 0-100 scale).

Health related quality of life

Four studies examined the effect of preoperative QoL on postoperative QoL in 760 patients after TKA. Eight studies examined this effect in 1436 patients with a THA (figure 1). A significant positive effect of preoperative QoL was found of 0.51 (95% CI 0.32 to 0.71) for patients after TKA and 0.37 (95% CI 0.21 to 0.53) after THA. This means that a patient with 1 point higher preoperative QoL on average achieves a 0.51 point (TKA) and 0.37 point (THA) higher postoperative QoL on the SF-36 scale. At the same time, if patients with a 1 point higher preoperative QoL reach a 0.51 point higher postoperative QoL after TKA, this also means that their improvement is 0.49 (0.51-1) points less. For THA this implies 0.63 (0.37-1) points less improvement postoperative. The results were heterogeneous, meaning that included studies differed with respect to the estimated effect for either TKA or THA.

Functioning

Six studies examined the effect of preoperative functioning on postoperative functioning in 1021 patients with a TKA and 10 studies examined this effect in 1271 patients with a

Table 1. Description of included TKA and THA databases

Arthroplasty	Study	n	Females (%)	Age mean (SD)	BMI mean (SD)	Follow-up
TKA	1	340	228 (67)	68.9 (9.3)	29.3 (7.6)	2 weeks, 3 months, 2-7 years
TKA	2	382	271 (71)	67.0 (9.7)	29.5 (4.7)	1 year
TKA	3	45	20 (44)	67.8 (6.5)	29.3 (5.1)	3, 6, 12 months
TKA	4	101	66 (65)	68.9 (9.1)	30.9 (5.1)	6 weeks, 6, 12 months, 5 years
TKA	5	496	274 (55)	65.9 (7.9)	27.6 (3.5)	6, 12, 24 months
TKA	6	169	120 (71)	69.8 (9.9)	29.2 (4.7)	6 weeks, 3 months, 1 year
TKA	7	41	22 (54)	62.2 (9.5)	32.0 (5.4)	3, 6 months, 4 years
TKA	8	209	127 (61)	66.4 (10.2)	29.7 (6.4)	6 weeks, 3, 6, 12 months
THA	1	498	319 (64)	65.7 (10.8)	26.9 (4.0)	2 weeks, 3 months, 2-7 years
THA	2	149	106 (71)	60.4 (6.9)	26.8 (4.2)	6 weeks, 3, 6, 12, 24 months
THA	3	398	247 (62)	66.6 (10.2)	27.2 (4.5)	1 year
THA	4	55	32 (58)	67.7 (9.7)	27.3 (3.6)	3, 6, 12 months
THA	5	73	46 (63)	65.2 (6.7)	28.0 (4.6)	6 weeks, 3, 6, 12, 24, 60 months
THA	6	26	18 (69)	62.9 (5.0)	24.5 (2.9)	6 weeks, 3, 6, 12 months
THA	7	354	228 (64)	65.9 (7.9)	26.4 (3.4)	3, 12 months
THA	8	100	58 (58)	68.7 (10.0)	28.2 (4.0)	6 weeks, 3, 12 months
THA	9	287	188 (66)	67.5 (10.6)	26.6 (4.1)	6 weeks, 3, 12 months
THA	10	73	46 (63)	66.7 (12.0)	26.5 (4.2)	3, 6, 12 months
THA	11	33	22 (67)	63.0 (11.9)	26.6 (4.3)	3, 6, 48 months
THA	12	354	257 (73)	69.0 (10.9)	28.2 (4.5)	6, 12, 24 months

THA (figure 2). We found a significant positive effect of 0.31 (95% CI 0.23 to 0.39) for TKA and 0.21 (95% CI 0.16 to 0.26) for THA. This means that a patient with a 1 point higher preoperative functioning on average achieves a 0.31 points higher postoperative functioning on the KOOS scale (TKA) and 0.21 points of the HOOS scale (THA). At the same time this means that these patients have a 0.69 and 0.79 point less improvement for TKA and THA respectively for every 1 point higher on preoperative functioning. The results were homogeneous meaning that the estimated effects did not differ between studies.

Table 2. The influence of patients characteristics on postoperative outcomes after TKA and THA

Arthroplasty	Patients characteristic	Outcome	Studies (n)	Patients (n)	Standardized regression coefficients (95% CI)	Transformed regression coefficient (0-100 scale)	I^2 (%)
TKA	Age	QoL	4	774	0.00 (-0.00, 0.01)	0.00	0.0
TKA	Age	Functioning	6	1021	-0.01 (-0.01, 0.00)	-0.18	0.0
TKA	Age	Pain	6	1102	0.01 (-0.00, 0.02)	0.16	47.0
TKA	Gender (women)	QoL	4	774	-0.05 (-0.23, 0.13)	-0.38	0.0
TKA	Gender (women)	Functioning	6	1021	-0.24 (-0.50, 0.01)	-4.12	53.6
TKA	Gender (women)	Pain	6	1102	-0.25 (-0.50, -0.01)	-3.92	50.5
TKA	BMI	QoL	4	774	-0.02 (-0.06, 0.02)	-0.23	76.1
TKA	BMI	Functioning	6	1021	-0.01 (-0.05, 0.02)	-0.18	62.5
TKA	BMI	Pain	6	1102	-0.03 (-0.05, -0.01)	-0.47	13.1
THA	Age	QoL	8	1436	-0.01 (-0.02, -0.01)	-0.08	0.0
THA	Age	Functioning	10	1271	-0.02 (-0.02, -0.01)	-0.33	0.0
THA	Age	Pain	10	1492	-0.01 (-0.01, -0.00)	-0.18	0.0
THA	Gender (women)	QoL	8	1436	-0.10 (-0.22, 0.01)	-0.78	0.0
THA	Gender (women)	Functioning	10	1271	-0.11 (-0.22, 0.01)	-1.95	10.9
THA	Gender (women)	Pain	10	1492	-0.11 (-0.21, -0.00)	-2.00	0.0
THA	BMI	QoL	8	1436	-0.03 (-0.04, -0.01)	-0.23	0.0
THA	BMI	Functioning	10	1271	-0.02 (-0.04, -0.01)	-0.35	0.0
THA	BMI	Pain	10	1492	-0.02 (-0.03, -0.00)	-0.36	0.0

Pain

Six studies examined the effect of preoperative pain on postoperative pain in 1102 TKA patients and 11 studies examined this effect in 1492 THA patients (figure 3). We found that every point increase in preoperative pain (i.e. less pain) was associated with 0.18 (95% CI 0.11 to 0.26) point increase in postoperative pain after a TKA and 0.15 (95% CI 0.08 to 0.21) after a THA. This also means that patients with less preoperative pain improve 0.82 points less after TKA and 0.85 points less after THA. The results were homogeneous meaning that the estimated effects did not differ between studies.

Combined results

Even though the independent effect of one variable may be small, the combined effect of different variables may result in clinically relevant differences. Table 3 shows some hypothetical scenarios in which several variables are combined. The first scenario is that a patient first loses some weight and reduces the BMI with 5 points to improve the

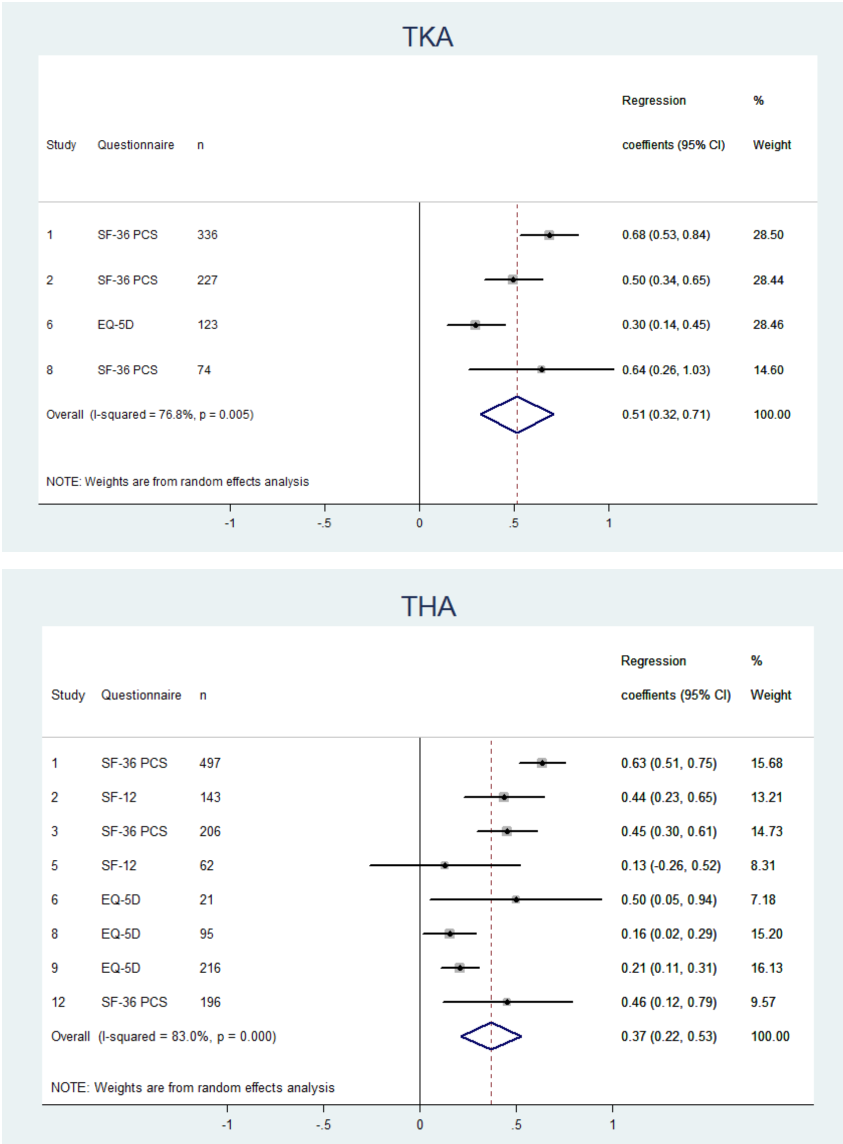

Figure 1. Forest plots - The influence of preoperative QoL on postoperative QoL after TKA (a) and THA (b)

postoperative functioning after THA. This takes some time (e.g. 5 years) and a higher age decreases the postoperative functioning. Suppose that due to the weight loss the preoperative functioning increases with 5 points (on a 0-100 scale). Taken together, this results in a 1.2 points higher postoperative outcome. The second scenario is that a surgeon thinks a patient is too young to perform a THA. If a patient receives this THA 10 years later, and during this 10 years the patient also gains weight due to an inactive

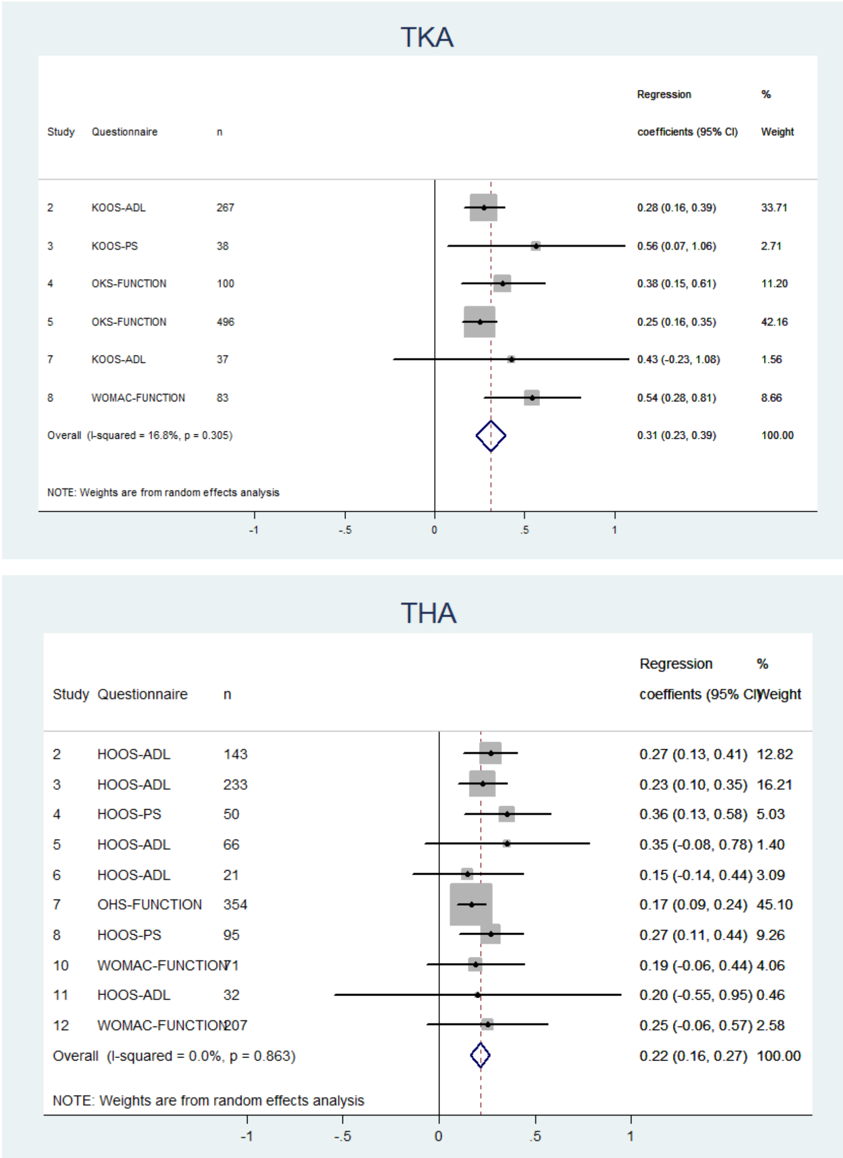

Figure 2. Forest plots - The influence of preoperative functioning on postoperative functioning after TKA (a) and THA (b)

lifestyle (e.g. 10 points of BMI) and the functioning also reduces with 10 points (on a 0-100 scale), his/her postoperative functioning will be 9 points lower compared to the situation if she/he had received THA surgery 10 years earlier. The effect of these scenarios on QoL and pain are also shown in table 3. Overall effects vary between 1.2 and 6.5 points better postoperative outcomes for scenario 1 and between 1.6 and 9 points worse postoperative outcomes for scenario 2.

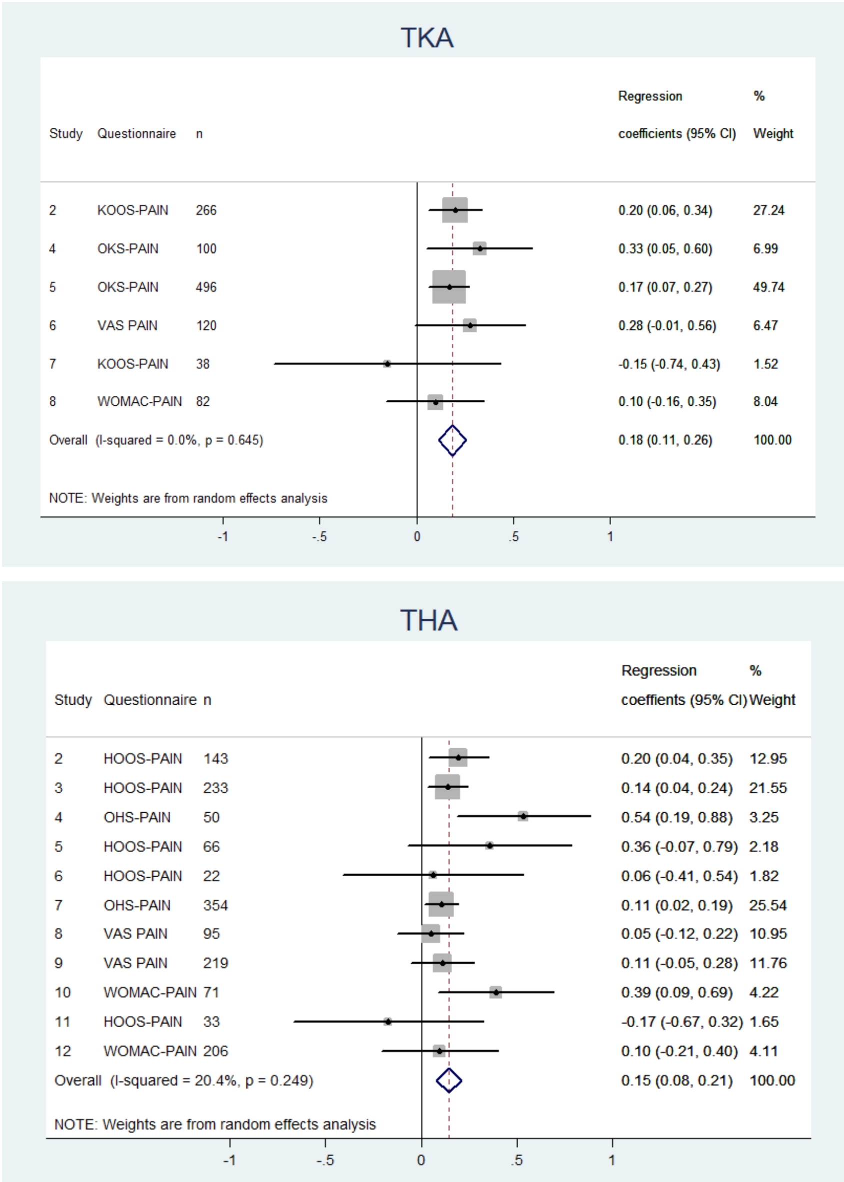

Figure 3. Forest plots - The influence of preoperative pain on postoperative pain after TKA (a) and THA (b)

Table 3. Combined data within scenarios

Scenario 1: A patient loses weight (X points) and increases preoperative status by Y points, this takes Z years

Arthroplasty	Assessed outcome	Effect of age	Effect of BMI	Effect of preoperative status	Total effect on postoperative outcome (points)[a]
X, Y, Z=5 (e.g. in 5 years BMI decreases from 30 to 25, KOOS QoL/ functioning/ pain increases from 35 to 40)					
TKA	QoL	0	0	5*0.51	2.6
	Functioning	0	0	5*0.31	1.6
	Pain	0	5*0.47	5*0.18	3.3
THA	QoL	5*-0.08	5*0.23	5*0.37	2.6
	Functioning	5*-0.33	5*0.35	5*0.22	1.2
	Pain	5*-0.18	5*0.36	5*0.15	1.7
X, Y, Z=10 (e.g. in 10 years BMI decreases from 35 to 25, KOOS QoL/ functioning/ pain increases from 35 to 45)					
TKA	QoL	0	0	10*0.51	5.1
	Functioning	0	0	10*0.31	3.1
	Pain	0	10*0.47	10*0.18	6.5
THA	QoL	10*-0.08	10*0.23	10*0.37	5.2
	Functioning	10*-0.33	10*0.35	10*0.22	2.4
	Pain	10*-0.18	10*0.36	10*0.15	3.3

Scenario 2: A patient gains weight (X points) and decreases preoperative status by Y points, this takes Z years

X, Y, Z=5 (e.g. in 5 years BMI increases from 25 to 30, HOOS QoL/ functioning/ pain decreases from 40 to 35)					
TKA	QoL	0	0	5*-0.51	-2.6
	Functioning	0	0	5*-0.31	-1.6
	Pain	0	5*-0.47	5*-0.18	-3.3
THA	QoL	5*-0.08	5*-0.23	5*-0.37	-3.4
	Functioning	5*-0.33	5*-0.35	5*-0.22	-4.5
	Pain	5*-0.18	5*-0.36	5*-0.15	-3.5
X, Y, Z=10 (e.g. in 10 years BMI increases from 25 to 35, HOOS QoL/ functioning/ pain decreases from 45 to 35)					
TKA	QoL	0	0	10*-0.51	-5.1
	Functioning	0	0	10*-0.31	-3.1
	Pain	0	10*-0.47	10*-0.18	-6.5
THA	QoL	10*-0.08	10*-0.23	10*-0.37	-6.8
	Functioning	10*-0.33	10*-0.35	10*-0.22	-9.0
	Pain	10*-0.18	10*-0.36	10*-0.15	-6.9

[a]On a 0-100 scale

DISCUSSION

The present pooled analysis of 1783 knee and 2400 hip OA patients shows that patients with a higher preoperative quality of life or functioning and less pain also have better postoperative outcomes but that they improve less. Furthermore, women and patients with a higher BMI had more postoperative pain and less improvement after both TKA and THA. Higher age and higher BMI was associated with lower postoperative QoL and functioning and more pain after a THA. However, preoperative quality of life, functioning and pain seem to be most consistently associated with outcomes after both TKA and THA.

It is important to realize that the effects found in our study are not only the effect of the surgery, but also the effect of regression to the mean (RTM). RTM occurs because values are observed with random error, such as random fluctuations in a subject [15]. This means that patients with low preoperative scores are more likely to have higher scores during the next measurement and that patients with high preoperative scores are more likely to have lower scores during the next measurement, even without surgery. This results on average in a larger "improvement" for patients with lower preoperative scores compared to patients with higher baseline scores. Although different methods have been proposed to estimate the size of the RTM effect, but no solution is available to distinguish the real change due to surgery from the change due to RTM.

Our results regarding the effect of preoperative status on outcomes are consistent with other studies that also found that patients with worse preoperative functioning had greater improvements [16-19], but did not achieve the postoperative level of those with higher preoperative functioning [20-26]. Contrary, other studies showed opposite results regarding the direction and size of the effect of age, gender and BMI. Santaguida et al. [27] performed a systematic review about patient characteristics affecting the prognosis after TKA/THA and concluded that an older age is related to worse functioning, but that age and sex do not influence postoperative pain level. We found that women had more pain after a TKA (4 points on a 100 point scale) and THA (2 points on a 100 point scale), even though this may not be a clinically relevant difference [28]. For TKA no association with age or gender and functioning was found. In addition, a previous review about prognostic variables in THA reported that preoperative functioning was most consistently associated with better outcomes [29]. In addition, another systematic review on preoperative predictors on outcomes in THA [30] concluded that only patients' poor preoperative functioning affects the outcome after THA. This was also found for patients with a TKA [31,32]. Consistent with our finding, Lingard et al. [32] found that patients with severe pain had worse outcomes after a TKA. Other studies also identified other variables, such as radiological scores or comorbidities. A disadvantage of using multiple studies with different protocols for data acquisition was that we could not include these variables. The linear mixed model had to be the equal for each study, so that regression coefficients in each study have the same meaning. Thus the prognostic variables found in this present study are not exhaustive; there may be other variables that are also associated with the outcome.

The effect of different preoperative variables on the postoperative outcomes after TKA and THA may seem to be small on itself, but if taken together they may add up to a clinically relevant effect. However, the scenarios should be interpreted with care, because these are hypothetical examples based on observational data and cannot be interpreted causally. The overall effects of the virtual scenarios which were calculated as examples vary between 1.2 and 6.5 points better postoperative outcomes and between 1.6 and 9 points worse postoperative outcomes. These scenarios provide more insights how small differences may add up or cancel each other out. This probably explains why most effects do not reach a clinically significant difference. Usually a 10% difference (i.e. 10 points on a 0-100 scale [28]) is considered as clinically relevant, but is a 10% difference the right criterion? Postoperative TKA/THA scores increases on average by 20-40 points on a 0-100 scale (results not shown) compared to preoperative scores regardless of the preoperative status. Thus is it realistic to use a difference of 10 points to define whether it is clinically relevant to operate now or wait, based on differences in preoperative variables?

The information regarding the combined effects of preoperative variables on postoperative outcomes will support orthopaedic surgeons to estimate differences in outcome after a joint replacement for specific patient groups, i.e. poorer outcomes for patients with a worse preoperative status, but with greater postoperative improvement compared to patients with higher preoperative scores. In addition, preoperative status may decline during a long surgical delay period and thereby lead to worse postoperative outcomes if no other non-surgical treatments are started. On the other hand, it may sometimes be better to first optimize the patient's preoperative condition or to reduce for example their BMI. The present study may support orthopaedic surgeons in their decision making by giving an estimate of the magnitude of the effect for different scenarios. Future studies should combine the results of our study with observational cohort studies among OA patients who did not have surgery yet, specific survival data from medical literature and the effects on survival of the artificial joint to assess optimal timing of surgery. This is needed to assess the long-term impact for the patient of the decision to perform surgery at a certain preoperative state of specific patient groups.

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Chapter 11

Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheumatoid arthritis (Review)

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ABSTRACT

Background

It is unclear whether there are differences in benefits and harms between mobile and fixed prostheses for total knee arthroplasty (TKA). The previous Cochrane review published in 2004 included two articles. Many more trials have been performed since then; therefore an update is needed.

Objectives

To assess the benefits and harms of mobile bearing compared with fixed bearing cruciate retaining total knee arthroplasty for functional and clinical outcomes in patients with osteoarthritis (OA) or rheumatoid arthritis (RA).

Search methods

We searched *The Cochrane Library*, PubMed, EMBASE, CINAHL and Web of Science up to 27 February 2014, and the trial registers ClinicalTrials.gov, Multiregister, Current Controlled Trials and the World Health Organization (WHO) International Clinical Trials Registry Platform for data from unpublished trials, up to 11 February 2014. We also screened the reference lists of selected articles.

Selection criteria

We selected randomised controlled trials comparing mobile bearing with fixed bearing prostheses in cruciate retaining TKA among patients with osteoarthritis or rheumatoid arthritis, using functional or clinical outcome measures and follow-up of at least six months.

Data collection and analysis

We used standard methodological procedures as expected by The Cochrane Collaboration.

Main results

We found 19 studies with 1641 participants (1616 with OA (98.5%) and 25 with RA (1.5%)) and 2247 knees. Seventeen new studies were included in this update.

Quality of the evidence ranged from moderate (knee pain) to low (other outcomes). Most studies had unclear risk of bias for allocation concealment, blinding of participants and personnel, blinding of outcome assessment and selective reporting, and high risk of bias for incomplete outcome data and other bias.

Knee pain

We calculated the standardised mean difference (SMD) for pain, using the Knee Society Score (KSS) and visual analogue scale (VAS) in 11 studies (58%) and 1531 knees (68%). No statistically significant differences between groups were reported (SMD 0.09, 95% confidence interval (CI) -0.03 to 0.22, P value 0.15). This represents an absolute risk difference of 2.4% points higher (95% CI 0.8% lower to 5.9% higher) on the KSS pain scale and a relative percent change of 0.22% (95% CI 0.07% lower to 0.53% higher). The results were homogeneous.

Clinical and functional scores

The KSS clinical score did not differ statistically significantly between groups (14 studies (74%) and 1845 knees (82%)) with a mean difference (MD) of -1.06 points (95% CI -2.87 to 0.74, P value 0.25) and heterogeneous results. KSS function was reported in 14 studies (74%) with 1845 knees (82%) as an MD of -0.10 point (95% CI -1.93 to 1.73, P value 0.91) and homogeneous results. In two studies (11%), the KSS total score was favourable for mobile bearing (159 vs 132 for fixed bearing), with MD of -26.52 points (95% CI -45.03 to -8.01, P value 0.005), but with a wide 95% confidence interval indicating uncertainty about the estimate.

Other reported scoring systems did not show statistically significant differences: Hospital for Special Surgery (HSS) score (seven studies (37%) in 1021 knees (45%)) with an MD of -1.36 (95% CI -4.18 to 1.46, P value 0.35); Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score (two studies (11%), 167 knees (7%)) with an MD of -4.46 (95% CI -16.26 to 7.34, P value 0.46); and Oxford total (five studies (26%), 647 knees (29%) with an MD of -0.25 (95% CI -1.41 to 0.91, P value 0.67).

Health-related quality of life

Three studies (16%) with 498 knees (22%) reported on health-related quality of life, and no statistically significant differences were noted between the mobile bearing and fixed bearing groups. The Short Form (SF)-12 Physical Component Summary had an MD of -1.96 (95% CI -4.55 to 0.63, P value 0.14) and heterogeneous results.

Revision surgery

Twenty seven revisions (1.3%) were performed in 17 studies (89%) with 2065 knees (92%). In all, 13 knees were revised in the fixed bearing group and 14 knees in the mobile bearing group. No statistically significant differences were found (risk difference 0.00, 95% CI -0.01 to 0.01, P value 0.58), and homogeneous results were reported.

Mortality

In seven out of 19 studies, 13 participants (37%) died. Two of these participants had undergone bilateral surgery, and for seven participants, it was unclear which prosthesis they had received; therefore they were excluded from the analyses. Thus our analysis included four out of 191 participants (2.1%) who had died: one in the fixed bearing group and three in the mobile bearing group. No statistically significant differences were found. The risk difference was -0.02 (95% CI -0.06 to 0.03, P value 0.49) and results were homogeneous.

Reoperation rates

Thirty reoperations were performed in 17 studies (89%) with 2065 knees (92%): 18 knees in the fixed bearing group (of the 1031 knees) and 12 knees in the mobile group (of the 1034 knees). No statistically significant differences were found. The risk difference was -0.01 (95% CI -0.01 to 0.01, P value 0.99) with homogeneous results.

Other serious adverse events

Sixteen studies (84%) reported nine other serious adverse events in 1735 knees (77%): four in the fixed bearing group (of the 862 knees) and five in the mobile bearing group (of the 873 knees). No statistically significant differences were found (risk difference 0.00, 95% CI -0.01 to 0.01, P value 0.88), and results were homogeneous.

Authors' conclusions

Moderate- to low-quality evidence suggests that mobile bearing prostheses may have similar effects on knee pain, clinical and functional scores, health-related quality of life, revision surgery, mortality, reoperation rate and other serious adverse events compared with fixed bearing prostheses in posterior cruciate retaining TKA. Therefore we cannot draw firm conclusions. Most (98.5%) participants had OA, so the findings primarily reflect results reported in participants with OA. Future studies should report in greater detail outcomes such as those presented in this systematic review, with sufficient follow-up time to allow gathering of high-quality evidence and to inform clinical practice. Large registry-based studies may have added value, but they are subject to treatment-by-indication bias. Therefore, this systematic review of RCTs can be viewed as the best available evidence.

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Summary of findings for the main comparison. Mobile bearing vs fixed bearing prosthesis for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheumatoid arthritis

Mobile bearing vs fixed bearing prosthesis for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheumatoid arthritis

Patient or population: patients with posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheumatoid arthritis
Settings: hospital
Intervention: fixed bearing
Comparison: mobile bearing

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Mobile bearing	Corresponding risk Fixed bearing				
Pain - measured as KSS pain Knee Society Score, subscore pain. Scale from 0 (severe pain) to 50 (no pain) Follow-up: 1-10.8 years	Mean SMD in the mobile bearing groups was **41.4 points**	Standardised mean pain score in the fixed bearing groups was **0.09 higher** (-0.03 lower to 0.22 higher)		1531 knees (68%) (11 studies, 58%)	⊕⊕⊕⊝ **Moderate**[a]	Transformed into Knee Society score, subscore pain (range 0 to 50) Absolute difference: 2.4% higher (-0.08% to 5.9%) Relative percent change: 0.22% (-0.07% to 0.53% higher) Not statistically significant
Function - measured as KSS function Knee Society Score, function. Scale from 0 to 100 (higher scores indicates better function) Follow-up: 0.5-10.8 years	Mean KSS function in the mobile bearing groups was **84.5 points**	Mean KSS function in the fixed bearing groups was **0.1 lower** (1.93 lower to 1.73 higher)		1865 knees (83%) (14 studies, 74%)	⊕⊕⊝⊝ **Low**[a,b]	Absolute difference: 0.1% higher (-1.93% to 1.73%) Relative percent change: 0.1% (-2.28% to 2.05% higher) Not statistically significant
Health-related quality of life - measured as SF-12 PCS SF-12 PCS. Scale from 0 to 100 (higher scores indicate better health-related quality of life) Follow-up: 2-2.5 years	Mean SF-12 PCS in the mobile bearing groups was **42.3 points**	Mean SF-12 PCS in the fixed bearing groups was **1.96 lower** (4.55 lower to 0.63 higher)		498 knees (22%) (3 studies, 16%)	⊕⊕⊝⊝ **Low**[a,b]	Absolute difference: 1.96% lower (-4.55% to 0.63%) Relative percent change: 4.63% (-10.75% to 1.49% higher) Not statistically significant

Revision surgery Follow-up: 1-9.8 years	**14 per 1000**	**11 per 1000** (4 to 24)	See comment RR 0.80 (0.26-1.74)	2065 knees (92%) (17 studies)	⊕⊕⊖⊖ **Low**[a,c]	Risks were calculated from pooled risk differences Absolute risk difference: 0.00 (-0.01 to 0.01) Relative percent change: 20% (I) (74% (W) to 74% (I) Not statistically significant
Mortality Follow-up: 1-2 years	**33 per 1000**	**22 per 1000** (-18 to 58)	See comment RR 0.69 (-0.55-1.78)	188 persons (12%) (4 studies)	⊕⊕⊖⊖ **Low**[a,c]	Risks were calculated from pooled risk differences Absolute risk difference: 0.02 lower (-0.06 to 0.03) Relative percent change: 31% (I) (211% (W) to 78% (I) Not statistically significant
Reoperation rate Follow-up: 1-9.8 years	**12 per 1000**	**12 per 1000** (2 to 22)	See comment RR 1.01 (0.14-1.86)	2065 (92%) (17 studies)	⊕⊕⊖⊖ **Low**[a,c]	Risks were calculated from pooled risk differences Absolute risk difference 0.01 lower (-0.01 to 0.01) Relative percent change: 1% (h) (86% (W) to 86% (I) Not statistically significant
Other serious adverse events Follow-up: 1-9.8 years	**6 per 1000**	**7 per 1000** (3 to 11)	See comment RR 1.16 (0.44-1.84)	1732 knees (77%) (17 studies)	**Low**[a,c]	Risks were calculated from pooled risk differences Absolute risk difference: 0.00 (-0.01 to 0.01) Relative percent change: 16% (h) (56% (W) to 84% (I) Not statistically significant

*The basis for the **assumed risk** (e.g. median control group risk across studies) is provided in footnotes. The **corresponding risk**(and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence.
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

BACKGROUND

Description of the condition

Osteoarthritis (OA) and rheumatoid arthritis (RA) are conditions that can affect the knee joints. OA and RA lead to pain, loss of function and a lower quality of life. In some people, damage and pain in the knee from arthritis are so severe that joint replacement is required. Approximately 10% of men and 18% of women older than 60 years have OA [1]. Because of the ageing society as well as increasing obesity, the prevalence of knee OA continues to increase [2]. The prevalence of RA varies between 0.3% and 1% [1].

Description of the intervention

Total knee arthroplasty (TKA) is a very common and reliable orthopaedic procedure for end-stage arthritis of the knee. TKA has proved to be a successful surgical intervention that reduces pain and enhances physical function. It is a frequently performed procedure, and the number of TKAs is expected to increase exponentially in future years [3]).

Recent decennia have seen an expansion of technological developments in TKA, usually introduced into clinical practice without appropriate assessment [4]. The mobile (meniscal or rotating) bearing TKA with a polyethylene insert has some freedom of movement and is an example of such a new development. The main goal of the mobile bearing insert is to decrease contact stresses at the implant interface [5,6]. Contradictory views exist as to whether the mobile bearing prosthesis will improve functionality as compared with the fixed bearing prosthesis for cruciate retaining TKA.

Why it is important to do this review

Previously, we performed a systematic review of the literature to assess whether mobile bearing total knee prostheses provide better functional outcomes in patients with OA and RA [7]. This previous review included two randomised controlled trials. Performing a meta-analysis therefore was not possible. Since the time of that review, many trials have been performed to study the clinical and functional outcomes of mobile bearing TKA in comparison with fixed bearing TKA. Thus, an update of the previous review is warranted.

Objectives

To assess the benefits and harms of mobile bearing compared with fixed bearing cruciate retaining total knee arthroplasty for functional and clinical outcomes in patients with osteoarthritis or rheumatoid arthritis.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) comparing mobile and fixed bearing cruciate retaining TKA published as full text in a peer-reviewed journal.

Types of participants

People who have had TKA for OA or RA.

Types of interventions

We included studies of primary, unconstrained, cruciate retaining, total (bi- or tricompartmental) knee arthroplasty with a mobile bearing (meniscal or rotational) or a fixed bearing polyethylene insert. We excluded studies with TKA after prior patellectomy and osteotomy.

Types of outcome measures

The outcome measurement in the studies had to be a functional or a clinical measure with a minimal follow-up of six months.

Major outcomes

- Knee pain (e.g. visual analogue score (VAS), Knee Society Score (pain), Western Ontario and McMaster Universities Arthritis Index (WOMAC) score (pain), Hospital for Special Surgery Score (HSS) (pain), Oxford Knee Score (OKS) (pain)).
- Clinical and functional questionnaire scores (e.g. WOMAC, Knee Injury and Osteoarthritis Outcome Score (KOOS), OKS, HSS, Bristol Knee Score, International Knee Documentation Committee Subjective Knee Form (IKDC) or Performance Outcome (Knee Society (functional) Score, Knee Society (clinical) Score), Knee Society (total) Score)).
- Health-related quality of life (e.g. Short Form (SF)-36, SF-12).
- Revision surgery.
- Mortality.
- Reoperation rate.
- Serious adverse events (excluding revision surgery, mortality and reoperation rate).

Minor outcomes

- Radiolucent lines.
- Femorotibial alignment.

- Performance outcome (flexion, extension, range of motion (ROM)).

Search methods for identification of studies

Electronic searches

In co-operation with a trained medical librarian, we composed a new search strategy. We searched the following databases on 27 February 2014: ***The Cochrane Library*** (2014, Issue 1), PubMed (1944 to 27 February 2014), EMBASE (Ovid version) (1980 to 27 February 2014), Web of Science (1945 to 27 February 2014) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EbscoHost-version) (1981 to 27 February 2014). In addition, we searched the following trial registries on 11 February 2014: ClinicalTrials.gov, Multi-register, Current Controlled Trials, the World Health Organization (WHO) International Clinical Trials Registry Platform and the Dutch trial registry.

The search strategy consisted of the AND combination of two main concepts: rheumatoid arthritis or osteoarthritis, and knee arthroplasty. For the different concepts, we used all relevant keyword variations, not only keyword variations in the controlled vocabularies of the various databases, but free-text word variations of these concepts as well. We optimised the search strategies for all consulted databases, taking into account differences in the various controlled vocabularies, as well as differences in database-specific technical variations (e.g. use of quotation marks). We composed three different versions of the search strategy.

- The intervention concept used as a major subject, the disease concept used both a major or minor subject.
- The intervention concept and the disease concept used as both major and minor subjects, combined with the combination “mobile/fixed” as an additional concept.
- A limited intervention concept combined with an extended “mobile/fixed” concept.

Finally, the results were limited to RCTs including human participants.

Searching other resources

We screened the reference lists of included studies to look for additional studies with the same selection criteria and processed them as the primary search results.

Data collection and analysis

We managed publications with the aid of Reference Manager. In addition, we recorded relevant information pertaining to database source, reason for exclusion and consensus of review authors. We conducted statistical analyses using Review Manager (RevMan) software 5.

Selection of studies
Four review authors (KN, BP, SH, PM) conducted the literature search in co-operation with a trained medical librarian and retrieved the references to be evaluated. Two review authors (KN, BP or SH, PM) independently selected trials for inclusion in the review. We resolved disagreements by consensus. When we could not reach consensus, we consulted a third review author (WJ) for the decisive vote.

We selected articles in two steps. In the first step, we excluded articles when it was apparent from either the title or the abstract that the study did not meet the criteria as mentioned in the criteria for considering studies for this review. In the second step, we excluded articles when it was apparent from inspection of the printed article:

- that it did not meet the inclusion criteria for the review; and
- that the population had already been reported in another included study (most informative publication was included as primary reference, and additional publications as secondary reference).

We documented the reason for exclusion for each reference.

Data extraction and management
We closely examined articles that met all selection criteria with the aid of a checklist and a data extraction form. One review author (SH or KN) entered data into RevMan 5, and another review author (PJ or WJ) checked the data.

Assessment of risk of bias in included studies
Two out of five possible review authors (KN, BP, WJ, SH, PM) assessed the risk of bias in duplicate independently. We assessed risk of bias using the tool of The Cochrane Collaboration [8]), including the domains random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. In the domain 'other bias,' we checked for homogeneity of data and co-interventions. We scored each domain as low, high or unclear. Under 'other bias,' we assessed co-interventions and baseline imbalance such as group homogeneity and subgroup homogeneity, because heterogeneity is often encountered and accounts for lack of power in many orthopaedic surgery trials.

When two review authors could not reach consensus, we consulted a third review author until consensus was reached.

Measures of treatment effect
Studies eligible for the review were RCTs comparing a cruciate retaining mobile (rotating

or meniscal) TKA against a fixed TKA.

Dichotomous data

For dichotomous outcomes, we calculated Mantel Haenszel random-effects risk ratios (RRs). This RR refers to the risk of an event in the experimental group relative to the risk of an event in the control group. Therefore the RR can be calculated only when events are reported in the study groups. If the events were rare and empty cells were found in one of the groups in many studies, we calculated Mantel Haenszel random-effects risk differences (RDs). Risk difference is the difference between observed risk in the two groups. The RD can be calculated even when no events are reported in one of the study groups.

Continuous data

For continuous outcomes, we calculated a random-effects mean difference (MD) weighted by the inverse variance. The mean difference is a standard statistic that measures the absolute difference between mean values in two groups in a clinical trial while taking into account the precision by which this is estimated. It estimates the amount by which the experimental intervention on average changes the outcome compared with the control group. In addition, when the same outcome was reported on different scales, using differing units and methods of assessment (e.g. pain scales), we pooled the results by calculating a standardised mean difference (SMD). We corrected differences in the direction of the scale by subtracting mean values from the maximum value of the scale. To facilitate interpretation of the SMD, we transformed it back into a common scale, using data from the most representative study, with the largest weighting as mobile bearing group baseline and standard deviation.

Unit of analysis issues

An issue for studies on TKA is the possibility to perform bilateral surgery in which one knee is randomly assigned to receive mobile bearing and the other knee to fixed bearing prostheses. As not all studies have this design, we will analyse knee pain, clinical and functional scores and health-related quality of life with and without including these studies performing bilateral knee surgery to assess whether this affects our results. For mortality, we excluded from the analysis participants who underwent bilateral surgery.

Dealing with missing data

Standard deviation (SD) was used when available, or we imputed it from ranges if available. If only the average was reported and no other information was available to calculate the SD, we imputed the average SD from other studies in the same meta-analysis.

Assessment of heterogeneity

We tested heterogeneity by using the I^2 statistic. The I^2 statistic can be interpreted as the percentage of total variability in a set of effect sizes due to between-studies variability.

- Thresholds for interpretation of I^2 of:
- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity; and
- 75% to 100%: show considerable heterogeneity.

Throughout this review, we considered results as heterogenous when I^2 was 50% or greater.

Assessment of reporting biases

To determine publication bias, we searched the following trial registries: ClinicalTrials.gov, Multiregister, Current Controlled Trials, the WHO International Clinical Trials Registry Platform and the Dutch trial registry.

Data synthesis

We used a random-effects model to pool data from each trial.
We conducted statistical analyses by using Review Manager 5.

Subgroup analysis and investigation of heterogeneity

We used the cutoff point of $I^2 \geq 50\%$ to indicate heterogeneity. If heterogeneity was present, we conducted subgroup analyses if possible. We intended to conduct subgroup analyses to investigate the effects of different follow-ups (one year, two years and more than two years of follow-up) on the observed effect.

Sensitivity analysis

We conducted sensitivity analyses to assess the effect on our results of including studies performing bilateral knee surgery. Therefore, we analysed knee pain, clinical and functional scores and health-related quality of life with and without including these studies to assess whether this would affect our results. Furthermore, if possible, we planned to assess the effect of including only high quality studies.

'Summary of findings' table

We reported all major outcomes in the 'Summary of findings' table generated using GRADEpro version 3.2.2.

Grading strength of the evidence

We assessed the strength of the evidence by using the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach, and added this information to the 'Summary of findings' table.

GRADE Working Group grades of evidence.

- **High quality:** Further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- **Very low quality:** We are very uncertain about the estimate.

Downgrading strength of the evidence

- We downgraded the quality of the evidence if any of these factors were present.
- Limitations in the design and implementation of available studies suggesting high likelihood of bias.
- Indirectness of evidence (indirect population, intervention, control, outcomes).
- Unexplained heterogeneity or inconsistency of results (including problems with subgroup analyses).
- Imprecision of results (wide confidence intervals).
- High probability of publication bias.

RESULTS

Description of studies

We found 19 studies (with 1641 participants and 2247 knees - 1616 participants with OA (98.5%) and 25 with RA (1.5%)), which were described in 22 articles. Seventeen of these studies were new since the time of the previous Cochrane review.

Results of the search

We searched the databases and identified 5660 references, of which 3290 were unique (Figure 1, PRISMA flowchart). Reference lists of studies selected for evaluation provided three additional titles, and citation tracking added two new references to the search. We screened 73 articles after removal of duplicates on the basis of title and abstract. We assessed the full text of 53 articles for eligibility. We excluded 34 articles, mostly because a posterior stabilised design was used for one or both types of prostheses in

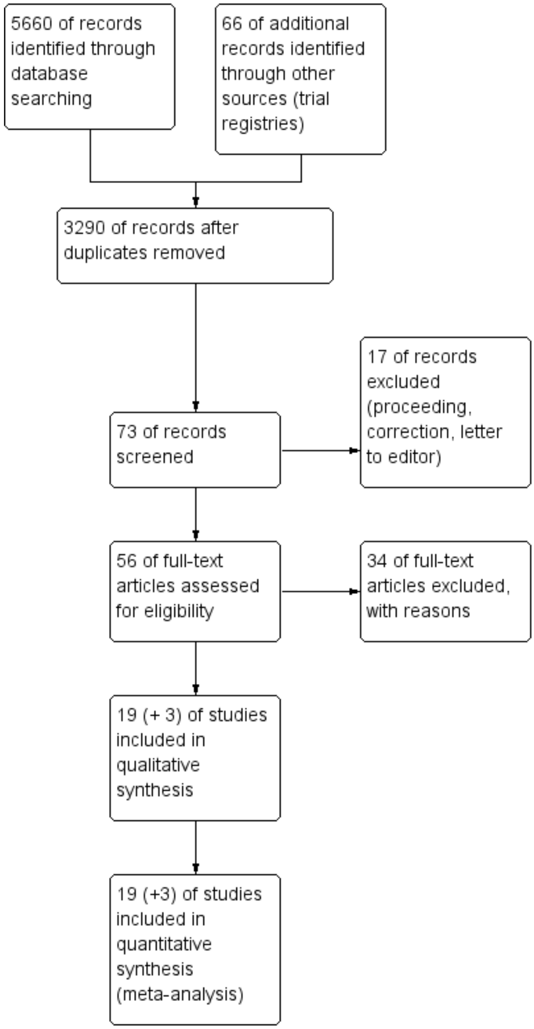

Figure 1. Study flow diagram (PRISMA)

the study. This left 19 studies for inclusion in the review and three additional articles, of which one described follow-up of an included study and two formed a subgroup of an included study.

Grey literature

We found nine proceedings that fulfilled the inclusion criteria. Five of these studies were later published as full text [9-13]. For one proceeding, no abstract was traceable [14]. The study of Chatterji et al. [15] found higher levels of dissatisfaction and patellar-femoral problems in the mobile bearing group. Jolles et al. [16] found better relative differences between preoperative and postoperative ROM and KSS scores at three months and six months for the fixed bearing TKA in comparison with the mobile bearing TKA. However, they did not describe postoperative comparisons of both prostheses. Tibesku et al. [17] found no functional advantage of mobile bearing TKA over fixed bearing TKA in a fluoroscopic study. Furthermore, we found two studies (NCT00208286; NCT01150929) in trial registries that may fulfil our inclusion criteria. However, no results were posted, and it was unclear whether these studies were cruciate retaining. In addition, we found one ongoing study (Characteristics of ongoing studies) without (complete) results.

Included studies

We included 22 reports of 19 studies in this review. See the characteristics of included studies table for details. All studies were stated by their authors to be RCTs comparing mobile (rotating or meniscal) bearing versus fixed bearing, cruciate retaining, primary TKA.

Intervention

Nineteen studies compared mobile bearing versus fixed bearing prostheses. Of the mobile bearing group, 10 studies used a rotating design. Most prostheses were PFC Sigma systems [18-24]. Other prostheses were balanSys [25], Columbus [26] and Trekking MB [27]. Nine studies used a meniscal design, and three of these used the LCS [11,28,29]. Other prostheses were Rotaglide [30,31], MBK [32], e.motion-FP [33], TMK [34] and Genesis II [35,36].

In the fixed bearing group, most prostheses were PFC Sigma [18-21,24,28]. Other prostheses were Nuffield [30], NexGen [31,32], balanSys [25], AMK [11,29], Medial Pivot [22], Genesis II [33,35,36], Columbus [26], Multigen Plus FB [27], Natural Knee [23] and AGC [34].

Six studies performed only bilateral knee surgeries [11,21,22,31,33,34]. Five studies included some bilateral surgeries (Hansson et al. [30] 52 knees in 42 patients; Henricson et al. [32]: 52 knees in 47 patients; Higuchi et al. [20]: 76 knees in 68 patients; Lampe et al. [26]: 100 knees in 96 patients; Munro et al. [24]: 54 knees in 46 patients).

Participant characteristics

We have reported age and gender of study groups in characteristics of included studies. Most studies included participants with osteoarthritis. Three studies included both participants with RA and those with OA (Kim et al. [11]: six RA, 110 OA; Kim et al. [21]: one RA, 173 OA; Watanabe et al. [31]: 18 RA, four OA). In total, 98.5% of participants had OA.

In general we found participant populations from different studies to be comparable, especially in studies with bilateral TKA [11,21,22,29,31,33,34]. Moreover, the groups are fairly homogeneous regarding etiology, with more than 90% of participants having OA. As we included only cruciate retaining TKA, the groups were homogeneous in this aspect.

However, selection criteria of included studies are sometimes absent, or they differ between studies, which might produce heterogeneous groups with regard to underlying disease [11,21,23,24,30,31].

Excluded studies

We excluded Aglietti et al. [37], Ball et al. [38], Bhan et al. [39], Breeman et al. [40], Breugem et al. [41] 2008, Chen et al. [42], Chiu et al. [43], Gioe et al. [44], Harrington et al. [45], Jawed et al. [46], Jolles et al. [47], KAT trial group [48], Kim et al. [49], Kim et al. [50], Kim et al. [51], Läderman et al. [52], Li et al.[53], Matsuda et al. [54], Sylvestre-Muñoz et al. [55], Pagnano et al. [56], Pijls et al. [57], Rahman et al. [58], Saari et al. [59], Shemshaki et al. [60], Tienboon et al. [61], Uvehammer et al. [62], Vasdev et al. [63], Wohlrab et al. [64], Woolson et al. [65], Wylde et al. [9] and Zeng et al. [66] because one, both or some of the implants used in these studies were posterior stabilised and thus were not posterior cruciate ligament retaining. In the trial NCT00289094, other inflammatory arthritis and avascular necrosis of bone were included. See also characteristics of excluded studies.

Risk of bias in included studies

The methodological quality scores of the individual studies are given in the 'Risk of bias' tables in the characteristics of included studies section. Figure 2 and Figure 3 show the risk of bias graph and the methodological quality summary, respectively, of all included studies. The studies Bailey et al. [18], Kim et al. [29], Lizaur-Utrilla et al. [27] and Price et al. [34] did not have high risk of bias in any of the domain assessed.

Allocation

The randomisation technique is described in most studies but is unclear in the following studies: Grodzki et al. [28], Henricson et al. [32], Kim et al. [11], Kim et al. [22], Lampe et al. [26], Möckel et al. [23] and Watanabe et al. [31]. Methods of allocation sequences described include minimisation technique, computer-generated random numbers and sequential pool of random numbers. Study authors describe concealment of allocation in Hanusch et al. [19], Henricson et al. [32], Jacobs et al. [25], Kim et al. [22], Lizaur-Utrilla et al. [27], Munro et al. [24] and Price et al. [34]. Methods described include sealed envelopes and telephone calls.

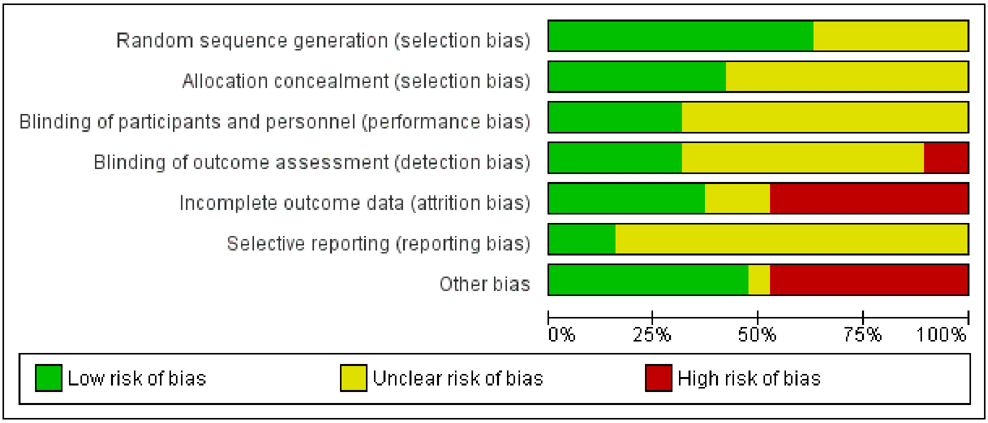

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

Blinding

Study authors describe use of patient blinding only in Bailey et al. [18], Jacobs et al. [25], Lampe et al. [26], Lizaur-Utrilla et al. [27], Price et al. [34] and Tibesku et al. [35,36]. They explain use of assessor blinding in Bailey et al. [18], Kim et al. [21] , Kim et al. [22], Lampe et al. [26], Lizaur-Utrilla et al. [27] and Tibesku et al. [35,36].

Incomplete outcome data

Most studies reported the drop-outs and had an acceptable drop-out rate. One study [23] had too many (> 20%) participants lost to follow-up, and another study [25] excluded 30 participants (28% of the fixed bearing group) as the result of randomisation error. Higuchi et al. [20] and Tibesku et al. [35,36] did not describe the drop-outs. The following studies used an intention-to-treat analysis: Grodzki et al. [28], Kim et al. [29], Kim et al. [33], Lizaur-Utrilla et al. [27], Möckel et al. [23], Munro et al. [24], Price et al. [34] and Watanabe et al. [31].

Selective reporting

We could find only online protocols for three included studies [18,25,26], and this limited our assessment of reporting bias. Data are selectively available for time points in these studies. Fourteen studies report short-term (up to one year) results [18-20,22-28,30,32-34]. Six studies report midterm (longer than one year to two years) results [18,21,27,30,32,35,36], and eight studies report long-term (longer than two years) results [11,21,22,27,29,31,33,34]. However, the outcomes that studies reported varied, as did follow-up results. For example, Hansson et al. [30] reported HSS total only at two follow-up points.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bailey 2014	+	?	+	+	?	+	+
Grodzki 2001	?	?	?	?	+	?	−
Hansson 2005	+	?	?	−	?	?	?
Hanush 2010	+	+	?	?	−	?	−
Henricson 2006	?	+	?	?	−	?	+
Higuchi 2009	+	+	?	?	?	?	−
Jacobs 2011	+	+	+	−	−	+	+
Kim 2001	?	?	?	?	−	?	−
Kim 2007	+	?	?	+	−	?	+
Kim 2009a	?	+	?	?	−	?	+
Kim 2009b	+	?	?	+	+	?	+
Kim 2010	+	?	?	?	+	?	−
Lampe 2011	?	?	+	+	−	+	−
Lizaur-Utrilla 2012	+	+	+	+	+	?	+
Möckel 2004	?	?	?	?	−	?	+
Munro 2010	+	+	?	?	+	?	−
Price 2003	+	+	+	?	+	?	+
Tibesku 2011	+	?	+	+	−	?	−
Watanabe 2005	?	?	?	?	+	?	−

Figure 3. Methodological quality summary: review authors' judgements about each methodological quality item for each included study

Other potential sources of bias

Other co-interventions used during the procedure of the arthroplasty were frequently not reported. Hansson et al. [30] and Higuchi et al. [20] did not describe treatment of the patella. Cementing is unclear in Hansson et al. [30], Higuchi et al. [20] and Price et al. [34].

Effects of interventions

See the 'Summary of findings' table for major outcome measures in the comparison of mobile versus fixed bearing prostheses (Summary of findings for the main comparison.

Major outcomes

Knee pain

We calculated the standardised mean difference (SMD) for pain, using the KSS pain and VAS scores for 11 studies (58%) and 1531 knees (68%). For studies that reported Oxford pain, HSS pain or WOMAC pain and also reported KSS pain, the KSS pain was used. The SMD was 0.09 (95% CI -0.03 to 0.22, P value 0.15). This represents an absolute risk difference of 2.4% points higher (95% CI 0.8% lower to 5.9% higher) on the KSS pain scale and a relative percent change of 0.22% (95% CI 0.07% lower to 0.53% higher) on the KSS pain scale, but these are not significant clinical or statistical differences.

All outcome measures for knee pain showed no statistically significant differences and wide confidence intervals, indicating considerable uncertainty in the estimates. Nine studies (47%) reported Knee Society pain score in 1392 (62%) knees. No significant differences were found; the mean difference was 0.41 (95% CI -0.06 to 0.88, P value 0.08) in favour of fixed bearing. The results are homogeneous (I^2 = 0%, P value 0.57). Three studies (16%) reported VAS pain in 300 knees (13%) with a mean difference of -0.13 points (95% CI -0.96 to 0.69, P value 0.75). The results are heterogeneous (I^2 = 77%, P = 0.01). Furthermore, Oxford pain was reported in two studies (11%) with 184 knees (8%) with a mean difference of -0.42 (95% -0.89 to 0.05, P value 0.08). Other pain outcomes are WOMAC pain and HSS pain, but these were not available for pooling. WOMAC pain was reported in only one study. HSS pain was reported in three studies, but two of these studies did not report ranges or SDs.

Clinical and functional scores

Given the differences in outcomes measured in different studies, calculating a single standardised mean difference was not appropriate.

The Knee Society score was reported in 14 studies (74%) (1845 knees (82%)). No significant differences between groups were found, and the mean difference in KSS clinical was -1.06 point (95% CI -2.87 to 0.74, P value 0.25). The mean difference in KSS function, as reported in 14 studies (1865 knees), was -0.10 points (95% CI -1.93 to 1.73, P value 0.91). KSS clinical showed heterogeneity (I^2 = 77%, P value < 0.01) and, for KSS function, homogeneous results (I^2 = 45%, P value 0.04). Furthermore, we found uncertainty in the estimate of the KSS total score based on two studies [28,35,36]with 71 knees. The mean difference between groups is -26.52 points (95% CI -45.03 to -8.01, P value 0.005). These results are homogeneous (I^2 = 0%, P = 0.80).

Other reported scoring systems also showed uncertainty in their estimates, including HSS (seven studies (37%) in 1021 knees (45%)) with a mean difference of -1.36 (95% CI -4.18 to 1.46, P value 0.35) (I^2 = 86%, P value < 0.01), WOMAC total score (two studies (11%) in 167 knees (7%)) with a mean difference of -4.46 (95% CI -16.26 to 7.34, P value 0.46) (I^2 = 87%, P value < 0.01) and Oxford total (five studies (26%) in 647 knees (29%) with a mean difference of -0.25 (95% CI -1.41 to 0.91, P value 0.67) (I^2 = 0%, P = 0.79). No other validated scoring systems (KOOS, WOMAC function, WOMAC stiffness, Oxford function) were available for pooling because no studies or just one study reported these outcomes.

Health-related quality of life

Only the SF-12 (PCS and MCS) was reported in three studies (16%) [18,24,27] with 498 knees (22%). The mean difference in PCS was -1.96 (95% CI -4.55 to 0.63, P value 0.14). The mean difference in MCS was -1.26 points (95% CI -4.75 to 2.22, P = 0.48). Both results were heterogeneous (I^2 = 61%, P value 0.09; I^2 = 80%, P value 0.007), respectively).

Revision surgery

Orthopaedic surgeons performed a total of 27 revisions in 17 studies (89%) with 2065 knees (92%) - 13 knees in the fixed bearing group (of the 1031 knees) and 14 knees in the mobile bearing group (of the 1034 knees). No significant differences between groups were found (RD 0.00, 95% CI -0.01 to 0.01, P value 0.58). Follow-up time of the studies ranged from 0.5 year to 10 to 12 years, and 13 studies reported a follow-up time less than three years. The groups were homogeneous (I^2 = 0%, P value 1.00). Higuchi et al. [20] and Tibesku et al. [35,36] did not report the number of revisions. Reasons for revision surgery were polyethylene bearing dislocation (mobile bearing), ligamentous instability between the femur and the tibia (fixed bearing), complete wear of the tibial bearing polyethylene (mobile bearing and fixed bearing), infection (mobile bearing and fixed bearing), severe osteolysis (fixed bearing), patella component added (fixed bearing), tibial aseptic loosening (fixed bearing) and dislocation of the meniscal component (mobile bearing).

Mortality

Seven studies (37%) reported mortality. A total of 13 participants died. However, two of those who died (in two studies – Price et al. [34]; Watanabe et al. [31]) had undergone bilateral surgery, so death could not be attributed to one particular group; they were thus excluded from the analysis. Hanusch et al. [19] reported four deaths and Munro et al. [24] reported three deaths, but it was unclear whether these participants received a fixed bearing or a mobile bearing prosthesis. Therefore, in our analyses we included one participant who died (of the 96 participants) in the fixed bearing group and three who died (of the 95 participants) in the mobile bearing group. No significant difference was found between groups in terms of RD (-0.02, 95% CI -0.06 to 0.03, P value 0.49). The groups were homogeneous (I^2 = 0%, P value 0.79). Kim et al. [33] stated that no deaths were related to surgery but did not report the number of persons who died. These studies thus were not included for this outcome.

Reoperation rate

A total of 30 reoperations were performed in 17 studies (89%) with 2065 knees (92%) - 18 knees in the fixed bearing group (of the 1031 knees) and 12 knees in the mobile bearing group (of the 1034 knees). No significant difference was found between groups in terms of RD (-0.01, 95% CI -0.01 to 0.01, P value 0.99). The groups were homogeneous (I^2 = 0%, P = 0.81). Higuchi et al. [20] 2009 and Tibesku et al. [35,36] did not report the number of reoperations. Reasons for reoperation were patella resurfacing (mobile bearing and fixed bearing), femoral fracture (fixed bearing), infection (fixed bearing and mobile bearing), skin-edge necrosis (mobile bearing and fixed bearing) and soft tissue revision for hematoma (mobile bearing).

Other serious adverse events

In all, 16 studies (84%) reported nine other serious adverse events in 1735 knees (77%) - four in the fixed bearing group (of the 862 knees) and five in the mobile bearing group (of the 873 knees). No significant difference was found (mean RD 0.00, 95% CI -0.01 to 0.01, P value 0.88). The groups were homogeneous (I^2 = 0%, P = 1.00). Serious adverse events included deep vein thrombosis or pulmonary embolism (three mobile bearing and two fixed bearing), deep peroneal nerve palsy (two mobile bearing and one fixed bearing) and periprosthetic infection (not described whether a revision or a reoperation was needed) (one fixed bearing). Revision surgeries, reoperations and mortality were excluded from this rate of other serious adverse events because they are reported individually.

Minor outcomes

Five studies (26%) reported overall (not stratified by tibial or femoral) radiolucent lines in 978 knees (44%). A total of 90 events occurred in the fixed bearing group (of the 489 knees) and 75 events in the mobile bearing group (of the 489 knees). No significant difference was found between groups (RR 1.20, 95% CI 0.93 to 1.55, P value 0.16). The results were homogeneous (I^2 = 0%, P value 0.84). Six studies (32%) reported tibial radiolucent lines in 1258 knees (56%). No significant difference was found between groups (RR 0.92, 95% CI 0.49 to 1.72, P value 0.79). The results were heterogeneous (I^2 = 68%, P value 0.008). Four studies (21%) reported femoral radiolucent lines in 1095 knees (49%). No significant difference was found between groups (RR 0.92, 95% CI 0.46 to 1.85, P value 0.82). The results were homogeneous (I^2 = 0%, P value 0.49).

Furthermore, six studies (32%) reported femorotibial alignment in 1047 knees (47%). No difference was found between groups; the mean difference was -0.40 (95% CI -0.86 to 0.06, P value 0.08). The results were heterogeneous (I^2 = 60%, P value 0.03).

Nine studies (47%) in 838 knees (37%) reported flexion. A significant difference in flexion was found in favour of mobile bearing, but with uncertainty in the estimate. The mean difference was -1.84 ° (95% CI -3.48 to -0.20, P value 0.03). The results are homogeneous (I^2 = 0%, P value 0.75). No significant difference was found regarding extension (four studies (21%), 291 knees (13%), 0.07 ° (95% CI -0.54 to 0.68, P value 0.82)). No heterogeneity was observed (I^2 = 0%, P value 0.43). Range of motion was reported in 10 studies (53%) in 1361 knees (61%). No significant difference between groups was found; the mean difference was -0.67 ° (95% CI -3.26 to 1.90, P value 0.61). However, the results were heterogeneous (I^2 = 77%, P value < 0.001) and the estimate is uncertain.

Subgroup analysis

We did not perform any subgroup analysis because the number of studies per subgroup would be too small.

Sensitivity analysis

Six studies performed only bilateral surgeries [11,21,29,31,33,34]. We found similar results in outcomes if we excluded these studies from the analyses. The only exception was HSS, which became significant in favour of mobile bearing when these studies were excluded, with a mean difference of -3.68 (95% CI -7.18 to -0.17, P value 0.04) based on four studies. However, the results were heterogeneous (I^2 = 72%, P value 0.01), with uncertainty in the estimate, and the difference is not clinically relevant. As very few studies had a low or unclear risk of bias, sensitivity analyses by quality of evidence were not possible.

Publication bias

We found two unpublished terminated trials (NCT00208286; NCT01150929) that may fulfil our inclusion criteria. However, no results were posted, and it was unclear whether these studies were cruciate retaining. It is thus possible that some selection bias could have occurred. In addition, we found one ongoing study (NCT00740376) without (complete) results.

DISCUSSION

Summary of main results

In our search, we found 19 randomised trials and three additional articles about already included studies. Seventeen of these studies were new compared with studies included in the previous review [7]. In short, both types of prostheses do not show clinically important differences in benefits and harms. Although some studies found results in favour of the mobile bearing total knee arthroplasty (TKA), no clinically relevant differences were found between mobile bearing and fixed bearing posterior cruciate retaining total knee arthroplasty regarding knee pain, clinical and functional questionnaire scores and health-related quality of life.

Knee pain was measured in 11 studies, but no clinically relevant differences were found. For clinical and functional scores, meta-analyses showed statistically significant differences only for the Knee Society Score (KSS) total score. However, this finding was based on two studies [28,35,36] and includes a very large 95% confidence interval, indicating uncertainty in the estimate. Health-related quality of life was measured in only three studies [18,24,27], and no clinically relevant differences were found.

Furthermore, no significant differences between groups were seen in revision surgery, mortality, reoperation rates and other serious adverse event rates. Especially the numbers of serious adverse events and revision surgery procedures hardly differed. We could include only four of the 13 reported deaths in our analysis because of bilateral surgeries, and because some studies did not report which prosthesis participants received. Reoperations were reported in 18 of the 1031 knees in the fixed bearing group and in 12 of the 1034 knees in the mobile bearing group. The difference in number of reoperations was caused mainly by findings from the study of Kim et al. [22]. These investigators had a high incidence of infection in the fixed bearing group, and the study was temporarily stopped by the Infection Control Committee at their hospital, but no specific factors leading to the high incidence of infection were found. Furthermore, most studies reported follow-up less than three years, so it is possible that there are differences in outcomes with longer follow-up, especially for these outcomes. Large registry-based studies with long-term follow-up may be of added value for further study potential differences in these outcomes. However, as these studies are subject to treatment-by-indication bias, findings must be interpreted cautiously.

The quality of the evidence, as assessed by the GRADE approach, ranged from moderate (knee pain) to low (other major outcomes) (Summary of findings for the main comparison).

Overall completeness and applicability of evidence

Results are frequently not split for different treatment modalities nor different patient categories. Although we can understand that the prime interest of some articles differs, we believe that reporting more detailed preoperative and postoperative data in orthopaedic surgery could greatly benefit interpretation of outcome results. Functional performance could be affected by patellar resurfacing. Resurfacing of the patella could increase the work line of the quadriceps tendon, thereby increasing muscle efficiency and thus walk ability capacity (e.g. staircase) of patients. Until the influence of such factors is known, it is paramount to have insight into the results per factor in each study, and thus to report data specifically for all subgroups. Otherwise it is impossible to draw conclusions about treatment efficacy within a particular study or to pool results from different studies.

Most of the included studies describe different types of prostheses for the comparison of mobile bearing versus fixed bearing TKA. It is therefore impossible to know whether observed results are due to use of a mobile bearing or fixed bearing TKA, or to differences in other design features or even preoperative patient characteristics. Accordingly, when such studies find a significant difference in outcomes between prostheses, this could be the result of these design differences rather than to use of a mobile bearing or fixed bearing TKA. Furthermore, it is currently unknown whether differences in outcome may change over time if either implant behaves differently with reference to survivorship. Applicability of the results of cohort-based clinical studies to the general population has long been a topic of controversy. Such data are available in national arthroplasty registers and can thereby contribute substantial added value to an informed discussion of arthroplasty outcomes [67], especially for outcomes that appear at long-term follow-up such as mortality and revision.

The KSS total was 26.52 points higher in favour of mobile bearing, but as mentioned before, but this finding was based on only two studies with a wide 95% CI (-45.03 to -8.01), indicating uncertainty in the estimate. The probability of publication bias was high, as only two studies reported this outcome instead of the more commonly reported KSS functional and KSS clinical separately. It is possible that although the KSS functional and the KSS clinical separately showed no significant differences, a significant difference would have been shown if both scores were summed up.

Furthermore, most (98.5%) of the participants had osteoarthritis (OA), so the results primarily reflect results in individuals with OA.

Quality of the evidence

The quality of the evidence as graded by the GRADE approach ranged from moderate to low. This assessment was based on risk of bias of individual studies, indirectness, inconsistency of results, imprecision of results and high probability of publication bias, and provides the rationale or justification for downgrading the quality of the evidence.

The quality of knee pain, measured by KSS pain as moderate, and thus further research are likely to have an important impact on our confidence in the estimate of effect and may change the estimate. The quality of evidence of this outcome measure was downgraded because of the risk of bias of individual studies (see Figure 3). This risk of bias was also responsible for downgrading of the quality of evidence in all other major outcome parameters (Summary of findings for the main comparison).

We did not downgrade any of the outcomes because of indirectness of the evidence. Only randomised controlled trials (RCTs) comparing fixed versus mobile bearings were included in different settings. Clinical and functional scores (range of motion (ROM)) and health-related quality of life measures (measured as Short Form (SF)-12 Physical Components Summary (PCS)) were downgraded because of unexplained heterogeneity. This heterogeneity may affect interpretation of results.

The number of serious adverse events (SAEs) resulting in revision and mortality was less than 300; this was also downgraded because of imprecision of results. These outcomes are graded as low quality, which means that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Potential biases in the review process

This review has several strengths and limitations. We composed a new search strategy in cooperation with a trained medical librarian, and, besides the search in databases, we also searched trial registries. We found two unpublished terminated trials (NCT00208286;NCT01150929) that may fulfil our inclusion criteria. However, no results were posted, and it was unclear whether these studies were cruciate retaining. It is thus possible that some selection bias could have occurred. In addition, we found one ongoing study (NCT00740376) without (complete) results. Two review authors independently selected trials for inclusion in the review and resolved disagreements by consensus. When no consensus could be found, a third review author was consulted for the decisive vote. Two review authors independently assessed in duplicate risk of bias. This reduces the possibility of observer bias. A limitation of this meta-analysis is that many studies report outcomes of only one postoperative follow-up moment, which limits the possibility of pooling intermediate results and may cause heterogeneity between studies. This also limits the possibility of analysing differences in follow-up moments. Furthermore, in our selection, we found rotating bearing and meniscal bearing types of implants. Differences could be present because of the anterior movement possibility of the meniscal bearing type. In the characteristics of included studies table, we have described each implant, so care providers can judge whether the results are applicable to their practice.

Agreements and disagreements with other studies or reviews

We found nine other systematic reviews on mobile bearing versus fixed bearing total knee arthroplasty.

Apostolopoulos et al. [68] reviewed clinical and basic scientific studies that compared clinical results, biomechanical features and kinematic patterns of fixed bearing versus mobile bearing knee designs. They concluded that clinical studies have not proved the superiority of mobile bearing.

Bo et al. [69] included 12 studies in a meta-analysis. They included RCTs with bilateral mobile bearing and fixed bearing total knee replacements. We included six of these studies. The study did not include retainment of the posterior cruciate as one of the inclusion criteria. Investigators found no differences in clinical, functional, satisfaction, complication and radiological results.

Cheng et al. [70] included nine articles in a meta-analysis; only two of these articles are included in our selection. Study authors selected RCTs comparing mobile bearing and fixed bearing, including posterior stabilised/PCL resection with a mean follow-up > 5 years. Researchers reported no differences in radiological outcomes or general health results between groups.

Van der Voort et al. [71] selected 41 studies; we included 14 of these articles. They included RCTs comparing mobile bearing and fixed bearing, regardless of whether or not they were cruciate retaining. Meta-analyses showed no clinically relevant differences in terms of revision rates, clinical outcome scores or patient-reported outcome measures between mobile bearing and fixed bearing total knee replacements (TKRs).

Smith et al. [72] identified 13 articles, but only four of these are included in our selection.

This study did not have retainment of the posterior cruciate as one of the inclusion criteria. This could explain the difference in included studies in comparison with our review. Study authors used a limited search strategy, which might explain the additional trials in our review. Regardless, this study could find no significant differences in clinical outcome scores.

Wen et al. [73] identified 15 articles, of which five are included in our selection. This can be explained by the inclusion of posterior stabilised/posterior cruciate ligament (PCL) resection designs in this review. This review could not find differences between the two designs in terms of clinical and radiological outcomes.

Post et al. [74] identified seven non-comparative long-term follow-up studies. They analysed not only functional outcomes, but also long-term survivorship with both designs. This review found no differences in clinical outcome scores.

Van der Bracht et al. [75] identified six articles, of which three are included in our selection. This can be explained by the inclusion of posterior stabilised/PCL resection designs and non-randomised studies in this review. Moreover, study authors searched in six major journals on orthopaedic surgery instead of searching medical databases. They found no superiority in the clinical outcome of mobile-bearing over fixed-bearing TKA.

Oh et al. [76] identified 10 articles, but only four of these are included in our selection. This can be explained by the inclusion of posterior stabilised/PCL resection designs and non-randomised studies in this review. Study authors used a limited search strategy, which might explain the additional trials in our review. Regardless, this review could find no differences in clinical outcome scores.

Although all of these reviews used different selection criteria to compare mobile bearing versus fixed bearing (e.g. uni/bilateral, posterior stabilised/cruciate retaining) and differed in outcome measures, their results are congruent with our findings. No clinically important differences were found regarding clinical, functional, complication and radiological outcomes.

AUTHORS' CONCLUSION

Implications for practice

Current evidence suggests similar patient outcomes for mobile bearing total knee arthroplasty and fixed bearing total knee arthroplasty, regarding knee pain, clinical and functional questionnaire scores, health-related quality of life, revision surgery, mortality, reoperation and other serious adverse events among patients. No statistically and clinically relevant differences were found for any of these outcomes. Also, given the moderate to low quality of the studies, we cannot draw firm conclusions for clinical practice.

Implications for research

Since the time of preparation of the previous version of this review, many new publications have reported randomised trials on this subject. To be able to compare and pool outcomes from different studies, the outcomes must be presented at comparable assessment moments. The present review clearly identifies the need for trials to present data at final follow-up, but also for intermediate follow-ups. In the included studies, we could find no evidence of significant or clinically relevant differences in favour of mobile bearing total knee arthroplasty in comparison with fixed bearing total knee arthroplasty. However, specific patient groups may benefit from a certain prosthesis, such as athletes. This is a potential area for further research. In addition, future studies should report in greater detail on the outcomes presented in this systematic review, with sufficient follow-up time to obtain high-quality evidence and inform clinical practice. Large registry-based studies may have added value, particularly for infrequent outcomes such as mortality, revision and serious adverse events. However, as these registry-based studies are subject to treatment-by-indication bias (which is not the case in RCTs), the present systematic review of RCTs can be viewed as the best available evidence.

A specific problem related to comparing different types of prostheses is that the differences are small, and consequently the effect on patient performance for a given parameter is hard to detect and can be detected only with large sample sizes. Even more, clinical differences are strongly associated with preoperative functional capacity [77]. The effect of an outcome parameter is often important in itself but of limited influence on the rest of the patient's performance. For example, the extent of migration in a radiostereophotogrammetric analysis (RSA) study should always be accompanied by functional and clinical parameters. We welcome the development of guidelines, such as those published in the *Journal of Bone and Joint Surgery* [78]. Because of these methodological problems, more rigorous statistical methods must be performed so the coherence of several aspects of the outcome can be evaluated.

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CHARACTERISTICS OF INCLUDED STUDIES

Bailey 2014

Methods	RCT stated Randomisation determined by a third party randomisation process to ensure similar demographics between the 2 groups Duration of the study: 2 years
Participants	Inclusion: primary knee OA requiring a primary TKA, age > 35 Exclusion: previous knee surgery, inflammatory arthroplasty, significant PMHx, complex surgery requiring bone grafting or revision prosthesis UK: 331 participants Fixed: n = 170, female 102, age 70.1 ± 7.9 years Mobile: n = 161, female 87, age 69.2 ± 8.6 years
Interventions	Fixed: PFC Sigma (Depuy) Mobile: PFC, rotating platform (Depuy) Decision to resurface the patella was made intraoperatively on the basis of intraoperative patellar tracking and clinical patellar wear Both the tibia and the femoral prosthesis were cemented
Outcomes	ROM, OKS, KSS, SF-12 and radiolucency Assessments: preoperative and at 12 and 24 months Average and SD given
Notes	Study funded by DePuy International No declarations of interest reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation determined by a third party randomisation process to ensure similar demographics between the 2 groups
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participant was blinded; surgeon was not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor was blinded; statistician who carried out the analysis was blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Drop-out rate was given and acceptable; not clear whether intention-to-treat analysis was used
Selective reporting (reporting bias)	Low risk	Protocol available and prespecified outcomes reported
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Grodzki 2001

Methods	RCT stated Randomisation technique not stated (1:2 factor?) Duration of study: 1 year
Participants	Inclusion: primary gonarthrosis Exclusion: local infection near the knee joint, RA, insulin-dependent diabetes mellitus, > 15 ° of varus/valgus, absolute medial or lateral collateral ligament instability Germany: 38 participants; sex ratio not stated Fixed: n = 12, age 73.9 (53-89) years Mobile: n = 26, age 73.1 (55-91) years
Interventions	Fixed: PFC Sigma (DePuy) Mobile: LCS, rotating platform (DePuy) Routine patellar resurfacing Tibial component cemented; femoral component cementless
Outcomes	KSS total, revision Assessments: preoperative and at 1 week, 2 weeks, 6 weeks, 3 months, 6 months and 1 year Average and standard deviation given
Notes	Funding not stated No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised allocation. Probably with factor 1:2
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop-out rate given and acceptable; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; co-interventions described in sufficient detail

Hansson 2005

Methods	RCT stated Randomisation technique not stated Duration of study: 2 years
Participants	No selection criteria stated; selection resulted in knee arthrosis grade II to IV Sweden: 42 participants (52 knees) Fixed: n = 27, 14 female, age 75 (64-86) years Mobile: n = 25, 12 female, age 74 (60-85) years
Interventions	Fixed: Niffield (Corin Medical) Mobile: Rotaglide, meniscal bearing (Corin Medical) Patellar resurfacing unclear Cementing unclear
Outcomes	RSA, ROM, alignment, HSS RSA: postoperative at 6 weeks and at 3 months, 6 months, 1 year and 2 years. Clinical scores: preoperative and at 1 and 2 years Average and range scores given
Notes	Study supported by Lund University and Corin Medical Ltd No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised allocation
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessor not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Drop-out rate given and acceptable; not clear whether intention-to-treat analysis was used
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Unclear risk	Unclear whether there was homogeneity in participant groups; co-interventions described in sufficient detail

Hanush 2010

Methods	RCT stated Randomisation based in part on minimisation technique, in part on schedule Duration of study: 13.4 months
Participants	Inclusion: patients with osteoarthritis, suitable for fixed bearing and mobile bearing Exclusion: patients with rheumatoid arthritis and those undergoing revision arthroplasty, requiring tibial component augmentation or a constrained prosthesis United Kingdom: 105 participants Fixed: n = 55, female 22, age 69.4 (± 7.9) years Mobile: n = 50, female 30, age 70 (± 8.4) years
Interventions	Fixed: PFC Sigma fixed bearing (DePuy) Mobile: PFC Sigma, rotating platform (DePuy) Routine patellar unresurfacing All components cemented
Outcomes	Flexion, extension, ROM, KSS pain (KSS), function (KSS); OKS pain (OKS), function (OKS); revision, osteolysis Assessments: preoperative and at 1-year follow-up Average and standard deviation given
Notes	Funded by DePuy International Study authors reported no conflict of interest

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation: in part minimisation technique, in part schedule
Allocation concealment (selection bias)	Low risk	Closed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	High risk	Drop-out rate given and acceptable; no intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; co-interventions described in sufficient detail

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Henricson 2006

Methods	RCT stated Randomisation based on sealed envelopes opened during surgery Duration of study: 2 years
Participants	Inclusion: primary gonarthrosis grade III-IV; age between 60 and 85 years; body weight < 120 kg; no gonarthrosis secondary to arthritis or trauma; no previous knee surgery Sweden: 47 participants (52 knees) Fixed: n = 26, 14 female, age 72 (62-83) years Mobile: n = 26, 16 female, age 72 (62-84) years
Interventions	Fixed: NexGen (Zimmer) Mobile: MBK, meniscal bearing (Zimmer) Some participants with patellar component All components cemented
Outcomes	RSA, KSS, HSS Assessments: preoperative and at 3, 12 and 24 months Average, range or 95% CI given
Notes	One of the study authors received funding from Zimmer Scandinavica

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised allocation
Allocation concealment (selection bias)	Low risk	Sealed envelopes opened during operation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	High risk	Drop-out rate given and acceptable; no intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Higuchi 2009

Methods	RCT stated Randomisation based on computer-generated random numbers Duration of study: 4 years
Participants	Inclusion: patients with osteoarthritis of the knee Exclusion: rheumatoid arthritis Japan: 68 participants (76 knees) 19 men and 49 women, age 68.4 (56-81) years
Interventions	Fixed: PFC (DePuy) Mobile: PFC Sigma, rotating platform (DePuy) Treatment of patella unclear Cementing unclear Flexion space with knee balancer
Outcomes	Flexion, extension Assessments: preoperative and at 12 months and 48 months Average and standard deviation given
Notes	Funding not stated No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Low risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No description of withdrawals and dropouts; not clear whether intention-to-treat analysis was used
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; unsure whether co-interventions are described in sufficient detail

Jacobs 2011

Methods	RCT, multi-centre Computer-generated block-stratified randomisation Duration of the study: 1 year
Participants	Inclusion: patient diagnosed with osteoarthritis; candidate for primary TKA; expected to undergo only 1 arthroplasty procedure within next 12 months; 60–75 years old; preoperative alignment (varus or valgus) < 10 °; BMI < 30; lives independently Exclusion: missing/insufficient PCL The Netherlands/Switzerland: 92 participants Fixed: n = 46, 32 female, age 67.6 (± 4.4) years Mobile: n = 46, 33 female, age 66.7 (± 4.6) years
Interventions	Fixed: balanSysTM type (Mathys Medical Ltd) Mobile: balanSysTM type (Mathys Medical Ltd) No patellar resurfacing Tibia and femur components cemented
Outcomes	Active flexion, KSS function, KSS clinical Assessments: preoperative and at 3 months, 6 months and 12 months Average and standard deviation given
Notes	Funded by Mathys Medical Ltd No declarations of interest reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated block-stratified randomisation
Allocation concealment (selection bias)	Low risk	Closed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participant blinded; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding attempted at any of the assessments
Incomplete outcome data (attrition bias) All outcomes	High risk	1 centre with 30 participants was excluded from analysis because of randomisation error; no intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	Protocol available and prespecified outcomes reported
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Kim 2001

Methods	RCT stated Randomisation technique not stated Duration of study: 7.4 years
Participants	Inclusion: all patients with bilateral simultaneous TKA No exclusion criteria; PCL status not considered, could be retained in all cases Korea: 116 participants (232 knees) 80 female, 36 male, 110 OA, 6 RA, age 65 (33-70) years
Interventions	Fixed: AMK (DePuy) Mobile: LCS, meniscal bearing (DePuy) Routine patellar resurfacing All components cemented
Outcomes	KSS, HSS, VAS for severity, location and frequency of pain, functional benchmarks, overall well-being and satisfaction, survival, radiolucency Short- (yearly) and long-term (> 6 years) follow-up stated, but only final follow-up results given Only point estimates given; not specified for indication groups
Notes	Funding not stated No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised allocation
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	High risk	Drop-out rate given and acceptable; no intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; co-interventions described in sufficient detail

Kim 2007

Methods	RCT stated Randomisation based on sequential pool derived from a table of randomised numbers Duration of study: 5.6 years
Participants	Inclusion and exclusion criteria not described Selection yielded bilateral procedures on 173 patients with osteoarthritis and on 1 patient with rheumatoid arthritis Korea: 174 patients (348 knees) 112 female, 62 male, age 67 (45-85) years
Interventions	Fixed: PFC Sigma (DePuy) Mobile: PFC Sigma, rotating platform (DePuy) Routine patellar resurfacing All components cemented Flexion space with bone resection
Outcomes	KSS, HSS, alignment, component positions, radiolucent lines, lateral patellar tilt Only final, long-term outcome (5.6 years) given Point estimates and ranges given
Notes	No benefits received from any commercial party No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Sequential pool based on a table of randomised numbers
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Drop-out rate given and acceptable; no intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Kim 2009a

Methods	RCT stated Randomisation technique not stated Duration of study: 2.6 years
Participants	Inclusion: bilateral cases with degenerative osteoarthritis with prior non-operative therapy Exclusion: rheumatoid arthritis, septic arthritis history Korea: 92 participants (184 knees) 85 female, 7 male, age 69.5 (± 7.92) years
Interventions	Fixed: Medial Pivot (Wright Medical) Mobile: PFC Sigma, rotating platform (DePuy) Routine patellar resurfacing All components cemented Flexion space with various bone referenced techniques
Outcomes	KSS, HSS, range of motion, satisfaction Only final follow-up (2.6 years) given Point estimates and ranges given
Notes	No commercial association of any of the study authors Study authors reported no conflict of interest

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised allocation
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding unclear
Incomplete outcome data (attrition bias) All outcomes	High risk	Drop-out rate given and acceptable; no intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Kim 2009b

Methods	RCT stated Randomisation based on sequential pool derived from a table of randomised numbers Duration of study: 10-12 years
Participants	Inclusion: patients younger than 55 requiring bilateral TKA Exclusion: criteria not mentioned Korea: 61 participants (122 knees) 45 female, 16 male, age 48.3 (34-55) years
Interventions	Fixed: AMK (DePuy) Mobile: LCS, meniscal bearing (DePuy) Routine patellar resurfacing All components cemented
Outcomes	KSS total, KSS functional, KSS pain, ROM, HSS total, HSS pain, alignment, radiolucent lines Assessments preoperative and at final follow-up 10 to 12 years postoperative Average given
Notes	No benefits or funds received in support of the study No declarations of interest reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequential pool based on a table of randomised numbers
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Observer blinded for radiographic findings
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop-out rate given and acceptable; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Kim 2010

Methods	RCT stated Randomisation performed using a randomisation table Duration of study: 2 years
Participants	Inclusion: osteoarthritic patients scheduled for bilateral TKA with flexion contracture < 15 °; mechanical tibial femoral angle < 20 °; intraoperative intact PCL Korea: 66 participants (132 knees) Fixed: n = 33 CR, 33 PS Mobile: n = 66, 64 female, age 70 (55-79) years
Interventions	Fixed: Genesis II (Smith and Nephew) Mobile: e.motion, meniscal bearing (BBraun-Aesculap) All patellae resurfaced All components cemented
Outcomes	Flexion, extension, KKS pain, KKS knee, KKS function, WOMAC stiffness, WOMAC pain, WOMAC function, preferred knee Assessments preoperative and at 6 months, 12 months and 24 months Average and standard deviation given
Notes	No funding stated No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation table
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop-out rate given and acceptable; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; co-interventions described in sufficient detail

Lampe 2011

Methods	RCT stated Randomisation technique not stated Duration of study: 1 year
Participants	Inclusion: osteoarthritic patients (40-90) with failed non-operative treatment, no previous ipsilateral bone or joint surgery, no deformity > 20° varus or 15° valgus, no option for osteotomy or unicompartmental implant Germany: 96 participants (100 knees) Fixed: n = 52, 39 female, age 69 (± 8) years Mobile: n = 48, 34 female, age 70 (± 7) years
Interventions	Fixed: Columbus (BBraun Aesculap) Mobile bearing: Rotating Platform (BBraun Aesculap) No patella resurfaced All components cemented
Outcomes	KSS knee, KSS function, KSS pain, flexion, Oxford, radiographic alignment Assessments preoperative and at 3 months, 6 months and 12 months Average, standard deviation and range given
Notes	Study was funded by BBraun Aesculap No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised allocation
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participant blinded; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Observer blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Drop-out rate given and acceptable; no intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	Protocol available and prespecified outcomes reported
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; co-interventions described in sufficient detail

Lizaur-Utrilla 2012

Methods	RCT Randomisation based on computer-generated random numbers table Duration of the study: 2.5 years
Participants	Inclusion: osteoarthritic patients with primary TKA, aged 70 years or older, without prior infection in the knee and with severe angular deformity or severe instability that required grafting, modular augmentation or a constrained design Spain: 119 participants Fixed: n = 58, 47 female, age 73.9 (± 3.2) years Mobile: n = 61, 47 female, age 74.6 (± 3.3) years
Interventions	Fixed: Trekking MB (Samo) Mobile: Multigen Plus FB (Lima) Patella resurfaced if there was degeneration Cementless femoral component design and a cemented tibial component
Outcomes	Maximum knee flexion assessments preoperative and at 3 months, 6 months, 12 months and 24 months KSS function, WOMAC, SF-12, VAS, radiolucent lines assessments preoperative and at 3 months, 6 months and 12 months, and yearly thereafter, but only final follow-up results given Average, standard deviation and range given
Notes	No funding stated Study authors reported no conflict of interest

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated random number tables
Allocation concealment (selection bias)	Low risk	Office staff
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participant blinded; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Observers blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop-out rate given and acceptable; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Munro 2010

Methods	RCT Randomisation based on computer-generated sequence with sealed envelopes Duration of study: 2 years
Participants	Inclusion: patients with degenerative knee disease undergoing TKA Exclusion: severe deformity (requiring femoral or tibial augment), inflammatory arthritis, younger than 45 years or older than 85 years, refusal of consent, previous failed TKA or unicompartmental arthroplasty, previous high tibial osteotomy, TKA of the contralateral knee New Zealand: 41 participants (48 knees) Fixed: n = 23, 10 female, age 67.7 (50-79) years Mobile: n = 25, 11 female, age 67.2 (47-83) years
Interventions	Fixed: PFC Sigma fixed-bearing (DePuy) Mobile: PFC Sigma, rotating-platform (DePuy) Patella: resurfacing at indication Cement for femoral and tibial components Flexion space with ligament balancing tool
Outcomes	SF-12 mental, SF-12 physical, KSS clinical, KSS function, WOMAC total, ROM, OKS, VAS pain, revisions, cancellous bone mineral density change, cortical bone mineral density change Assessments: preoperative and at 6 weeks, 12 months and 24 months Average and range given
Notes	Study was partially funded by DePuy International No declarations of interest reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Assessor for clinical evaluations blinded to implant type
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop-out rate given and acceptable; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; co-interventions described in sufficient detail

Möckel 2004

Methods	RCT stated Randomisation technique not stated Duration of study: 6 months
Participants	Inclusion criteria: PCL sufficient Exclusion criteria: other existing implants in lower extremities, factors influencing gait analysis, BMI > 35 Germany: 53 participants 45 female, 17 male, mean age 69 years
Interventions	Fixed: Natural Knee (Centerpulse) or Maxim (Biomet Merck) Mobile: PFC Sigma, rotating platform (DePuy) No patellar resurfacing All components cemented
Outcomes	ROM, KSS, gait analysis, alignment 3 months and 6 months follow-up given Average and some range given
Notes	No funding stated No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised allocation
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	High risk	Drop-out rate given: > 20% lost at 6 months; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Price 2003

Methods	RCT, multi-centre Randomisation based on computer-generated randomisation to side of prosthesis Duration of study: 1 year
Participants	Inclusion: osteoarthritis, bilateral procedures Exclusion: no previous patellectomy or high tibial osteotomy, PCL status not clear as authors state AGC can be used in both sacrificing and retaining procedures; status of the PCL could not be identified. Study authors mention that the PCL is usually retained United Kingdom and Australia: n = 40 (80 knees) 24 female, age 73.1 (54.8-86.4) years
Interventions	Fixed: AGC (Biomet Merck) Mobile: TMK, meniscal bearing (Biomet Merck) No routine arthroplasty of patella Cementing unclear
Outcomes	KSS, KSS pain subscore, Oxford score, Oxford pain sub score, ROM Only short-term (1-year) outcome Average and standard deviation given
Notes	1 or more study authors have received benefits; benefits have been directed at affiliated non-profit party

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation to side of prosthesis
Allocation concealment (selection bias)	Low risk	Telephone call
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participant blinded to implant type
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Some assessors potentially unblinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop-out rate given and acceptable; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	Homogeneity in participant groups on prognostic factors; co-interventions described in sufficient detail

Tibesku 2011

Methods	RCT stated Randomisation based on computer-generated list Duration of study: 2 years
Participants	Inclusion: 50-80 years, unilateral primary osteoarthritis, absence of mediolateral instability, deviation of the long leg axis of less than 10° Exclusion: any co-morbidity that negatively influenced gait Germany: 33 participants Fixed: n = 17, 12 female, age 66 (± 10) years Mobile: n = 16, 9 female, age 65 (± 9) years
Interventions	Fixed: Genesis II (Smith and Nephew) Mobile: Genesis II, meniscal bearing (Smith and Nephew) No patellar resurfacing Cementing unclear
Outcomes	Flexion, KSS, HSS, SF-36, Tegner, UCLA, VAS pain, gait analysis Assessments preoperative and at final follow-up 24 months postoperative Average and standard deviation given
Notes	No funding stated No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated list
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participant blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Observer blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	No description of withdrawals and dropouts; no intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; co-interventions not described in sufficient detail

Watanabe 2005

Methods	RCT stated Randomisation technique not stated Duration of study: 98 months
Participants	Selection criteria not described Selection resulted in bilateral procedures in 18 patients with rheumatoid arthritis and 4 with osteoarthritis Japan: 22 participants (44 knees) 21 female, age 59.6 (35-78) years
Interventions	Fixed: NexGen CR (Zimmer) Mobile: Rotaglide, meniscal bearing (Corin) Patellar resurfacing in all knees 20 of 22 knees fully cemented, 2 hybrid
Outcomes	KSS, flexion, extension, femorotibial angle, radiolucent lines Only final follow-up (98.6/96.2 months) results given Average and range given
Notes	No funding stated No declarations of interest reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised allocation
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant blinding not described; surgeon not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Drop-out rate given and acceptable; intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	High risk	No homogeneity in participant groups on prognostic factors; no subgroups given that are homogeneous; unsure whether co-interventions are described in sufficient detail

Characteristics of excluded studies

Study	Reason for exclusion
Aglietti 2005	Fixed bearing type had a posterior stabilised design
Ball 2011	Posterior stabilised implants
Bhan 2005	Posterior stabilised implants
Breeman 2013	Treatment of PCL dependents of individual surgeon's preference (updated KAT trial)
Breugem 2008	Posterior stabilised implants
Chen 2013	Cruciate ligaments excised
Chiu 2001	Fixed bearing type had a posterior stabilised design
Gioe 2009	Posterior stabilised implants
Harrington 2009	Posterior stabilised and cruciate retaining implants used
Jawed 2012	Posterior cruciate ligament sacrificed in all cases
Jolles 2012	Posterior stabilised implants
KAT trial group 2009	Treatment of PCL dependents of individual surgeon's preference
Kim 2007b	LCS stated as designed for implantation with resection of the PCL
Kim 2012	Posterior stabilised implants
Kim 2012b	LCS stated as designed for implantation with resection of the PCL
Li 2008	Posterior stabilised implants
Läderman 2008	Posterior stabilised implants
Matsuda 2010	Posterior stabilised implants
McGonagle 2012	Treatment of PCL dependents of individual surgeon's preference
Munoz 2008	Posterior stabilised implants
NCT00289094	Included also other inflammatory arthritis and avascular necrosis of bone
Pagnano 2004	Posterior stabilised implants
Pijls 2012	Posterior stabilised implants
Rahman 2010	Posterior stabilised implants
Saari 2003	Treatment of PCL dependents of individual surgeon's preference
Shemshaki 2012	Posterior stabilised implants
Tienboon 2012	Posterior stabilised implants
Uvehammer 2007	Treatment of PCL dependents of individual surgeon's preference
Vasdev 2009	Posterior stabilised implants
Wohlrab 2009	Posterior stabilised implants
Woolson 2004	Posterior stabilised implants
Woolson 2011	Posterior stabilised implants
Wylde 2008	Mixture of patients who had had the posterior cruciate sacrificed and retained
Zeng 2011	Posterior stabilised implants

DATA AND ANALYSES

Comparison 1. Mobile vs fixed bearing, major outcome: knee pain

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 KSS pain	9	1392	Mean Difference (IV, Random, 95% CI)	0.41 [-0.06, 0.88]
2 VAS pain	3	200	Mean Difference (IV, Random, 95% CI)	-0.13 [-0.96, 0.69]
3 Oxford pain	2	184	Mean Difference (IV, Random, 95% CI)	-0.42 [-0.89, 0.05]
4 Knee pain (combined scores)	12	1592	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.03, 0.22]

Comparison 2. Mobile vs fixed bearing, major outcome: clinical and functional scores

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 KSS clinical	14	1845	Mean Difference (IV, Random, 95% CI)	-1.06 [-2.87, 0.75]
2 KSS function	14	1865	Mean Difference (IV, Random, 95% CI)	-0.10 [-1.93, 1.73]
3 KSS total	2	71	Mean Difference (IV, Random, 95% CI)	-26.52 [-45.03, -8.01]
4 HSS	7	1021	Mean Difference (IV, Random, 95% CI)	-1.36 [-4.18, 1.46]
5 WOMAC total	2	167	Mean Difference (IV, Random, 95% CI)	-4.46 [-16.26, 7.34]
6 Oxford total	5	647	Mean Difference (IV, Random, 95% CI)	-0.25 [-1.41, 0.91]

Comparison 3. Mobile vs fixed bearing, major outcome: health-related quality of life

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Revision surgery	17	2065	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.01, 0.01]

Comparison 4. Mobile vs fixed bearing, major outcome: revision surgery

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Revision surgery	17	2065	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.01, 0.01]

Comparison 5. Mobile vs fixed bearing, major outcome: mortality

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality	3	191	Risk Difference (M-H, Random, 95% CI)	-0.02 [-0.06, 0.03]

Comparison 6. Mobile vs fixed bearing, major outcome: reoperation rate

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Reoperation rate	17	2065	Risk Difference (M-H, Random, 95% CI)	8.25 [-0.01, 0.01]

Comparison 7. Mobile vs fixed bearing, major outcome: other serious adverse events

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Serious adverse events	16	1735	Risk Difference (M-H, Random, 95% CI)	-6.52 [-0.01, 0.01]

Comparison 8. Mobile vs fixed bearing, minor outcomes: radiological outcomes

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Radiolucent lines (tibial)	6	1258	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.49, 1.72]

2 Radiolucent lines (femoral)	4	1095	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.46, 1.85]
3 Radiolucent lines (overall)	5	978	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.93, 1.55]
4 Femorotibial alignment	6	1047	Mean Difference (IV, Random, 95% CI)	-0.40 [-0.86, 0.06]

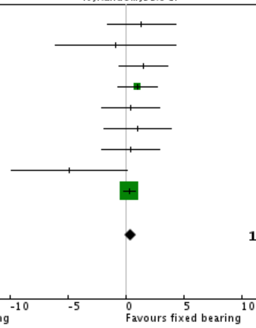
Comparison 9. Mobile vs fixed bearing, minor outcomes: performance outcome

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Flexion	9	838	Mean Difference (IV, Random, 95% CI)	-1.84 [-3.48, -0.20]
2 Extension	4	291	Mean Difference (IV, Random, 95% CI)	0.07 [-0.54, 0.68]
3 Range of motion	10	1456	Mean Difference (IV, Random, 95% CI)	-0.67 [-3.21, 1.87]

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 1 Mobile vs fixed bearing, major outcome: knee pain
Outcome: 1 KSS pain

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Bailey 2014	170	42.7 (14.1)	161	41.4 (13.3)	2.5 %	1.30 [-1.65, 4.25]
Hanush 2010	55	41.7 (13.9)	50	42.6 (13.2)	0.8 %	-0.90 [-6.08, 4.28]
Kim 2001 (1)	116	48.1 (8.5)	116	46.6 (7.8)	4.9 %	1.50 [-0.60, 3.60]
Kim 2007	174	49 (10)	174	48 (5)	7.8 %	1.00 [-0.66, 2.66]
Kim 2009a	33	48.1 (4.4)	33	47.7 (5.7)	3.6 %	0.40 [-2.06, 2.86]
Kim 2009b (2)	61	45 (8.5)	61	44 (7.8)	2.6 %	1.00 [-1.90, 3.90]
Kim 2010	33	48.1 (4.4)	33	47.7 (5.7)	3.6 %	0.40 [-2.06, 2.86]
Price 2003	39	41.5 (12.5)	39	46.4 (10.1)	0.9 %	-4.90 [-9.94, 0.14]
Watanabe 2005 (3)	22	50 (0.01)	22	49.7 (1.3)	73.3 %	0.30 [-0.24, 0.84]
Total (95% CI)	**703**		**689**		**100.0 %**	**0.41 [-0.06, 0.88]**

Heterogeneity: Tau² = 0.0; Chi² = 6.69, df = 8 (P = 0.57); I² =0.0%
Test for overall effect: Z = 1.73 (P = 0.084)
Test for subgroup differences: Not applicable

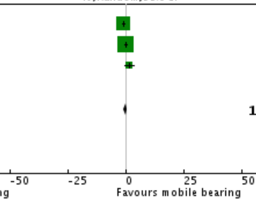


(1) SD based on average SD's other studies
(2) SD based on average SD's other studies
(3) SD calculated from range, range in mobile group was 50-50

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 1 Mobile vs fixed bearing, major outcome: knee pain
Outcome: 2 VAS pain

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Lizaur-Utrilla 2012	58	8 (1.4)	61	8.8 (1.6)	41.6 %	-0.80 [-1.34, -0.26]
Munro 2010	23	0 (0.5)	25	0 (0.8)	45.8 %	0.0 [-0.37, 0.37]
Tibesku 2011	17	3.06 (3.5)	16	1.5 (2.3)	12.7 %	1.56 [-0.45, 3.57]
Total (95% CI)	**98**		**102**		**100.0 %**	**-0.13 [-0.96, 0.69]**

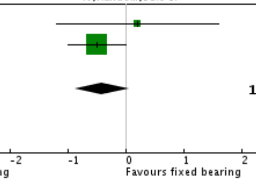
Heterogeneity: Tau² = 0.35; Chi² = 8.78, df = 2 (P = 0.01); I² =77%
Test for overall effect: Z = 0.32 (P = 0.75)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 1 Mobile vs fixed bearing, major outcome: knee pain
Outcome: 3 Oxford pain

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Hanush 2010	55	8.1 (3.9)	50	7.9 (3.4)	11.3 %	0.20 [-1.20, 1.60]
Price 2003	39	2.9 (1.15)	40	3.4 (1.11)	88.7 %	-0.50 [-1.00, 0.00]
Total (95% CI)	**94**		**90**		**100.0 %**	**-0.42 [-0.89, 0.05]**

Heterogeneity: Tau² = 0.0; Chi² = 0.86, df = 1 (P = 0.35); I² =0.0%
Test for overall effect: Z = 1.76 (P = 0.079)
Test for subgroup differences: Not applicable



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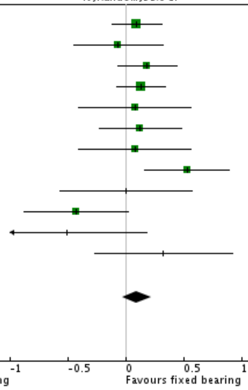
Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 1 Mobile vs fixed bearing, major outcome: knee pain
Outcome: 4 Knee pain (combined scores)

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Std. Mean Difference IV,Random,95% CI
Bailey 2014	170	42.7 (14.1)	161	41.4 (13.3)	16.3 %	0.09 [-0.12, 0.31]
Hanush 2010	55	41.7 (13.9)	50	42.6 (13.2)	7.9 %	-0.07 [-0.45, 0.32]
Kim 2001 (1)	116	48.1 (8.5)	116	46.6 (7.8)	13.5 %	0.18 [-0.07, 0.44]
Kim 2007	174	49 (10)	174	48 (5)	16.7 %	0.13 [-0.08, 0.34]
Kim 2009a	33	48.1 (4.4)	33	47.7 (5.7)	5.5 %	0.08 [-0.41, 0.56]
Kim 2009b (2)	61	45 (8.5)	61	44 (7.8)	8.9 %	0.12 [-0.23, 0.48]
Kim 2010	33	48.1 (4.4)	33	47.7 (5.7)	5.5 %	0.08 [-0.41, 0.56]
Lizaur-Utrilla 2012	58	2 (1.4)	61	1.2 (1.6)	8.5 %	0.53 [0.16, 0.89]
Munro 2010	23	0 (0.5)	25	0 (0.8)	4.2 %	0.0 [-0.57, 0.57]
Price 2003	39	41.5 (12.5)	39	46.4 (10.1)	6.2 %	-0.43 [-0.88, 0.02]
Tibesku 2011	17	6.94 (3.5)	16	8.5 (2.3)	2.9 %	-0.51 [-1.21, 0.18]
Watanabe 2005 (3)	22	50 (0.01)	22	49.7 (1.3)	3.9 %	0.32 [-0.27, 0.92]
Total (95% CI)	**801**		**791**		**100.0 %**	**0.09 [-0.03, 0.22]**

Heterogeneity: Tau² = 0.01; Chi² = 15.36, df = 11 (P = 0.17); I² =28%
Test for overall effect: Z = 1.43 (P = 0.15)
Test for subgroup differences: Not applicable

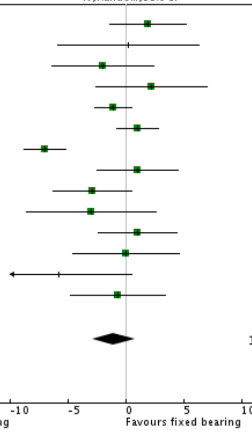


(1) SD based on average SD's other studies
(2) SD based on average SD's other studies
(3) SD calculated from range, range in mobile group was 50-50

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 2 Mobile vs fixed bearing, major outcome: clinical and functional scores
Outcome: 1 KSS clinical

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Bailey 2014	170	85.2 (13.7)	161	83.3 (16.4)	7.9 %	1.90 [-1.36, 5.16]
Hanush 2010	55	84.5 (16.2)	50	84.3 (15.8)	4.8 %	0.20 [-5.92, 6.32]
Henricson 2006 (1)	26	89 (8.3)	23	91 (7.5)	6.5 %	-2.00 [-6.42, 2.42]
Jacobs 2011	46	93.1 (9.5)	46	90.9 (13.5)	6.1 %	2.20 [-2.57, 6.97]
Kim 2001	116	93.3 (6.3)	116	94.4 (6.2)	9.8 %	-1.10 [-2.71, 0.51]
Kim 2007	174	91 (6.3)	174	90 (10.3)	9.6 %	1.00 [-0.79, 2.79]
Kim 2009a (2)	92	87 (7.5)	92	94 (5)	9.5 %	-7.00 [-8.84, -5.16]
Kim 2009b	61	91 (9.7)	61	90 (9.88)	7.6 %	1.00 [-2.47, 4.47]
Kim 2010 (3)	33	92.9 (7.7)	33	95.8 (6.2)	7.7 %	-2.90 [-6.27, 0.47]
Lampe 2011	43	85 (14)	40	88 (12)	5.2 %	-3.00 [-8.60, 2.60]
Munro 2010	23	89 (5.3)	25	88 (6.8)	7.6 %	1.00 [-2.43, 4.43]
Möckel 2004 (4)	40	81 (9)	23	81 (9)	6.3 %	0.0 [-4.62, 4.62]
Price 2003	39	84.6 (15.5)	39	90.4 (12.71)	4.6 %	-5.80 [-12.09, 0.49]
Watanabe 2005	22	91.1 (6.8)	22	91.8 (7)	6.9 %	-0.70 [-4.78, 3.38]
Total (95% CI)	**940**		**905**		**100.0 %**	**-1.06 [-2.87, 0.75]**

Heterogeneity: Tau² = 8.03; Chi² = 56.07, df = 13 (P<0.00001); I² =77%
Test for overall effect: Z = 1.15 (P = 0.25)
Test for subgroup differences: Not applicable

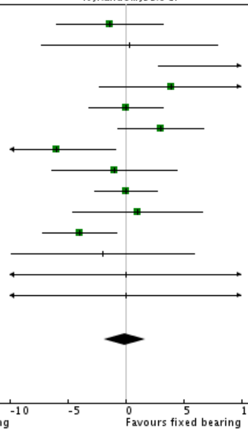


(1) SD estimated from range
(2) SD estimated from range
(3) SD based on average SD's other studies
(4) SD derived from graph

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 2 Mobile vs fixed bearing, major outcome: clinical and functional scores
Outcome: 2 KSS function

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Bailey 2014	170	72 (21.3)	161	73.4 (21.1)	8.5 %	-1.40 [-5.97, 3.17]
Hanush 2010	55	76.7 (18.2)	50	76.4 (21.3)	4.4 %	0.30 [-7.32, 7.92]
Henricson 2006 (1)	26	100 (11.3)	26	90 (15)	4.8 %	10.00 [2.78, 17.22]
Jacobs 2011	46	88.8 (12.8)	46	84.9 (17.3)	5.9 %	3.90 [-2.32, 10.12]
Kim 2001 (2)	116	93 (12.5)	116	93 (12.5)	11.7 %	0.0 [-3.22, 3.22]
Kim 2007 (3)	174	86 (17.5)	174	83 (17.5)	10.5 %	3.00 [-0.68, 6.68]
Kim 2009a	92	80 (17.5)	92	86 (17.5)	7.6 %	-6.00 [-11.06, -0.94]
Kim 2009b (4)	61	85 (14.63)	61	86 (15.86)	7.0 %	-1.00 [-6.41, 4.41]
Kim 2010	33	98.3 (5.6)	33	98.3 (5.6)	13.1 %	0.0 [-2.70, 2.70]
Lampe 2011	43	88 (13)	40	87 (13)	6.7 %	1.00 [-4.60, 6.60]
Lizaur-Utrilla 2012	58	87.28 (9.6)	61	91.3 (8.2)	11.7 %	-4.02 [-7.24, -0.80]
Munro 2010	23	79 (11.3)	25	81 (16.3)	4.2 %	-2.00 [-9.88, 5.88]
Möckel 2004 (5)	27	79 (14.63)	12	79 (15.86)	2.6 %	0.0 [-10.53, 10.53]
Watanabe 2005 (6)	22	65.5 (25)	22	65.5 (25)	1.4 %	0.0 [-14.77, 14.77]
Total (95% CI)	**946**		**919**		**100.0 %**	**-0.10 [-1.93, 1.73]**

Heterogeneity: Tau² = 4.77; Chi² = 23.47, df = 13 (P = 0.04); I² =45%
Test for overall effect: Z = 0.11 (P = 0.91)
Test for subgroup differences: Not applicable

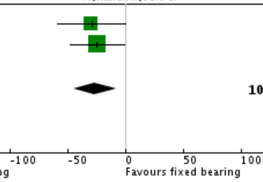


(1) SD estimated from range
(2) SD estimated from range
(3) SD estimated from range
(4) SD estimated of average SD's other included studies
(5) SD estimated of average SD's other included studies
(6) SD estimated from range

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 2 Mobile vs fixed bearing, major outcome: clinical and functional scores
Outcome: 3 KSS total

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Grodzki 2001	12	130.1 (48.7)	26	159.6 (27.6)	39.3 %	-29.50 [-59.03, 0.03]
Tibesku 2011	17	134.41 (41)	16	159 (27.7)	60.7 %	-24.59 [-48.34, -0.84]
Total (95% CI)	**29**		**42**		**100.0 %**	**-26.52 [-45.03, -8.01]**

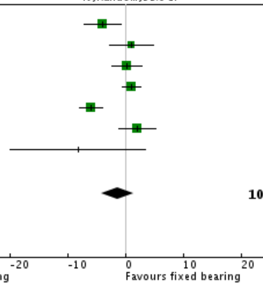
Heterogeneity: Tau² = 0.0; Chi² = 0.06, df = 1 (P = 0.80); I² =0.0%
Test for overall effect: Z = 2.81 (P = 0.0050)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 2 Mobile vs fixed bearing, major outcome: clinical and functional scores
Outcome: 4 HSS

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Hansson 2005 (1)	25	87 (5.5)	25	91 (5.8)	15.2 %	-4.00 [-7.13, -0.87]
Henricson 2006 (2)	26	94 (4.3)	26	93 (9)	13.9 %	1.00 [-2.83, 4.83]
Kim 2001 (3)	116	94 (10)	116	93.8 (9.5)	16.3 %	0.20 [-2.31, 2.71]
Kim 2007	174	89 (6.8)	174	88 (7.8)	17.7 %	1.00 [-0.54, 2.54]
Kim 2009a (4)	92	87 (6.5)	92	93 (6.8)	17.2 %	-6.00 [-7.92, -4.08]
Kim 2009b (5)	61	89 (8.75)	61	87 (8.91)	15.2 %	2.00 [-1.13, 5.13]
Tibesku 2011	17	73.5 (19.4)	16	81.8 (14.6)	4.5 %	-8.30 [-19.97, 3.37]
Total (95% CI)	**511**		**510**		**100.0 %**	**-1.36 [-4.18, 1.46]**

Heterogeneity: Tau² = 11.08; Chi² = 42.77, df = 6 (P<0.00001); I² =86%
Test for overall effect: Z = 0.94 (P = 0.35)
Test for subgroup differences: Not applicable

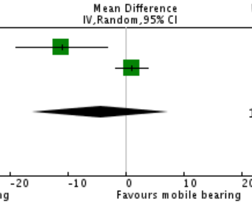


(1) SD estimated from range
(2) SD estimated from range
(3) SD estimated from range
(4) SD estimated from range
(5) SD estimated from average other studies

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 2 Mobile vs fixed bearing, major outcome: clinical and functional scores
Outcome: 5 WOMAC total

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Lizaur-Utrilla 2012	58	71.4 (23.8)	61	82.5 (20.2)	45.1 %	-11.10 [-19.05, -3.15]
Munro 2010	23	97 (2.3)	25	96 (6.8)	54.9 %	1.00 [-1.83, 3.83]
Total (95% CI)	**81**		**86**		**100.0 %**	**-4.46 [-16.26, 7.34]**

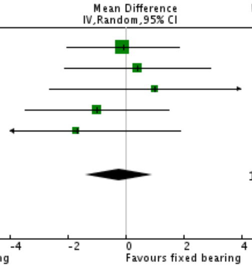
Heterogeneity: Tau² = 63.94; Chi² = 7.90, df = 1 (P = 0.005); I² =87%
Test for overall effect: Z = 0.74 (P = 0.46)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 2 Mobile vs fixed bearing, major outcome: clinical and functional scores
Outcome: 6 Oxford total

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Bailey 2014	170	24 (8.4)	161	24.1 (9.5)	36.0 %	-0.10 [-2.04, 1.84]
Hanush 2010	55	21.4 (7)	50	21 (6.2)	21.2 %	0.40 [-2.13, 2.93]
Lampe 2011	43	21 (9)	40	20 (8)	10.1 %	1.00 [-2.66, 4.66]
Munro 2010	23	17 (3.3)	25	18 (5.3)	22.0 %	-1.00 [-3.48, 1.48]
Price 2003	40	37.6 (8.6)	40	39.3 (7.6)	10.7 %	-1.70 [-5.26, 1.86]
Total (95% CI)	**331**		**316**		**100.0 %**	**-0.25 [-1.41, 0.91]**

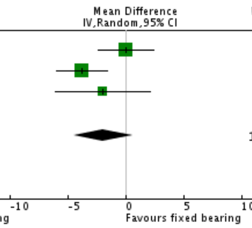
Heterogeneity: Tau² = 0.0; Chi² = 1.72, df = 4 (P = 0.79); I² =0.0%
Test for overall effect: Z = 0.43 (P = 0.67)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 3 Mobile vs fixed bearing, major outcome: health-related quality of life
Outcome: 1 SF-12 PCS

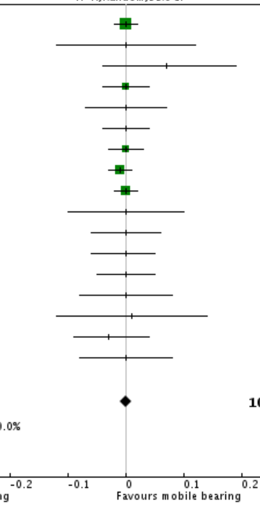
Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Bailey 2014	170	39.9 (11.3)	161	39.9 (11.1)	37.5 %	0.0 [-2.41, 2.41]
Lizaur-Utrilla 2012	58	37.6 (6.2)	61	41.4 (6.1)	39.5 %	-3.80 [-6.01, -1.59]
Munro 2010	23	44 (8.3)	25	46 (6)	23.0 %	-2.00 [-6.13, 2.13]
Total (95% CI)	**251**		**247**		**100.0 %**	**-1.96 [-4.55, 0.63]**

Heterogeneity: Tau² = 3.15; Chi² = 5.18, df = 2 (P = 0.08); I² =61%
Test for overall effect: Z = 1.49 (P = 0.14)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 4 Mobile vs fixed bearing, major outcome: revision surgery
Outcome: 1 Revision surgery

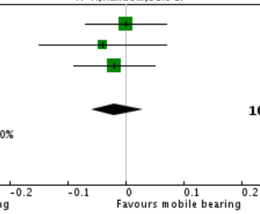
Study or subgroup	Fixed bearing n/N	Mobile bearing n/N	Weight	Risk Difference M-H,Random,95% CI
Bailey 2014	1/170	1/161	27.3 %	0.00 [-0.02, 0.02]
Grodzki 2001	0/12	0/26	0.6 %	0.0 [-0.12, 0.12]
Hansson 2005	2/27	0/25	0.5 %	0.07 [-0.04, 0.19]
Hanush 2010	0/55	0/50	5.7 %	0.0 [-0.04, 0.04]
Henricson 2006	0/26	0/26	1.5 %	0.0 [-0.07, 0.07]
Jacobs 2011	0/46	0/46	4.4 %	0.0 [-0.04, 0.04]
Kim 2001	2/116	2/116	6.8 %	0.0 [-0.03, 0.03]
Kim 2007	0/174	2/174	20.5 %	-0.01 [-0.03, 0.01]
Kim 2009a	0/96	0/96	18.8 %	0.0 [-0.02, 0.02]
Kim 2009b	5/61	5/61	0.8 %	0.0 [-0.10, 0.10]
Kim 2010	0/33	0/33	2.3 %	0.0 [-0.06, 0.06]
Lampe 2011	1/52	1/48	2.5 %	0.00 [-0.06, 0.05]
Lizaur-Utrilla 2012	1/58	1/61	3.6 %	0.00 [-0.05, 0.05]
Munro 2010	0/23	0/25	1.3 %	0.0 [-0.08, 0.08]
Möckel 2004	1/19	1/23	0.4 %	0.01 [-0.12, 0.14]
Price 2003	0/40	1/40	1.7 %	-0.03 [-0.09, 0.04]
Watanabe 2005	0/23	0/23	1.2 %	0.0 [-0.08, 0.08]
Total (95% CI)	**1031**	**1034**	**100.0 %**	**0.00 [-0.01, 0.01]**



Total events: 13 (Fixed bearing), 14 (Mobile bearing)
Heterogeneity: Tau² = 0.0; Chi² = 3.26, df = 16 (P = 1.00); I² =0.0%
Test for overall effect: Z = 0.55 (P = 0.58)
Test for subgroup differences: Not applicable

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 5 Mobile vs fixed bearing, major outcome: mortality
Outcome: 1 Mortality

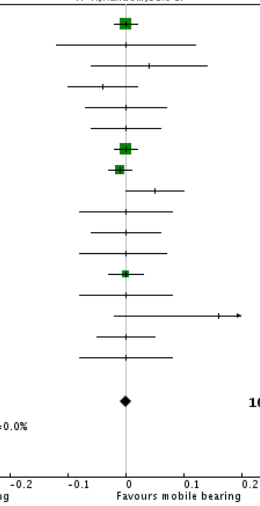
Study or subgroup	Fixed bearing n/N	Mobile bearing n/N	Weight	Risk Difference M-H,Random,95% CI
Hansson 2005	0/27	0/25	41.2 %	0.0 [-0.07, 0.07]
Henricson 2006	0/23	1/24	18.0 %	-0.04 [-0.15, 0.07]
Jacobs 2011	1/46	2/46	40.8 %	-0.02 [-0.09, 0.05]
Total (95% CI)	**96**	**95**	**100.0 %**	**-0.02 [-0.06, 0.03]**



Total events: 1 (Fixed bearing), 3 (Mobile bearing)
Heterogeneity: Tau² = 0.0; Chi² = 0.46, df = 2 (P = 0.79); I² =0.0%
Test for overall effect: Z = 0.69 (P = 0.49)
Test for subgroup differences: Not applicable

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 6 Mobile vs fixed bearing, major outcome: reoperation rate
Outcome: 1 Reoperation rate

Study or subgroup	Fixed bearing n/N	Mobile bearing n/N	Weight	Risk Difference M-H,Random,95% CI
Bailey 2014	1/170	1/161	26.6 %	0.00 [-0.02, 0.02]
Grodzki 2001	0/12	0/26	0.5 %	0.0 [-0.12, 0.12]
Hansson 2005	1/27	0/25	0.8 %	0.04 [-0.06, 0.14]
Hanush 2010	0/55	2/50	1.8 %	-0.04 [-0.10, 0.02]
Henricson 2006	0/26	0/26	1.4 %	0.0 [-0.07, 0.07]
Jacobs 2011	1/46	1/46	2.1 %	0.0 [-0.06, 0.06]
Kim 2001	0/116	0/116	26.6 %	0.0 [-0.02, 0.02]
Kim 2007	1/174	2/174	19.7 %	-0.01 [-0.03, 0.01]
Kim 2009a	6/96	1/96	2.7 %	0.05 [0.00, 0.10]
Kim 2009b	3/61	3/61	1.3 %	0.0 [-0.08, 0.08]
Kim 2010	0/33	0/33	2.3 %	0.0 [-0.06, 0.06]
Lampe 2011	2/52	2/48	1.3 %	0.00 [-0.08, 0.07]
Lizaur-Utrilla 2012	0/58	0/61	7.1 %	0.0 [-0.03, 0.03]
Munro 2010	0/23	0/25	1.2 %	0.0 [-0.08, 0.08]
Möckel 2004	3/19	0/23	0.2 %	0.16 [-0.02, 0.33]
Price 2003	0/40	0/40	3.3 %	0.0 [-0.05, 0.05]
Watanabe 2005	0/23	0/23	1.1 %	0.0 [-0.08, 0.08]
Total (95% CI)	**1031**	**1034**	**100.0 %**	**0.00 [-0.01, 0.01]**

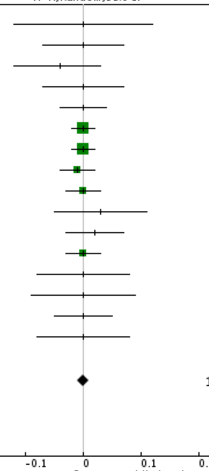


Total events: 18 (Fixed bearing), 12 (Mobile bearing)
Heterogeneity: Tau² = 0.0; Chi² = 10.92, df = 16 (P = 0.81); I² =0.0%
Test for overall effect: Z = 0.02 (P = 0.99)
Test for subgroup differences: Not applicable

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 7 Mobile vs fixed bearing, major outcome: other serious adverse events
Outcome: 1 Serious adverse events

Study or subgroup	Fixed bearing n/N	Mobile bearing n/N	Risk Difference M-H,Random,95% CI	Weight	Risk Difference M-H,Random,95% CI
Grodzki 2001	0/12	0/26		0.6 %	0.0 [-0.12, 0.12]
Hansson 2005	0/27	0/25		1.4 %	0.0 [-0.07, 0.07]
Hanush 2010	1/55	3/50		1.3 %	-0.04 [-0.12, 0.03]
Henricson 2006	0/26	0/26		1.4 %	0.0 [-0.07, 0.07]
Jacobs 2011	0/46	0/46		4.3 %	0.0 [-0.04, 0.04]
Kim 2001	0/116	0/116		26.7 %	0.0 [-0.02, 0.02]
Kim 2007	1/174	1/174		29.6 %	0.0 [-0.02, 0.02]
Kim 2009a	0/96	1/96		9.3 %	-0.01 [-0.04, 0.02]
Kim 2009b	0/61	0/61		7.5 %	0.0 [-0.03, 0.03]
Kim 2010	1/34	0/33		1.2 %	0.03 [-0.05, 0.11]
Lampe 2011	1/52	0/48		2.7 %	0.02 [-0.03, 0.07]
Lizaur-Utrilla 2012	0/58	0/61		7.2 %	0.0 [-0.03, 0.03]
Munro 2010	0/23	0/25		1.2 %	0.0 [-0.08, 0.08]
Möckel 2004	0/19	0/23		0.9 %	0.0 [-0.09, 0.09]
Price 2003	0/40	0/40		3.3 %	0.0 [-0.05, 0.05]
Watanabe 2005	0/23	0/23		1.1 %	0.0 [-0.08, 0.08]
Total (95% CI)	**862**	**873**		**100.0 %**	**0.00 [-0.01, 0.01]**

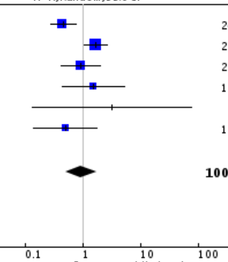
Total events: 4 (Fixed bearing), 5 (Mobile bearing)
Heterogeneity: Tau² = 0.0; Chi² = 2.78, df = 15 (P = 1.00); I² =0.0%
Test for overall effect: Z = 0.15 (P = 0.88)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 8 Mobile vs fixed bearing, minor outcomes: radiological outcomes
Outcome: 1 Radiolucent lines (tibial)

Study or subgroup	Fixed bearing n/N	Mobile bearing n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Bailey 2014	18/170	38/161		24.4 %	0.45 [0.27, 0.75]
Kim 2001	35/116	21/116		25.0 %	1.67 [1.04, 2.68]
Kim 2007	11/174	12/174		20.0 %	0.92 [0.42, 2.02]
Kim 2009a	6/92	4/92		13.7 %	1.50 [0.44, 5.14]
Lizaur-Utrilla 2012	1/58	0/61		3.4 %	3.15 [0.13, 75.86]
Watanabe 2005	3/22	6/22		13.5 %	0.50 [0.14, 1.75]
Total (95% CI)	**632**	**626**		**100.0 %**	**0.92 [0.49, 1.72]**

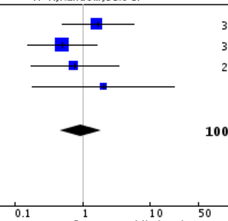
Total events: 74 (Fixed bearing), 81 (Mobile bearing)
Heterogeneity: Tau² = 0.35; Chi² = 15.50, df = 5 (P = 0.01); I² =68%
Test for overall effect: Z = 0.26 (P = 0.79)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 8 Mobile vs fixed bearing, minor outcomes: radiological outcomes
Outcome: 2 Radiolucent lines (femoral)

Study or subgroup	Fixed bearing n/N	Mobile bearing n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Bailey 2014	7/170	4/161		33.5 %	1.66 [0.49, 5.55]
Kim 2001	4/116	8/116		35.6 %	0.50 [0.15, 1.61]
Kim 2007	3/174	4/174		22.3 %	0.75 [0.17, 3.30]
Kim 2009a	2/92	1/92		8.6 %	2.00 [0.18, 21.67]
Total (95% CI)	**552**	**543**		**100.0 %**	**0.92 [0.46, 1.85]**

Total events: 16 (Fixed bearing), 17 (Mobile bearing)
Heterogeneity: Tau² = 0.0; Chi² = 2.43, df = 3 (P = 0.49); I² =0.0%
Test for overall effect: Z = 0.23 (P = 0.82)
Test for subgroup differences: Not applicable



Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 8 Mobile vs fixed bearing, minor outcomes: radiological outcomes
Outcome: 3 Radiolucent lines (overall)

Study or subgroup	Fixed bearing n/N	Mobile bearing n/N	Weight	Risk Ratio M-H,Random,95% CI
Jacobs 2011	24/46	21/46	37.0 %	1.14 [0.75, 1.74]
Kim 2001	39/116	29/116	39.5 %	1.34 [0.90, 2.02]
Kim 2007	14/174	16/174	13.8 %	0.88 [0.44, 1.74]
Kim 2009a	8/92	5/92	5.6 %	1.60 [0.54, 4.71]
Kim 2009b	5/61	4/61	4.1 %	1.25 [0.35, 4.43]
Total (95% CI)	**489**	**489**	**100.0 %**	**1.20 [0.93, 1.55]**

Total events: 90 (Fixed bearing), 75 (Mobile bearing)
Heterogeneity: Tau² = 0.0; Chi² = 1.45, df = 4 (P = 0.84); I² =0.0%
Test for overall effect: Z = 1.41 (P = 0.16)
Test for subgroup differences: Not applicable

0.1 0.2 0.5 1 2 5 10
Favours fixed bearing Favours mobile bearing

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 8 Mobile vs fixed bearing, minor outcomes: radiological outcomes
Outcome: 4 Femorotibial alignment

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Kim 2001	116	4.5 (1.8)	116	5.3 (0.8)	26.3 %	-0.80 [-1.16, -0.44]
Kim 2007	174	5.3 (2.8)	174	5.4 (3.2)	19.6 %	-0.10 [-0.73, 0.53]
Kim 2009a	92	5 (2)	92	6 (1.8)	21.6 %	-1.00 [-1.55, -0.45]
Kim 2009b	61	4.8 (2.3)	61	5.1 (2.3)	15.6 %	-0.30 [-1.12, 0.52]
Lizaur-Utrilla 2012	58	5.2 (2.4)	61	4.7 (2.9)	13.2 %	0.50 [-0.45, 1.45]
Watanabe 2005	21	7.5 (4)	21	6.8 (3.3)	3.7 %	0.70 [-1.52, 2.92]
Total (95% CI)	**522**		**525**		**100.0 %**	**-0.40 [-0.86, 0.06]**

Heterogeneity: Tau² = 0.17; Chi² = 12.55, df = 5 (P = 0.03); I² =60%
Test for overall effect: Z = 1.72 (P = 0.085)
Test for subgroup differences: Not applicable

-2 -1 0 1 2
Favours fixed bearing Favours mobile bearing

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 9 Mobile vs fixed bearing, minor outcomes: performance outcome
Outcome: 1 Flexion

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Hanush 2010	58	105.2 (13.6)	61	110.1 (13.6)	11.3 %	-4.90 [-9.79, -0.01]
Higuchi 2009	43	113 (13)	40	115 (11)	10.1 %	-2.00 [-7.17, 3.17]
Jacobs 2011	33	130 (10.2)	33	131.6 (9.2)	12.2 %	-1.60 [-6.29, 3.09]
Kim 2001	22	106.9 (8.8)	22	106.9 (10)	8.7 %	0.0 [-5.57, 5.57]
Kim 2010	17	106 (13)	16	102 (12)	3.7 %	4.00 [-4.53, 12.53]
Lampe 2011	45	110.8 (15.6)	31	115.8 (13.6)	6.2 %	-5.00 [-11.61, 1.61]
Lizaur-Utrilla 2012	58	108.7 (12.6)	61	109.5 (11.4)	14.4 %	-0.80 [-5.12, 3.52]
Tibesku 2011	33	129.2 (10.8)	33	130.2 (8.7)	12.0 %	-1.00 [-5.73, 3.73]
Watanabe 2005	116	120.9 (13.75)	116	123.2 (13.75)	21.5 %	-2.30 [-5.84, 1.24]
Total (95% CI)	**425**		**413**		**100.0 %**	**-1.84 [-3.48, -0.20]**

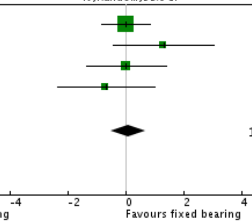
Heterogeneity: Tau² = 0.0; Chi² = 5.03, df = 8 (P = 0.75); I² =0.0%
Test for overall effect: Z = 2.20 (P = 0.028)
Test for subgroup differences: Not applicable

-10 -5 0 5 10
Favours mobile bearing Favours fixed bearing

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 9 Mobile vs fixed bearing, minor outcomes: performance outcome
Outcome: 2 Extension

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Hanush 2010	55	0.7 (2)	50	0.7 (2.3)	54.6 %	0.0 [-0.83, 0.83]
Higuchi 2009	45	1.6 (4.5)	31	0.3 (3.2)	12.5 %	1.30 [-0.43, 3.03]
Kim 2010 (1)	33	0 (2.6)	33	0 (3.1)	19.6 %	0.0 [-1.38, 1.38]
Watanabe 2005 (2)	22	0.4 (1.3)	22	1.1 (3.8)	13.3 %	-0.70 [-2.38, 0.98]
Total (95% CI)	**155**		**136**		**100.0 %**	**0.07 [-0.54, 0.68]**

Heterogeneity: Tau² = 0.0; Chi² = 2.78, df = 3 (P = 0.43); I² =0.0%
Test for overall effect: Z = 0.22 (P = 0.82)
Test for subgroup differences: Not applicable

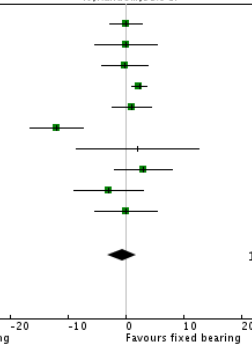


(1) SD based on average SD's other studies
(2) SD estimated from range

Review: Mobile bearing vs fixed bearing prostheses for posterior cruciate retaining total knee arthroplasty for postoperative functional status in patients with osteoarthritis and rheu
Comparison: 9 Mobile vs fixed bearing, minor outcomes: performance outcome
Outcome: 3 Range of motion

Study or subgroup	Fixed bearing N	Fixed bearing Mean(SD)	Mobile bearing N	Mobile bearing Mean(SD)	Weight	Mean Difference IV,Random,95% CI
Bailey 2014	170	104 (13)	161	104 (13)	12.7 %	0.0 [-2.80, 2.80]
Hansson 2005 (1)	122	117 (12.2)	25	117 (12.8)	8.9 %	0.0 [-5.46, 5.46]
Hanush 2010	55	100.8 (10.1)	50	101 (11)	10.9 %	-0.20 [-4.25, 3.85]
Henricson 2006	26	112.7 (1.9)	26	110.4 (2.5)	14.6 %	2.30 [1.09, 3.51]
Kim 2007	174	131 (17.5)	174	130 (15)	11.8 %	1.00 [-2.42, 4.42]
Kim 2009a (2)	92	115 (16.3)	92	127 (15)	10.2 %	-12.00 [-16.53, -7.47]
Kim 2009b	61	120 (30)	61	118 (29.5)	4.2 %	2.00 [-8.56, 12.56]
Munro 2010	23	117 (8.8)	25	114 (8.8)	9.5 %	3.00 [-1.98, 7.98]
Möckel 2004 (3)	27	105 (8.8)	12	108 (8.8)	8.2 %	-3.00 [-8.98, 2.98]
Price 2003	40	105.3 (12.6)	40	105.3 (11.9)	9.0 %	0.0 [-5.37, 5.37]
Total (95% CI)	**790**		**666**		**100.0 %**	**-0.67 [-3.21, 1.87]**

Heterogeneity: Tau² = 11.12; Chi² = 39.60, df = 9 (P<0.00001); I² =77%
Test for overall effect: Z = 0.52 (P = 0.61)
Test for subgroup differences: Not applicable



(1) SD estimated of average SD's other included studies
(2) SD estimated from range
(3) SD estimated from range

11

Chapter 12

General Discussion

The aim of the present thesis was to extend the knowledge in the field of implementation science by examining how care delivery for patients with hip and knee OA or sciatica can be optimized. Part 1 focused on the optimization of care delivery for patients with hip and knee OA and sciatica, when evidence is available in existing guidelines on what optimal care is. It is then important to gain insight into reasons why guidelines are not always followed (i.e. barriers and facilitators) to improve implementation. However, sometimes evidence underlying the guideline is still lacking and more evidence needs to be generated. Guidelines for patients with hip and knee OA for example do not include specific information on when to perform a THA or TKA. Since this evidence about optimal timing of THA or TKA is still lacking, more evidence is needed on which determinants influence outcome after surgery so that the timing of surgery is optimal and will lead to the best possible outcomes. Therefore, part 2 focused on getting more evidence regarding determinants that will optimize surgical care in hip and knee OA.

Part 1 Implementation of evidence based guidelines

Part 1 aimed to contribute knowledge to improve guideline uptake regarding the use of non-surgical and surgical interventions in hip and knee OA and sciatica care. In hip and knee OA care, recommended non-surgical treatments are underused, while in sciatica care there is a lack of use of shared decision making (SDM) when to choose between non-surgical and surgical treatment. From the literature it is known that an inventory of barriers and facilitators is useful for the development of a tailor-made implementation strategy [1-3]. Such an inventory reduces the number of costly trials evaluating different implementation strategies [4-6]. Therefore, barriers and facilitators for the implementation of non-surgical interventions in hip and knee OA [7] and the use of SDM in sciatica care were determined [8]. By comparing two different implementation issues in different conditions, it is possible to determine whether generalized knowledge can be extracted from these different studies, or to conclude that it is necessary to perform a barriers and facilitators assessment for each implementation issue.

Barriers and facilitators for the implementation of guidelines: general findings

Although hip and knee OA and sciatica are two different conditions with different implementation issues, barriers and facilitators reported by health care providers showed similarities. For the implementation of evidence based guideline recommendations it appeared that knowledge and attitude of health care providers and organization of care played an important role whether guidelines were applied.

Knowledge and attitudes

First, barriers and facilitators related to knowledge and attitudes of health care providers appeared to influence the use of guidelines in hip and knee OA and sciatica. In hip and knee OA, an important barrier for the use of non-surgical care was lack of knowledge on the effectiveness of non-surgical interventions among orthopaedic surgeons. In sciatica care, an important barrier was knowledge about the outcomes of surgical and non-surgical treatment options in primary and secondary care, resulting in lack of usage of SDM in sciatica care. Sciatica patients also indicated that knowledge, in the form of information provision about treatment options and potential harm and benefits played a role in the usage of SDM. The finding that knowledge is important in the uptake of guidelines is in line with the literature. A systematic review regarding barriers to apply evidence-based medicine (EBM) also found that the most common barrier in management and decision making was a lack of knowledge [9], which is consistent with the findings in this thesis.

Implicitly related to the lack of knowledge was the attitude of orthopaedic surgeons to the effectiveness of non-surgical treatments. An example of this is the attitude of orthopaedic surgeons towards physical therapy: they think physical therapy is not an effective treatment for patients with hip OA. This attitude towards the effectiveness was associated with lower use of non-surgical treatments. However, this attitude towards physical therapy was not found in a previous study among GP's [10]. The discrepancy in views may be due to different health care professionals seeing patients with the same condition at different stages: GP's often are the first health care provider in a care trajectory, whereas orthopaedic surgeons more often see the patients who have already used several non-surgical treatments but still have complaints with the overall benefit being less.

Organization of care

Other important overlapping barriers and facilitators perceived by health care providers in both conditions concerned the organization of care, such as communication and collaboration between health care providers from different disciplines. This is possibly due to the multidisciplinary character of care for hip and knee OA and sciatica patients. In both conditions, there are not only multiple disciplines involved (e.g. GP and physical therapist), but they are also working within different settings of care (primary, secondary and tertiary care). Moreover, some treatments concerned interventions which can only be delivered by a specific health care provider, such as a physical therapist or dietician, so that referral by a physician or advice for self-referral is needed. Both health care providers and patients found that a good collaboration between health care providers was important for the use of non-surgical treatments in both conditions. Another example of barriers and facilitators related to the organization of care was a good patient-health provider relationship for the use of guidelines in both sciatica and OA care. In sciatica care, the quality of professional-patient relationship was considered as most important for the use of SDM in sciatica care. In OA care good guidance by the physical therapist was associated with more use of physical therapy. Other studies did not mention the organization of care frequently as a barrier or facilitator. This can possibly be explained by the fact that previous studies into barriers and facilitators only included one discipline or one setting, whereas the barriers and facilitators in this thesis were assessed for two conditions where care is provided by multiple disciplines and in multiple settings. Furthermore, previous research mainly focused on barriers and facilitators at the patient level [11,12], but the results of this thesis show that it is important to also focus on other levels, such as the organization.

Barriers and facilitators: condition specific findings

Besides similarities in barriers and facilitators perceived by health care providers and patients, also condition specific barriers and facilitators were found regarding implementation of recommendations in guidelines. For OA care, the use of non-surgical treatment was hampered by the pressure that orthopaedic surgeons perceived from patients to perform a surgery and by the experience and advices from patients' environment, which was not mentioned as an important barrier or facilitator in sciatica care. In sciatica care on the other hand, SDM was hampered by the assumption of health care providers that patients want to recover quickly. As a consequence of this assumption they did not make a shared decision, but recommended surgery. It is important though to determine patients' views on the importance of speed of recovery and this is part of the SDM process.

Comparison of identified barriers and facilitators with the literature

The results in this thesis showed that knowledge and attitude of health care providers and organization of care played an important role whether guidelines were applied, but is this also consistent with the literature? A recent systematic review on barriers for the implementation of guidelines included 106 studies [9]. In total, 155 barriers were identified. The most commonly reported barriers were: lack of resources (24/155 barriers) (e.g. inadequate facilities, lack of medical resources) and inadequate access (22/155 barriers) (e.g. guidelines are too complicated or difficulty to find the information). Other common barriers were lack of time and research (e.g. conflicting methods, literature not being compiled in one place), which is also related to knowledge. Another systematic review focused on barriers and facilitators to implement SDM in clinical practice [13]. In this review only 7 out of the 38 studies reported that lack of knowledge (familiarity) was a barrier for using SDM. The three most often reported barriers were: time constraints (22/38 studies) and lack of applicability due to patient characteristics (18/38 studies) and the clinical situation (16/38 studies). The three most often reported facilitators were: provider motivation (23/38 studies) and positive impact on the clinical process (16/38 studies) and patient outcomes (16/38 studies)[13].

The previously mentioned reviews found some barriers and facilitators consistent with the findings in this thesis, but also different barriers and facilitators were found between the literature and this thesis. Part of these differences may be explained by the multidisciplinary character of care for hip and knee OA and sciatica patients. This comes with different barriers and facilitators compared to monodisciplinary care, which is mostly described in the literature. Next to this explanation, the difference in barriers and facilitators may also be caused by the use of different methods. So far, the use of qualitative methods is most common. For example in a review about barriers and facilitators to implement SDM 21 of the 38 studies used qualitative methods exclusively, 11 used quantitative methods exclusively and only six studies used mixed methods [13]. With a qualitative study, the perspective of a respondent takes the center stage and the purpose is to gain some deeper understanding on the respondent's perspective [14]. This is difficult, if not impossible, to reach with a quantitative design. Using only quantitative methods it is possible that the researchers' personal hypothesis is tested instead of a rather complete set of possible barriers and facilitators since no 'new' perspectives will be explored [15]. On the other hand, information on the importance of each barrier or facilitator is also needed, warranting the need for a quantitative approach.

In this thesis, a combination of qualitative and quantitative studies was employed, with the aim to obtain a complete view on barriers and facilitators. The added value of this approach was demonstrated by the observation that barriers and facilitators most often mentioned in the qualitative part of the studies in this thesis [16], were not always consistent with the highest ranked barriers or facilitators [17]. For example during interviews about SDM in sciatica care, health care providers mentioned lack of knowledge about treatment options only a few times, whereas it was ranked as an important barrier in the subsequent survey [17]. Likewise, lack of time during a consultation was mentioned often during interviews, and is also the most mentioned barrier for SDM in other studies [18]. But in the quantitative part, time during a consultation only took a 33rd place, and did not occur in any of the health care providers top 5. This emphasizes the importance of a combination of methods to determine barriers and facilitators.

Implementation strategies

The identification of barriers and facilitators is just the first step for the implementation of guidelines. If barriers and facilitators are identified, an effective implementation strategy needs to be developed. Different methods can be used to develop an implementation strategy. One of these methods is the intervention mapping approach of Bartholomew et al.[19]. This method begins with the creation of matrices in which the specific recommendations of guidelines are set against the most important barriers and facilitators. Subsequently, a project team can brainstorm about the interventions needed to achieve the performance objective in the presence of the barrier or facilitator mentioned in the matrix. During this process a theoretical model can be identified to change the barriers and facilitators. The theoretical model proposed by Woolf [20] was used in this thesis that links the intensity of enforcement to the scientific and clinical quality of guidelines, called the "mechanism of action" of practice guidelines. This model says that guideline recommended outcomes can be reached through the steps of changing practitioner's knowledge, attitudes, and behavior [20]. Eventually, the cells of the matrices are gradually filled with interventions [21] and the formulated strategy components are translated into interventions.

In this thesis two specific implementation strategies for the management of the two conditions using the intervention mapping approach were developed. Figure 1 shows the identified overlapping and condition specific barriers and facilitators related to each level of the mechanism of action (knowledge, attitude and behavior), the theory-based model that was used [20] and the different interventions geared at these barriers and facilitators to improve the implementation of the use of non-surgical treatments in hip and knee OA care and the use of SDM in sciatica care. The proposed interventions were interactive education, feedback about the use of SDM (specific for sciatica), tools for patients and health care providers such as an information booklet, obesity clinics (specific for OA) and agreements between disciplines. Figure 1 also shows at which barriers and facilitators these interventions are geared and with which level of the mechanism of action the barriers and facilitators are associated. The results of the inventory of barriers and facilitators indicated that both implementation strategies should be geared at improving the knowledge and attitude of health care providers and the organization of care.

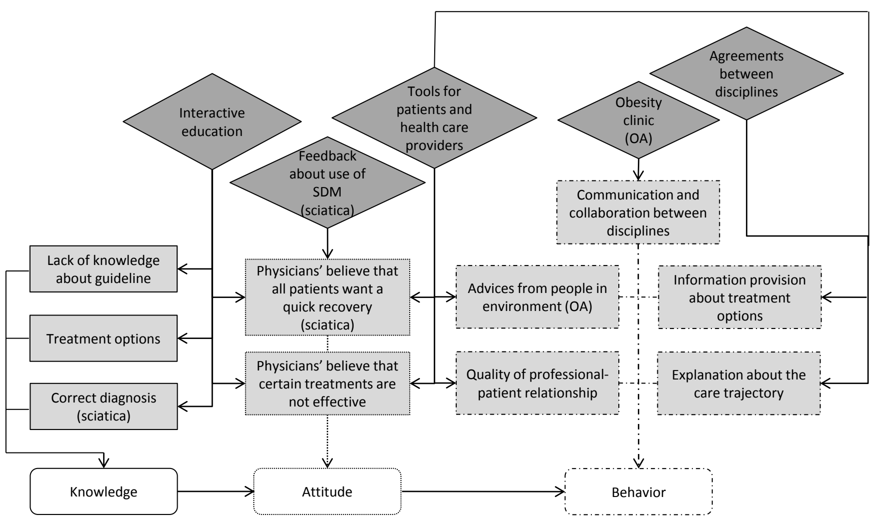


Figure 1. The mechanism of action [20] with identified barriers and facilitators at each level and different interventions to improve the implementation of the guidelines of hip and knee OA and sciatica

Knowledge and attitude

Both implementation strategies should be geared at improving knowledge and attitude of health care providers by providing interactive education [4] on specific topics (e.g. about evidence underpinning the effectiveness of different treatments and SDM). For example a barrier for not using physical therapy was that orthopaedic surgeons did not belief in the effectiveness of this treatment for OA. This could be due to not making a clear distinction between the effectiveness of physical therapy in the non-surgical management of hip and knee OA and physical therapy in end stage OA where the indication for surgery is already set. The first physical therapy intervention aims to reduce patients' symptoms in early stage OA and may thereby delay or diminish the need of surgery. This treatment is proven to be effective and recommended in multiple guidelines [22-26]. The second intervention concerns specific preoperative physical therapy programs aiming to improve postoperative recovery, which is not proven to be effective [27-30]. Interactive education about this and other topics can be provided to extend their knowledge for example by using e-learnings. The duration of interactive education in trainings may be less than 10 hours since research has shown that short-term training (less than 10 hours) is as successful as longer training for promoting patient-centered care (e.g. using SDM) within clinical consultations [31].

The interactive education only focusses on health care providers while it is also important to involve patients. Research has shown that interventions targeting patients and healthcare professionals together show more promise than those targeting only one or the other [32]. Therefore, in addition to interactive education, specific tools for both patients and health care providers may improve the information provision and thereby improve knowledge and facilitate the decision making. An example of such a tool is the BART (Beating osteoARThritis) stepped care strategy for hip and knee OA, which is already available and introduced in primary care [33,34]. Part of this strategy is a booklet for patients, containing information about the disease and different treatments. However, this strategy should be updated, since treatments like glucosamine, hyaluronic acid and TENS are not proven effective treatments but still included in the stepped care strategy. Therefore health care providers may question this strategy rather than using it. For sciatica, a decision tool is also already available [35]. This tool may be useful to facilitate the SDM process. Research has shown that offering decision aids increases the number of patients who prefer non-surgical treatments, improve patient knowledge and reduce decisional conflict. It helps surgeons and patients to achieve well-considered and shared treatment decisions [36].

Organization of care

Even when health care providers have sufficient knowledge and their attitude towards recommendations is positive, the organization of care remains a problem. Therefore, another part of the implementation strategies for both conditions is geared at improving the organization of care. An example concerns the relative underuse of the dietician in obese patients. Making referrals to a dietician in primary care, whom they may not know personally, was a barrier. During the interviews with orthopaedic surgeons some mentioned a successful collaboration with obesity clinics in their hospital. Dietary therapy becomes even more important due to the increasing number of obese people and an obesity clinic may facilitate this dietary therapy. However, additional research is necessary to assess the feasibility and cost-effectiveness of obesity clinics.

Another improvement that can be made regarding the organization is that the care trajectory should become clearer by making agreements between disciplines about the moment of information provision in both OA and sciatica care. For example who is responsible for which part of the information provision or guidance in which step of the care trajectory? This is especially important in multidisciplinary settings such as in OA and sciatica care.

Generalized knowledge of implementation strategies

The previously mentioned elements on knowledge, attitude and organization of care are not restricted to one specific disease or health care system. Therefore, interventions geared at these topics may also be used for implementation of guidelines in other patients groups or other implementation problems with multiple disciplines involved. However, the condition specific barriers and facilitators that were also identified suggests that that there is no “one size fits all” solution for the implementation of guidelines, and implementation strategies should be partly tailored to a specific implementation problem. An inventory of disease specific barriers and facilitators remains necessary and may lead to more disease specific interventions. Therefore, in addition to interactive education and optimizing the organization of care, a strategy for OA should also focus on involving patient’s environment (partner, family members) for example during a consultation and if possible also provide the decision tools to these persons. Whereas the implementation strategy for SDM in sciatica care should also be targeted at feedback about the use of SDM. This can be done for example by examining the use of SDM from patients and professionals perspective, using the SDM-9 [37], the Dyadic OPTION scale [38,39], and the Control Preference Scale [40] and report the numbers to the health care provider. Since many health care providers already perceived they used SDM in sciatica care even when they in fact did not, feedback can provide them more insights into their actual use of SDM.

Comparison of implementation strategies with the literature

Other studies developed implementation strategies, but used different methods. Although a structured approach including barrier assessment for the development of guideline implementation strategies is advocated, it is not yet commonly used. A scoping review on trends in guideline implementation found that only one out of the 32 studies mentioned the identification of barriers [41]. Another systematic review including 39 studies that examined the effect of interventions to improve adoption of SDM in different conditions showed that only three of the 39 studies based their interventions on barriers assessments [32]. These three studies used multifaceted interventions and were all effective [42-44], while overall the authors of the review concluded that it was uncertain whether interventions to improve adoption of SDM are effective given the low quality of the evidence [32].

Besides that the implementation strategies in this thesis are based on identified barriers and facilitators, they also target both patients and health care providers. Gagliardi et al. [41] found that most studies focused on health care providers only. Legaré et al. [32] included 39 in a review, only three targeted more than one type of health care providers, but all these three studies had favorable outcomes. The authors also concluded that interventions targeting patients and healthcare professionals together show more promise than those targeting only one or the other [32].

Where to go next?

Most studies known in literature examined the effect of interventions without barriers assessment, in a monodisciplinary setting (only one type of health care provider) or among health care providers only (no patients included). This led to a low quality of evidence regarding effectiveness of interventions to improve adoption of SDM [32]. In the studies in this thesis, barriers assessments were performed, in a multidisciplinary setting and among both health care providers and patients. Since the literature shows that such strategies are more effective [4-6] than interventions without barriers assessment, in a monodisciplinary setting (only one type of health care provider) or among health care providers only (no patients included), the proposed implementation strategies are likely to improve the use of non-surgical care in OA and SDM in sciatica. Future studies should assess whether the developed implementation strategies are indeed effective. This could be done for example by a cluster RCT or a controlled before-after study among health care providers including an effect-, process- and economic evaluation in intervention and control hospitals and primary health care providers in the same region. The control group should receive usual care (passive dissemination of evidence) and the intervention group should receive the strategies as described above. No such interventions have been performed so far regarding improvement of the use of non-surgical care in OA and SDM in sciatica.

Part 2 The optimization of surgical care in hip and knee osteoarthritis

Care delivery cannot always be optimized by implementing existing guidelines, for example when evidence underlying the guideline is lacking. The hip and knee OA guidelines are for example not specific about when to perform a THA of TKA, partly because evidence is lacking about what the optimal timing of surgery is. If evidence is lacking, more knowledge needs to be generated to develop evidence based recommendations in guidelines and thereby optimize care. Specific issues about this topic that were addressed in part 2 of this thesis were: what are the evidence based indications to perform surgery and what are criteria and determinants to achieve the best possible patient outcomes after surgery? And does the type of prosthesis matter?

Criteria and determinants to reach the best outcomes after surgery

Guidelines are based on the best available evidence, but it is important to realize that sometimes the evidence is limited, and thus recommendations in guidelines are more expert based than evidence based. A review in this thesis showed that currently evidence-based indication criteria for THA or TKA are lacking, so that it is more important to generate more evidence about this topic. To strengthen the evidence base for indication criteria, knowledge is needed on which patients reach the best outcomes after surgery. A literature search on the determinants suggested that future research should focus on preoperative function to decide when THA will be most effective. However, most results were contradictory both with respect to the association and direction of age, gender and BMI with postoperative outcomes. These conflicting results can possibly be due to the high risk of bias in many included studies or estimates based on studies with a lack of power. Thus regardless of the amount of existing studies, when all included studies are of low quality, more original research of high quality is needed.

To gather more evidence about which determinants influence outcomes after THA or TKA, a pooled analysis of 19 prospective observational cohort studies with OA patients (2400 THA and 1783 TKA) was performed from hospitals throughout the Netherlands so that lack of power could not be an issue. This pooled analysis showed that patients with better preoperative quality of life functioning and less pain had better postoperative outcomes.

Timing of surgery

OA is often described as a progressive disease, meaning a (slowly) worsening condition over time. Optimal timing suggests that surgery can be delayed, but to what extent if the disease is worsening over time and given the above described results, that patients who received a joint replacement earlier in their clinical course (and thus with a better preoperative status) have a better outcome? There are two aspects that need to be considered. First, the natural course of the disease i.e. the prognosis of OA should be examined to assess whether worsening occurs in all patients. The second question that needs to be answered is whether the same outcomes can be reached when surgery is delayed and only non-surgical treatment is given rather than THA or TKA.

Natural course of OA

Given the results in this thesis that patients with a better preoperative status have better postoperative results, it is important to examine whether functioning or pain in hip or knee OA patients become worse over time, so if a worsening of functioning or pain in hip or knee OA patients is followed by further worsening or whether this fluctuates randomly over time. Indications for such fluctuations were found in a study of De Rooij et al.[45]. The authors performed a meta-analysis on prognosis of pain and physical functioning in patients with knee OA in studies with a follow-up up to 8 years. They could not draw any conclusions with regard to the course of pain and physical functioning, due to the high heterogeneity across studies.

Other studies that examined progression of OA also found inconclusive results. Van Dijk et al.[46] described the limitations in activities in hip or knee OA patients in a three-year cohort study and found that at group level, limitations in activities of patients with hip or knee OA seemed fairly stable during the first three years of follow-up. However, at the level of individual patients, considerable variation occurred from deterioration to improvement. The same results were found after a follow-up of five years [47]. In another systematic review it was found that pain and functional status in hip or knee OA patients deteriorate slowly with limited evidence for worsening after three years. In specific subgroups, prognosis in the first three years of follow-up was either worse or better [48]. Bastick et al.[49] tried to identify these subgroups of patients who deteriorate. The authors examined prognostic factors for radiographic progression of knee OA in a meta-analysis and concluded that baseline knee pain, presence of Heberden nodes, varus alignment, and high levels of serum markers hyaluronic acid and tumor necrosis factor-α predicted knee OA progression. However, they also concluded that evidence for the majority of determined associations, was limited, conflicting, or inconclusive. The above mentioned studies showed heterogeneous findings regarding to progression of OA and thus it is important to gain more insights into subgroups of patients. Which patients deteriorate during time, which patients remain stable and which patients improve after a couple of years? Based on the previously described literature, there is no conclusive evidence whether there is continuous worsening or random fluctuation in pain and functioning over time for all patients or only for some subgroups.

Non-surgical versus surgical treatment

In addition to uncertainties about the natural course of the disease, the second question is whether the same outcomes can be reached if surgery is delayed with non-surgical treatment. The recommended non-surgical treatments in guidelines are proven to be effective, but are outcomes comparable with outcomes after THA or TKA? Recently, Skou et al.[50] performed a randomized controlled trial (RCT) in which patients were randomly assigned in two groups. Patients in one group received a TKA followed by 12 weeks of nonsurgical treatment, patients in the other group received only 12 weeks of non-surgical treatment. The authors concluded that patients with a TKA followed by non-surgical treatment resulted in greater pain relief and functional improvement after 12 months than did non-surgical treatment alone, but that both groups had clinically relevant improvements. In addition, TKA was associated with a higher number of serious adverse events. Thus a TKA resulted in greater pain relief and functional improvement, but also in a higher number of serious adverse events. Furthermore, the lifespan of a prosthesis is limited and outcomes are usually worse after revision than after primary arthroplasty [51]. Non-surgical treatments also resulted in clinically relevant improvements. Thus the best treatment option remains unclear. Furthermore, long term results are unknown and need to be examined. In addition, no such a study was conducted for THA. It is important to assess whether a comparable study for THA should have the same results. Future studies are needed to examine whether a delay in surgery achieves the same outcomes for patients.

Type of prosthesis

If the decision is made to replace a joint, the orthopaedic surgeon has to decide which implant should be used to reach the best possible outcomes. Therefore, another question in this thesis was: does the type of prosthesis matter? In recent decades a large variety of types of prostheses have become available. An example of a new development is the mobile (meniscal or rotating) bearing TKA with a polyethylene insert that has some freedom of movement. New types of prostheses are often introduced in clinical practice without appropriate assessment [52]. Therefore, in this thesis the mobile bearing prosthesis with a fixed bearing prosthesis were compared using a meta-analysis of RCTs. Existing RCTs were included comparing mobile bearing with fixed bearing prostheses in cruciate retaining TKA among patients with OA or rheumatoid arthritis, using functional or clinical outcome measures and follow-up of at least six months. Moderate-to low-quality evidence suggests that mobile bearing prostheses may have similar effects on knee pain, clinical and functional scores, health-related quality of life, revision surgery, mortality, reoperation rate and other serious adverse events compared with fixed bearing prostheses in posterior cruciate retaining TKA. However, the meta-analysis was underpowered to detect differences in revision rate, specific reasons for revision and mortality. Because of the low numbers of revisions and mortality it is difficult to show differences using RCTs that on average have a follow-up period of a few years.

To show possible differences regarding these outcomes and after a longer follow-up period, the scope may be widened to observational studies and include studies that report outcomes in greater detail, with sufficient follow-up time to allow gathering of high-quality evidence and to inform clinical practice. Large registry-based studies may have added value, but they are subject to confounding by indication. More complex analyses are needed to control for this type of confounding and thereby improve the quality of evidence, for example by using an instrumental variable.

Where to go next?

In part 2, knowledge is generated to develop evidence based recommendations in the hip and knee OA guideline. However, a number of issues remain that need to be resolved before a clear guideline recommendation about the optimal timing of THA/TKA can be formulated. This thesis showed that a better preoperative status leads to better postoperative outcomes, however if a patient's status remain stable during the course of OA, postponing a surgery does not lead to a worse preoperative status with worse postoperative outcomes. In addition, previous studies searching for predictors or determinants for the best outcome and the studies in this thesis showed that evidence is often contradictory. Furthermore, research has shown that 10-20% of the patients are not satisfied after primary THA/TKA [53-56] while nothing seems to be clinically wrong with their prosthesis. Maybe there is not just one solution for all patients and researchers should stop quantifying all OA patients with their predefined assumptions and focus on patients' perspectives. For example why are patients not satisfied? What were their expectations? And were these expectations met? These are questions that cannot be answered with a prediction model or other quantitative methods, although researchers tried to do so [57-59]. These questions can be answered using qualitative methods. Qualitative methods shift the balance between the researcher and the researched and remains open to concepts that emerge may be completely different. It can be used to get detailed findings on people's views and experiences, which cannot be examined using quantitative methods only.

Conclusion

Part 1 of this thesis showed that there are general topics that need be focused on when evidence based guideline recommendations need to be implemented in a multidisciplinary setting, regardless of the condition. These topics are knowledge and attitude of health care providers and organization of care. Future implementation studies can start focusing on these topics if it is not feasible to perform a barrier assessment. However, also different barriers and facilitators for each different condition were found. This shows that each different condition needs a barrier assessment to be able to gear an implementation strategy at all existing barriers and facilitators. This will most likely result in improved implementation of evidence based guidelines.

If information in the literature is lacking, more knowledge needs to be generated to develop evidence based recommendations in guidelines. Part 2 of this thesis showed that evidence based recommendations for indication criteria for THA or TKA are lacking in the literature. Pooling multiple cohort studies in the Netherlands showed that preoperative status is the most important variable for outcome after both THA and TKA, i.e. patients with better preoperative quality of life, functioning and less pain had better postoperative outcomes. This does not mean that patients who received a joint replacement earlier in their clinical course have a better outcome. To determine whether this is true, more knowledge is needed about the progression of OA in different subgroups and whether the same outcomes can be reached with non-surgical treatment as with THA and TKA since literature about these topics is inconclusive.

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Chapter 13

Summary

Many decisions are made in health care. For example when a patient is diagnosed with a certain disease the patient and health care provider are facing multiple decisions. One of these decisions for some musculoskeletal non-acute conditions is to choose between non-surgical and surgical treatments. Surgery is then often not the first choice of treatment. Initial treatment includes non-surgical treatments and surgery is only considered if the patient does not respond sufficiently to non-surgical treatment. Hip and knee osteoarthritis (OA) and sciatica are both non-acute conditions in which the decision of non-surgical versus surgical treatment is complex.

This thesis aims to contribute to the optimal use of non-surgical treatment and timing of surgery among hip and knee OA and sciatica patients. Guidelines are important in this respect because these are based on the best available evidence, it is known from the literature that health care providers do not always follow guidelines. If the evidence regarding use of non-surgical treatment and when to perform surgery is already specific and included in the guideline, efforts can be undertaken to facilitate implementation of these guidelines. To that end, it is important to gain insight into reasons why guidelines are not always followed (i.e. barriers and facilitators). This is the focus of part 1 of this thesis.

However, care delivery cannot always be optimized by implementing existing guidelines. The hip and knee OA guidelines are for example not specific about when to perform a total hip or knee arthroplasty (THA or TKA), partly because evidence is lacking about what the optimal timing of surgery is. If evidence is lacking, more knowledge needs to be generated to develop evidence based recommendations in guidelines and thereby optimize care. Specific issues about this topic that are addressed in part 2 of this thesis are: what are the evidence based indications to perform surgery and what are criteria and determinants to achieve the best possible patient outcomes after surgery? And does the type of prosthesis influence these outcomes?

Part 1 Implementation of evidence based guidelines

The first part of this thesis focuses on implementation strategies to improve guideline uptake regarding the use of non-surgical and surgical interventions in hip and knee OA and sciatica care. National and international evidence-based guidelines for hip and knee OA recommend to start with (a combination of) non-surgical treatments, followed by surgical intervention if a patient does not respond sufficiently to non-surgical treatment options. In chapter 2, 3 and 4 the development of an implementation strategy to improve the use of non-surgical treatments in hip and knee OA is described. *Chapter 2* describes the two steps that need to be taken to develop such a strategy. First, current use of preoperative non-surgical treatments in patients with hip and knee OA was explored using internet-based surveys, one among 174 patients who had undergone TKA or THA no longer than 12 months ago or being on the waiting list for surgery with a confirmed date within 3 months and one among 172 orthopaedic surgeons. In *Chapter 3* the results of this first step are described. The results showed that most recommended non-surgical treatments (education about OA/ treatment options, lifestyle advice, dietary therapy, physical therapy, acetaminophen, NSAIDs, and glucocorticoid injections) were used frequently as single therapy. However, the combination of all these treatments is used in only a small percentage (6%) of hip and knee OA patients. Dietary therapy in overweighed patients was used least frequently.

The second step was to identify barriers and facilitators for the use of non-surgical treatments in orthopaedic practice. In *Chapter 4* the results of this second step are described. To identify potential barriers and facilitators, semi-structured interviews were performed among 10 orthopaedic surgeons and 5 patients who received a TKA or THA no longer than 12 months ago. All barriers and facilitators mentioned in the interviews were used to develop two internet-based surveys to examine which barriers and facilitators were associated with the use and prescription of non-surgical treatments. The surveys were completed by 172 orthopaedic surgeons and 174 patients. Most barriers and facilitators among patients were associated with the use of physical therapy, lifestyle advice and dietary therapy. Among orthopaedic surgeons, most were associated with prescription of acetaminophen, dietary therapy and physical therapy. Examples of barriers and facilitators among patients included "People in my environment had positive experiences with a surgery", and "Advise of people in my environment to keep on moving". For orthopaedic surgeons examples were "Lack of knowledge about the guideline", "Agreements/ deliberations with primary care" and "Short communication lines with a dietician". Also the belief in the efficacy of these treatments was associated with increased prescription.

In sciatica care, guidelines recommend that the team of professionals involved in sciatica care and patients jointly decide about treatment options, so-called interprofessional shared decision making (SDM). This is based on evidence that patients with persisting leg pain after six to eight weeks have similar clinical outcomes after prolonged non-surgical treatment or surgery at one year follow-up. However, there are strong indications that SDM for sciatica patients is not integrated in daily practice. *Chapter 5* describes the steps that need to be taken to develop a strategy to embed SDM in daily practice based on a barrier and facilitator assessment. *Chapter 6* describes the exploration of barriers and facilitators using 40 semi-structured interviews among professionals of each (para) medical discipline involved in sciatica care (general practitioners (GP's), physical therapists, neurologists, neurosurgeons, and orthopaedic surgeons). In addition, three focus groups were conducted among patients. The results show that professionals and patients mentioned more barriers than facilitators for SDM in sciatica care. Professionals perceived most barriers at the level of the organizational context, and facilitators at the level of the individual professional. Patients reported most barriers and facilitators at the level of the individual professional. Several barriers and facilitators correspond with barriers and facilitators found in the literature (e.g., lack of time, motivation) but also new barriers and facilitators were identified. Many of these new barriers mentioned by both professionals and patients were related to the multidisciplinary setting, such as lack of visibility, lack of trust in expertise of other disciplines, and lack of communication between disciplines.

Next, the identified barriers and facilitators were ranked in *Chapter 7* using Maximum Difference Scaling, to assess which barriers and facilitators found in the qualitative interviews were the most important for the use of shared decision making according to GPs, physical therapists, neurologists, neurosurgeons, orthopaedic surgeons, and patients. Professionals assigned the highest importance to: quality of professional-patient relationship, importance of quick recovery of patient, and knowledge about treatment options. Patients assigned the highest importance to: correct diagnosis by professionals, information provision about treatment options and potential harm and benefits, and explanation of the professional about the care trajectory, which were reported both as barrier and facilitator. Therefore, knowledge, information provision and a good relationship seemed to be the most important conditions for SDM perceived by both patients and professionals.

Part 2 The optimization of surgical care in hip and knee osteoarthritis

In OA care, it is unclear what the optimal timing is to perform a THA or TKA. If evidence is lacking, more knowledge needs to be generated to develop evidence based recommendations in guidelines and thereby optimize care. Part 2 of this thesis therefore focused on studying criteria and determinants to reach the best possible outcomes after surgical care. In *Chapter 8* the availability of evidence-based indication criteria for primary THA and TKA in OA was assessed in 6 guidelines and 18 papers. The quality of the guidelines differed. Across guidelines and included studies, four studies stated that no evidence-based indication criteria are available. In the other studies, 12 THA, 10 TKA and 2 THA/ TKA indication sets were found. Indication criteria concerning THA/ TKA consisted of the following domains: pain (in respectively 10 and 11 sets), function (7 and 12 sets), radiological changes (9 and 10 sets), failed non-surgical therapy (4 and 8 sets) and other indications (7 and 6 sets). Specific cut-off values or ranges were often not stated and the level of evidence was low.

In *Chapter 9* the literature was reviewed on which factors predict outcomes after THA to guide decisions on when surgery is most effective. Databases and trial registries were searched for prospective studies including hip OA patients who underwent primary THA. Studies with preoperative measurements on predictors, with at least one year follow-up were included. Thirty-five studies were included (138,039 patients). Overall, there was low quality of evidence. Studies were heterogeneous in the predictors tested and in the observed directions of the associations. Preoperative function (13 studies) and radiological OA (6 studies) were predictors with the most consistent findings. Worse preoperative functioning and more severe radiological OA were associated with larger postoperative improvement. However, these patients never reached the level of postoperative functioning as patients with better preoperative functioning or less severe radiological OA. For age, gender and pain the results of studies were conflicting. For BMI, some studies (n=5) found worse outcomes for patients with higher BMI. However, substantial improvement was still achieved regardless of their BMI.

Thus regardless of the amount of existing studies, when all included studies are of low quality, more original research of high quality is needed. Therefore, individual patient data from 19 prospective cohorts in the Netherlands with 1783 knee OA patients and 2400 hip OA patients was pooled to determine preoperative variables for outcomes after a THA and TKA in *Chapter 10*. The results showed that patients with a higher preoperative quality of life or functioning have a higher postoperative quality of life or functioning and patients with less preoperative pain have less postoperative pain. Furthermore, women and patients with a higher BMI had more postoperative pain and less improvement after both THA and TKA. Higher age and higher BMI were associated with lower postoperative QoL and functioning and more pain after a THA.

Another factor that may predict outcomes after a TKA is the type of prosthesis. *Chapter 11* compares two types of knee prostheses in a meta-analysis: mobile and fixed bearing. Randomized controlled trials comparing mobile bearing with fixed bearing prostheses in cruciate retaining TKA among patients with OA or rheumatoid arthritis were selected, using functional or clinical outcome measures and follow-up of at least six months. Moderate-to low-quality evidence suggests that mobile bearing prostheses may have similar effects on postoperative knee pain, clinical and functional scores, health-related quality of life, revision surgery, mortality, reoperation rate and other serious adverse events compared with fixed bearing prostheses in posterior cruciate retaining TKA.

General discussion

The aim of the present thesis was to extend the knowledge in the field of implementation science by examining how care delivery for patients with hip and knee OA or sciatica can be optimized. In the first part strategies to improve guideline uptake in hip and knee OA and sciatica care were searched for. Looking across the different studies described in the first part of this thesis, there seem to be general domains relevant for implementation of evidence based guideline recommendations in a multidisciplinary setting. These domains are knowledge, attitude of health care providers and organization of care. Future implementation studies can start focusing on these topics if it is not feasible to perform a barrier assessment. However, also different barriers and facilitators were found for each specific condition. This shows that implementation problems of each specific condition ideally needs a barrier assessment to be able to gear an implementation strategy at all existing barriers and facilitators. This will most likely result in improved implementation of evidence based guidelines.

In the second part of this thesis, a search for new evidence related to the question of optimal timing of THA/ TKA in hip and knee OA patients was done. Regarding the issue of optimal timing, information in the literature is lacking. Pooling multiple cohort studies in the Netherlands showed that preoperative status is the most important variable for outcome after both THA and TKA, i.e. patients with better preoperative quality of life, functioning and less pain had better postoperative outcomes. This does not necessarily mean that patients who received a joint replacement earlier in their clinical course have a better outcome. Given the results that patients with a better preoperative status have better postoperative results, it is important to examine whether functioning or pain in hip or knee OA patients become worse over time, so if a worsening of functioning or pain in hip or knee OA patients is followed by further worsening or whether this fluctuates randomly over time. To determine whether patients deteriorate over time, more knowledge is needed about the progression of OA in different subgroups. In addition, it is important to assess the same outcomes can be reached with non-surgical treatment as with THA and TKA. Focusing on these questions in future research is likely to improve quality of care delivered to these patients.

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Nederlandse samenvatting

In de gezondheidszorg worden vele beslissingen genomen. Eén van deze beslissingen voor diverse niet-acute aandoeningen van het bewegingsapparaat is de keuze om conservatief of chirurgisch te behandelen. Bij deze aandoeningen wordt eerst geprobeerd om met conservatieve behandelingen de symptomen te verminderen en wordt overgegaan tot een chirurgische ingreep wanneer een patiënt onvoldoende baat heeft bij conservatieve behandelingen. Heup en knieartrose en lage rughernia zijn voorbeelden van dergelijke niet-acute aandoeningen waar de beslissing voor conservatieve of chirurgische behandeling complex is.

Het doel van dit proefschrift is om bij te dragen aan optimaal gebruik van conservatieve en chirurgische behandelingen bij patiënten met artrose van de heup of knie en patiënten met een lage rughernia te optimaliseren. Richtlijnen zijn hierbij belangrijk, omdat ze gebaseerd zijn op de best beschikbare wetenschappelijke literatuur, maar toch worden ze niet altijd nageleefd door zorgverleners. Wanneer de richtlijnen aangeven bij welke patiënten en wanneer conservatief en wanneer chirurgisch moet worden behandeld, kan er worden gekeken hoe implementatie van deze richtlijnen gefaciliteerd kan worden. Inzicht in de belemmerende en bevorderende factoren is hierbij essentieel om een effectieve implementatiestrategie te ontwikkelen. Deel 1 van dit proefschrift richt zich daarom op het uitbreiden van kennis over deze belemmerende en bevorderende factoren.

De optimalisatie van zorg kan echter niet altijd bereikt worden door de implementatie van richtlijnen. Richtlijnen voor de behandeling van heup- en knieartrose zijn bijvoorbeeld niet specifiek over wanneer een patiënt een totale heup- of knieprothese moet krijgen. Dit komt deels omdat er een gebrek aan kennis is over wat de optimale timing van een operatie is. Wanneer deze kennis ontbreekt, moet er meer kennis worden verworven om goede aanbevelingen te kunnen doen en daarmee de zorg te optimaliseren. Daarom wordt in deel 2 van dit proefschrift meer kennis verworven over criteria en determinanten die nodig zijn om de chirurgische zorg te optimaliseren. Specifieke vragen zijn: wat zijn de beschikbare wetenschappelijk onderbouwde indicaties voor een operatie en welke determinanten bepalen de uitkomst na een operatie? En in welke mate beïnvloedt het type gewrichtsprothese de uitkomst?

Deel 1 Implementatie van wetenschappelijke richtlijnen

Het eerste deel 1 van dit proefschrift richt zich op implementatiestrategieëen om het gebruik van aanbevelingen in richtlijnen voor de behandeling van heup- en knieartrose en de lage rughernia te verbeteren. Richtlijnen voor heup- en knieartrose adviseren om eerst te starten met (een combinatie van) conservatieve therapieën en pas te opereren als een patiënt onvoldoende baat heeft bij deze behandelingen. In de ***hoofdstukken 2, 3 en 4*** worden de stappen beschreven die nodig zijn om een implementatiestrategie te ontwikkelen om het gebruik van conservatieve therapie te verbeteren. ***Hoofdstuk***

2 beschrijft de studie opzet met de twee stappen die moeten worden genomen om een dergelijke implementatiestrategie te ontwikkelen. Als eerste is onderzocht in welke mate conservatieve therapieën op dit moment worden gebruikt. Een online vragenlijst werd ingevuld door 172 orthopedisch chirurgen en 174 patiënten die niet langer dan 12 maanden geleden een heup- of knieprothese hadden gehad of binnen 3 maanden geopereerd zouden worden. In ***hoofdstuk*** 3 worden de resultaten van deze eerste stap beschreven. Uit het vragenlijstonderzoek bleek dat de meeste conservatieve behandelingen (voorlichting over artrose/ behandelopties, leefstijladvies, diëtist, fysiotherapie, paracetamol, NSAIDs en glucocorticoïd injecties) als aparte behandelingen regelmatig werden gebruikt, maar dat weinig patiënten met heup- of knieartrose (6%) alle aanbevolen behandelingen kregen. Dieetadvies bij patiënten met overgewicht werd het minst gebruikt.

De tweede stap bestaat uit een analyse van belemmerende en bevorderende factoren voor het gebruik van verschillende conservatieve therapieën, voordat een heup of knie vervangende operatie wordt uitgevoerd. De resultaten van deze stap zijn beschreven in ***hoofdstuk** 4*. Om mogelijke belemmerende en bevorderende factoren te identificeren zijn 10 semigestructureerde interviews afgenomen bij 10 orthopedisch chirurgen en bij 5 patiënten die niet langer dan 12 maanden geleden een heup- of knieprothese hebben gekregen. Alle genoemde belemmerende en bevorderende factoren genoemd in deze interviews zijn gebruikt om twee vragenlijsten te ontwikkelen. De vragenlijsten zijn ingevuld door 172 orthopedisch chirurgen en 174 artrosepatiënten. Hieruit bleek dat de meeste belemmerende en bevorderende factoren onder patiënten waren geassocieerd met het gebruik van fysiotherapie, leefstijladvies en dieetadvies. Voorbeelden hiervan zijn “mensen in mijn omgeving hadden goede ervaringen met operatie” en “advies van mijn omgeving om te blijven bewegen”. Onder orthopedisch chirurgen waren de meeste belemmerende en bevorderende factoren geassocieerd met het voorschrijven van paracetamol, dieet en fysiotherapie. Voorbeelden zijn “gebrek aan kennis over de richtlijn, “afspraken/ overleg met de eerste lijn” en “korte lijnen met een diëtist”. Daarnaast was geloof in de werking van de behandeling geassocieerd met toename in het voorschrijven van deze behandeling.

De richtlijnen voor lage rughernia adviseren dat de betrokken zorgverleners samen met de patiënt besluiten welke behandeling het beste bij de patiënt past, oftewel om gedeelde besluitvorming toe te passen. Dit is gebaseerd op onderzoek dat heeft uitgewezen dat de uitkomsten van conservatieve en chirurgische behandeling bij patiënten met een lage rughernia na 1 jaar nagenoeg gelijk zijn. Toch zijn er aanwijzingen dat gedeelde besluitvorming nog niet veel wordt toegepast in de dagelijkse praktijk. ***Hoofdstuk** 5* beschrijft de stappen die moeten worden genomen om een strategie te ontwikkelen voor de implementatie van gedeelde besluitvorming. ***Hoofdstuk** 6* beschrijft de eerste stap, namelijk de exploratie van belemmerende en bevorderende factoren. Hiervoor werden 40 semigestructureerde interviews onder betrokken zorgverleners (huisartsen, fysiotherapeuten, neurologen, neurochirurgen, orthopedisch chirurgen) gehouden en drie focusgroepen met patiënten. Uit de interviews en focusgroepen bleek dat patiënten en zorgverleners meer belemmerende dan bevorderende factoren ervoeren. Zorgverleners ervoeren de meeste hinder op het gebied van organisatie van zorg en zagen de belangrijke bevorderende factoren bij kennis, attitude en ervaring van de individuele zorgverlener. Patiënten zagen de meeste bevorderende en belemmerende factoren bij de kennis, attitude en ervaring van de individuele zorgverlener. Een aantal geïdentificeerde belemmerende en bevorderende factoren kwam overeen met de bestaande literatuur (bijv. gebrek aan tijd, motivatie), maar er werden ook nieuwe factoren genoemd door zowel patiënten als zorgverleners. Veel van deze factoren waren gerelateerd aan de multidisciplinaire setting, zoals gebrek aan zichtbaarheid in de zorg, gebrek aan vertrouwen in zorgverleners van andere disciplines en gebrek aan communicatie tussen disciplines.

Vervolgens werden de geïdentificeerde belemmerende en bevorderende factoren gerangschikt in *hoofdstuk 7* met behulp van Maximum Difference Scaling om vast te stellen welke factoren nu het meest belangrijk zijn voor het gebruik van gedeelde besluitvorming volgens de betrokken zorgverleners en patiënten. Zorgverleners vonden de volgende belemmerende en bevorderende factoren het belangrijkste voor het gebruik van gedeelde besluitvorming: kwaliteit van de patiënt-zorgverlener relatie, belang dat de patiënt snel herstelt en kennis over behandelopties. Patiënten vonden de volgende belemmerende en bevorderende factoren het belangrijkste: juiste diagnose door de zorgverlener, voorlichting over de voor- en nadelen van behandelingen en uitleg van de zorgverlener over het te doorlopen zorgtraject. Zorgverleners en patiënten ervoeren dus kennis, voorlichting en een goede relatie als de meest belangrijke voorwaarden voor het toepassen van gedeelde besluitvorming.

Deel 2 Het optimaliseren van chirurgische zorg bij heup- en knieartrose

Bij patiënten met heup- of knieartrose is het onduidelijk wat de beste timing voor een totale heup-(THP) en knieprothese (TKP) is. Het is dan dus zaak om meer kennis te verwerven, zodat aanbevelingen in richtlijnen kunnen worden opgesteld om daarmee de kwaliteit van zorg te optimaliseren. Deel 2 van dit proefschrift richt zich daarom op criteria en determinanten die de uitkomst na een operatie bepalen. In *hoofdstuk 8* wordt gekeken naar de beschikbaarheid van wetenschappelijk onderbouwde indicatiecriteria voor totale heup- en knie prothese (THP/TKP) in 6 richtlijnen en 18 artikelen. De kwaliteit van de richtlijnen verschilde. In de geïncludeerde richtlijnen en artikelen, werd in 4 studies gesteld dat er geen wetenschappelijk onderbouwde indicatiecriteria waren. In de andere studies werden 12 THP, 10 TKP en 2 THP/TKP indicatiesets gevonden. De indicatiecriteria bij TKP en THP hadden betrekking op de volgende domeinen: pijn (in respectievelijk 10 en 11 sets), functieverlies (7 en 12 sets), radiologische afwijkingen (9 en 10 sets), falende conservatieve therapie (4 en 8 sets) en overige indicaties (7 en 6 sets). Specifieke afkapwaardes of ranges als indicatie voor een operatie werden vaak niet genoemd en het bewijs was van lage kwaliteit.

In ***hoofdstuk 9*** is door middel van een systematische literatuurstudie gekeken welke preoperatieve factoren de uitkomst na een THP voorspellen, om te kijken wanneer een operatie het meest effectief is. Hierbij is gezocht in databases en trial registers naar prospectieve studies onder patiënten met heupartrose die een THP hadden ondergaan. Studies waarbij preoperatieve voorspellers gemeten waren met een follow-up van tenminste 1 jaar na de operatie werden geïncludeerd. Vijfendertig studies met in totaal 138,039 patiënten die hieraan voldeden werden geïncludeerd. Gemiddeld genomen was de kwaliteit van de gevonden studies laag. Studies waren heterogeen in de preoperatieve factoren die werden bestudeerd en effecten verschilden van richting. Preoperatieve functie (13 studies) en radiologische ernst van artrose (6 studies) waren de voorspellende factoren met de meest consistente bevindingen. Slechtere preoperatieve functie en de meest ernstige radiologische ernst van artrose waren geassocieerd met een grotere mate van postoperatieve verbetering, maar deze patiënten bereikten uiteindelijk niet hetzelfde postoperatieve niveau als patiënten met een betere preoperatieve functie of een minder ernstige radiologische ernst van artrose. Ten aanzien van leeftijd, geslacht en pijn verschilden de resultaten van de studies. Enkele studies (n=5) vonden dat patiënten met een hogere Body Mass Index (BMI) slechtere uitkomsten hadden. Echter, zij concludeerden dat ondanks dit verschil, patiënten toch aanzienlijk verbeterden ongeacht hun BMI.

Wanneer de bestaande studies van slechte kwaliteit zijn, is meer onderzoek nodig van betere kwaliteit. Daarom zijn in ***hoofdstuk 10*** individuele patiënt data van 19 bestaande prospectieve cohorten in Nederland met een follow-up van minstens 1 jaar samengevoegd om vast te stellen welke preoperatieve variabelen uitkomsten na een THP of TKP voorspellen. Deze cohorten bevatten samen 1783 patiënten met een TKP en 2400 patiënten met een THP. Uit de resultaten bleek dat patiënten met een betere preoperatieve kwaliteit van leven of functie ook een betere postoperatieve kwaliteit van leven en functie hadden en dat patiënten met minder preoperatieve pijn ook minder postoperatieve pijn hadden. Verder bleek dat vrouwen en patiënten met een hogere BMI meer pijn en minder verbetering hadden na zowel een THP als een TKP. Een hogere leeftijd en een hogere BMI waren geassocieerd met een lagere postoperatieve kwaliteit van leven en functie en meer pijn na een THP.

Een andere factor die uitkomsten na een knievervangende operatie kan bepalen is het type prothese dat gebruikt wordt. In ***hoofdstuk 11*** worden daarom twee knieprotheses (mobile en fixed bearing) met elkaar vergeleken in een meta-analyse. Dit is gedaan door bestaande gerandomiseerde onderzoeken met controlegroep (RCT's) te selecteren die mobile en fixed bearing protheses met elkaar vergeleken bij kruisbandsparende TKP's onder patiënten met artrose of reumatoïde artritis. Deze studies werden geselecteerd als ze functionele of klinische uitkomsten hadden gemeten bij een follow-up van ten minste zes maanden. Uit de meta-analyse bleek dat mobile en fixed bearing protheses gelijke uitkomsten hebben met betrekking tot postoperatieve pijn, klinische en functionele scores, kwaliteit van leven, revisies, mortaliteit, her operaties en ernstige complicaties. Het wetenschappelijke bewijs hiervoor was van gemiddelde tot lage kwaliteit.

Algemene discussie

Het doel van dit proefschrift was om kennis op het gebied van implementatie te vergroten door te onderzoeken hoe de zorg aan bij patiënten met heup- of knieartrose of een lage rughernia geoptimaliseerd kan worden. In het eerste deel hebben is gezocht naar implementatiestrategieën om het gebruik heup- en knieartrose en lage rughernia richtlijnen te bevorderen. Uit de onderzoeken beschreven in het eerste deel van het proefschrift lijken er een aantal algemene domeinen van belang te zijn bij de implementatie van wetenschappelijk onderbouwde aanbevelingen in richtlijnen in een multidisciplinaire setting. Deze domeinen betreffen de kennis, attitude van zorgverleners en de organisatie van zorg. Toekomstige implementatiestudies zouden dus kunnen beginnen met deze onderwerpen, als het niet haalbaar is om een probleem analyse uit te voeren naar specifieke belemmerende en bevorderende factoren. Naast deze algemene belemmerende en bevorderende factoren werden er ook belemmerende en bevorderende factoren gevonden die specifiek waren voor beide aandoeningen. Dit toont aan dat bij de implementatie van richtlijnen voor elke verschillende aandoening idealiter toch een aparte probleem analyse nodig is om de implementatie te richten op alle belemmerende en bevorderende factoren. Dit zal waarschijnlijk resulteren in een verbeterde implementatie van wetenschappelijk onderbouwde richtlijnen.

Het tweede deel van dit proefschrift richtte zich op vragen gerelateerd aan de optimale timing van een THP/TKP bij patiënten met heup- of knieartrose. Bestaande wetenschappelijke literatuur over de optimale timing is op dit moment nog onvoldoende om aanbevelingen op te baseren. De gepoolde analyse van bestaande prospectieve studies in Nederland liet zien dat de preoperatieve status van patiënten voor een totale heup- of knieprothese de meest belangrijke factor is bij het voorspellen van de postoperatieve uitkomst. Oftewel patiënten met een betere preoperatieve kwaliteit van leven of functie en minder pijn hadden ook een betere postoperatieve kwaliteit van leven, functie en minder pijn. Dit betekent niet direct dat patiënten die eerder een gewricht vervangende operatie ondergaan ook betere uitkomsten hebben. Om hier meer inzicht in te krijgen is het nodig om te onderzoeken of bijvoorbeeld functie slechter wordt met de tijd en of een verslechtering in functie wordt gevolgd door een verdere verslechtering, of dat het ook weer kan verbeteren en dus het ziekteverloop random fluctueert over de tijd. Om hier antwoord op te krijgen is meer kennis nodig over het ziekteverloop van artrose in verschillende subgroepen van patiënten. Verder is het belangrijk om te onderzoeken of de resultaten die met een gewricht vervangende operatie worden bereikt, ook kunnen worden bereikt met conservatieve behandelingen. Toekomstig onderzoek zal zich hierop moeten richten om de kwaliteit van zorg nog verder te verbeteren.

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Presentations

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Hofstede SN, Nouta KA, Jacobs W, van Hooff ML, Wymenga AB, Pijls BG, Nelissen RGHH, Marang-van de Mheen PJ: Mobile bearing vs fixed bearing totale knie prothesen bij kruisband sparende operaties NOV najaarsvergadering, Veldhoven, 2014 *(oral presentation)*

Hofstede SN, Gademan MGJ, Vliet Vlieland TP, Nelissen RG, Marang-van de Mheen PJ, for the ARGON study group: Optimale timing voor totale heup- en knieprothese, NOV najaarsvergadering, Veldhoven, 2014 *(oral presentation)*

Hofstede SN: The Dutch Implementation Study of interprofessional Shared Decision Making in Sciatica (DISC study). Symposium Hernia en Stenose: Eenheid in verscheidenheid, Leiden, 2013 *(invited speaker)*

Hofstede SN, Marang-van de Mheen PJ, Stiggelbout AM, Vleggeert-Lankamp CLA, Assendelft WJJ, Vliet Vlieland TPM, Van Bodegom-Vos L: Most important factors influencing implementation of shared decision making in sciatica treatment perceived by professionals and patients: International Shared Decision Making (iSDM) conference, Lima, Peru, 2013 *(poster presentation)*

Hofstede SN, Marang-van de Mheen PJ, Stiggelbout AM, Vleggeert-Lankamp CLA, Assendelft WJJ, Vliet Vlieland TPM, Van Bodegom-Vos L: Barrières en facilitatoren bij de gezamenlijke besluitvorming voor een behandeling bij het Lumbosacraal Radiculair Syndroom (LRS). Platform SDM/ GB, Utrecht, 2012 *(oral presentation)*

Hofstede SN, Marang-van de Mheen PJ, Stiggelbout AM, Vleggeert-Lankamp CLA, Assendelft WJJ, Vliet Vlieland TPM, Van Bodegom-Vos L: Barriers and facilitators to implement shared decision making in treatment of sciatica patients. Society for medical decision making (SMDM) conference, Phoenix, USA, 2012 *(poster presentation)*

CURRICULUM VITAE

Stefanie Nathalie Hofstede werd geboren op 30 januari 1987 in de Haarlemmermeer en is opgegroeid in Hoofddorp. In 2005 behaalde zij haar VWO diploma aan de Katholieke Scholengemeenschap Hoofddorp. In datzelfde jaar begon ze aan de studie Gezondheidswetenschappen aan de Vrije Universiteit. In 2008 behaalde zij haar Bachelor Gezondheidswetenschappen en in 2010 haar Master of Health Sciences in de richting Infectious Diseases and Public Health. Tijdens haar studie deed ze wetenschapsstages bij KWF Kankerbestrijding en bij de Universidad de Carabobo in Venezuela.

Na het afronden van haar opleiding heeft zij enkele maanden als vrijwilliger bij het gezondheidscentrum La Salud in Honduras gewerkt, waarbij huis-aan-huis bezoeken werden afgelegd om kinderen die niet naar het gezondheidscentrum waren gekomen voor hun vaccinaties alsnog te vaccineren. In 2012 startte zij haar promotieonderzoek bij de afdelingen Kwaliteit van Zorg en Orthopaedie in het Leids Universitair Medisch Centrum. De resultaten van dit onderzoek staan beschreven in dit proefschrift. Tijdens het promotietraject presenteerde zij de resultaten op diverse symposia en congressen. Naast haar onderzoek volgde zij de Master of Epidemiology in het Leids Universitair Medisch Centrum, die zij momenteel aan het afronden is. Onderdelen hiervan waren het volgen van diverse epidemiologische cursussen en optreden als docent bij epidemiologische werkgroepen.

Sinds 2013 neemt zij deel aan het ARGON (Artrose Research Groep Orthopedie Nederland) consortium, een consortium voor klinische studies op het gebied van artrose vanuit de Nederlandse Orthopedische Vereniging. Sinds 2015 is zij lid van de Nederlandse Orthopaedische Vereniging en sinds 2016 van de Vereniging voor Epidemiologie.

In januari 2016 is zij gestart als post-doctoral researcher op de afdeling Kwaliteit van Zorg in het Leids Universitair Medisch Centrum op een project dat tot doel heeft om een samenvattende uitkomstmaat door te ontwikkelen, die een completer en beter interpreteerbaar beeld geeft van de kwaliteit van zorg in ziekenhuizen dan bestaande indicatoren.

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Naast het promotietraject is de werkplek niet minder belangrijk. Daarom wil ik graag al mijn collega's van de afdelingen Kwaliteit van Zorg en Orthopaedie bedanken voor prettige werksfeer en samenwerking. In het bijzonder mijn (oud)kamergenoten Fania, Veronique, Anja en Hanna. Wat fijn dat ik altijd op jullie hulp of een luisterend oor kon rekenen. Jullie zijn/waren geweldige collega's. Rob, bedankt dat je mij de kans gaf om bij de orthopaedie het tweede deel van mijn proefschrift uit te voeren. Maaike, samen hebben wij dit tweede deel uitgevoerd. Wat hebben we zitten zwoegen op alle databases, ze zeggen gedeeld leed is half leed en dat bleek helemaal waar.

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