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**CHAPTER 1**

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**GENERAL INTRODUCTION**

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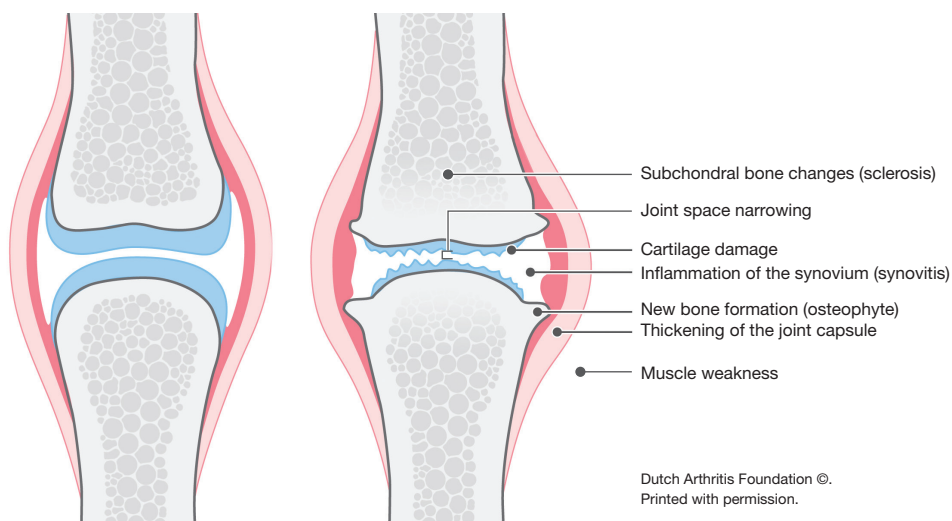
The purpose of this thesis is to assess health care in patients with hip or knee osteoarthritis (OA) after implementation of the stepped care strategy (SCS) to manage hip or knee OA and to evaluate the success of this implementation in order to identify targets to improve an implementation on a larger scale. This SCS was developed in the Netherlands under the name BART, i.e. Beating osteoARthritis (Figure 1). This introduction chapter outlines the disease and its management. Furthermore, it details on the current practice, the need to improve OA management, and discusses the opportunities of a nationwide implementation.

## Osteoarthritis

OA is a prevalent chronic joint disorder, with a substantial impact on individuals and society.<sup>1,3</sup> It can occur in any synovial joint, but patients consult their general practitioner (GP) most frequently for their hip and knee joints. In the Netherlands, the estimated number of patients with knee and hip OA is 312.000 and 238.000 respectively (poll 2007). These numbers are based on Dutch GP-registers, whereas the actual numbers are probably 2-3,5 times higher as most of the patients with OA are not known by their GP.<sup>4</sup> Due to demographic changes and the growing problem of obesity, the prevalence is expected to rise in the next three decades.<sup>5,6</sup>



**Figure 1.** Stepped care strategy named BART, i.e. Beating osteoARthritis



**Figure 2.** A normal joint and osteoarthritic joint

OA is characterized by a failure of the repair process of damaged cartilage due to bio-mechanical changes in the joint.<sup>7</sup> However, recent evidence shows an additional and integrated role of bone and synovial tissue, and patchy chronic synovitis that is evident in the disease.<sup>8</sup> Patients with hip or knee OA present similar symptoms (Figure 2). Usage-related pain is the most important symptom, often worse towards the end of the day, relieved by rest. Other typical symptoms are morning or inactivity stiffness, impaired function, and bone deformation; all contributing to the disability of OA and diminishing of patients' quality of life.<sup>7</sup> The extent and severity of symptoms vary considerably among patients.<sup>9</sup> Identified risk factors of hip and knee OA are increasing age, intense sport activity, higher body mass index, previous injury, and genetic predisposition. Additional risk factors of knee OA are muscle weakness, smoking, malalignment, and female gender.<sup>7,10</sup> However, the prevention of OA is difficult, as these factors increase the risk for OA only moderately and the presence of single factors might not be strong enough to justify their use in identifying subjects who should receive preventive interventions.<sup>10</sup> The presence of multiple risk factors and their interaction with each other, are probably the key factors to identify people at major risk.

In general, hip and knee OA develops progressively over several years. An extensive systematic review shows a deterioration of pain and functional status in patients with hip or knee OA after 3 years of follow-up.<sup>9</sup> However, this was not seen for the first 3 years of follow-up. Prognostic factors of the progression of OA include biomechanical, psychological, and clinical factors.<sup>11-13</sup> Those factors that are modifiable, e.g. reduced muscle strength, laxity of the knee joint, proprioceptive inaccuracy, overweight, and a lack of physical activity, are therefore considered important elements for treatment.

## Diagnosis and treatment

Several national and international guidelines describe the management for hip or knee OA and give recommendations regarding the diagnosis and treatment.<sup>14-20</sup> These guidelines show that there are several disciplines involved in the management of OA, e.g. GPs, practice nurses, exercise and physical therapists, dietary therapists, occupational therapists, rheumatologist, and orthopaedic surgeons. Even more, a central role of the patient in the management is advocated. Especially in early stages, clinical management of OA is targeted at improving patients' self-management by e.g. education, lifestyle advice. To achieve effectiveness and efficiency in treatment, the patient should take part in their own care.<sup>21</sup>

Most current guidelines state that the diagnosis of OA relies on medical history and physical examination.<sup>20,22</sup> Radiological assessment is not necessary, as the radiographic changes are not always accompanied by symptoms of pain, stiffness, or loss of function and conversely joint pain is not always associated with radiological abnormalities.<sup>23</sup> Thus, a confident diagnosis can be made without radiological assessment.

As there is no known cure for OA, treatment consists of symptomatic treatment, i.e. non-surgical and surgical treatment options. Although joint replacement surgery might be the only intervention with a large effect size, the general tendency in the guidelines is that surgery should be postponed as long as possible, as the life spans of prostheses are not indefinitely (approximately 15 years<sup>24</sup>). Postponing surgery can be done with a range of non-surgical treatment options. In this thesis we will focus on the non-surgical treatment options. The core non-surgical treatment consists of pharmaceutical and non-pharmaceutical interventions and are mainly performed in primary health care.<sup>25</sup>

The evidence for efficacy of non-surgical options is presented in a recent update for OA management (Table 1).<sup>20</sup> Effect sizes of the non-surgical options range from small for education and weight reduction to moderate for pharmacological options like non-steroid anti-inflammatory drugs (NSAIDs). In general, the guidelines are consistent regarding their recommendations about the use of these options.<sup>24</sup> For example, all guidelines recommend patient education, lifestyle advice, physical therapy, and medication (i.e. acetaminophen and NSAIDs). Guidelines are inconsistent regarding glucosamine, transcutaneous electro nerve stimulation, and intra-articular injections hyaluronic acid, probably because the efficacy of these options is still under debate.<sup>26-30</sup>

## Current practice

The Dutch health care system foresees that everyone has a health insurance. Insurers are obliged to offer a package with state-controlled insured treatments and may offer additional packages at extra costs, e.g. dental care or exercise therapy.<sup>31</sup> GPs are the free accessible physician and gatekeeper for the majority of other forms of health care. Since 2006, direct access to a physical therapist is established, however the GP remains the gatekeeper to specialized medical care. Therefore, in general people consult their GP if they have a new

**Table 1.** Evidence for efficacy of various options of therapy for hip and knee osteoarthritis<sup>20</sup>

Treatment options	Joint	Effect Size (95%CI)*	
		Pain	Functioning
Education	Both	0.06 (0.03-0.10)	0.06 (0.02-0.10)
Physical therapy (aerobic)	Knee	0.52 (0.34-0.70)	0.46 (0.25-0.67)
Glucosamine sulphate	Both	0.04 (-0.07-0.14)†	0.07 (-0.08-0.21)
Weight reduction	Knee	0.20 (0.00-0.39)	0.23 (0.04-0.42)
Acetaminophen	Both	0.14 (0.05-0.23)	0.09 (-0.03-0.22)
Oral NSAIDs	Both	0.29 (0.22-0.35)	
Topical NSAIDs	Knee	0.44 (0.27-0.62)	0.36 (0.24-0.39)
Opioids (e.g. tramadol)	Any	0.78 (0.59-0.98)‡	0.31 (0.24-0.39)
Intra-articular corticosteroids	Knee	0.58 (0.34-0.75)	0.20 (-0.14-0.53)

\* Cohen's d Equivalent: Effect size of 0.20=small, 0.50=moderate, and 0.80=large.

† Taken into account only the trials in which allocation concealment was adequate.

‡ There was, however, substantial heterogeneity in outcomes which did not appear related to the particular opioid used or to the methodological quality of the RCTs.

health problem. However, there is no specific guideline for GPs to manage hip or knee OA. Even more, only a small number of GPs in the Netherlands is specialized in musculoskeletal disorders (i.e. GPs with special interest, in Dutch “kaderhuisartsen”). Therefore, there is an urgent need for a protocol to guide non-surgical management for patients with hip or knee OA that can be used as a framework for all health care providers involved in OA care. To our knowledge, there is no comprehensive review describing the quality of all aspects of OA management in current practice. However, several studies focus on specific inadequacies regarding the use of diagnostic procedures and non-surgical treatment options. In the Netherlands, patients with hip or knee OA are infrequently referred to physical therapy and do receive non-steroidal anti-inflammatory drugs more often than the recommended first-choice medication acetaminophen in primary health care.<sup>32</sup> Also, it was found that patients who were referred to secondary care did not receive all conservative treatment options prior to their referral; 80% of the patients who were referred to a specialized rheumatology outpatient clinic did not receive the core elements of treatments (i.e. acetaminophen, NSAID, and physical therapy) first or did receive these core elements inadequately.<sup>33</sup> Further, it seems that pain and limitations in functioning are not the main determinants of health care use in people with OA, however it was rather the chronicity of the pain.<sup>34</sup> These inadequacies have also been shown in other countries. Canadian and German researchers reported inappropriate prescription of NSAIDs and unnecessarily use of diagnostic tests like X-rays in primary care.<sup>35,36</sup>

In a study from the UK, patients with OA reported inappropriate levels of pain medication in relation to their levels of pain.<sup>37</sup> Even more, the provision of options like exercise, weight loss, and written information seemed to be under-used and not in line with guideline recommendations.<sup>38,39</sup> Although French GPs agree to a high extent with the EULAR recommendations, they under-use non-pharmacological interventions.<sup>40</sup> Non-adherence regarding recommendations about non-pharmacological treatment options has also been shown in the Canadian health care management.<sup>41</sup>

## **Stepped care strategy**

Possible explanations for these inadequacies are the lack of recommendations about the indication for and timing of treatment options and the poor incorporation of guideline recommendations in clinical practice. A stepped care model has been suggested to use limited resources to the greatest extent, by presenting the optimal order when a range of interventions is available.<sup>42</sup> Such a model can be used as a framework for both health care providers as patients. A SCS has already been proven to be effective in other chronic conditions, like diabetes mellitus<sup>43</sup>, depression<sup>44</sup>, and back pain.<sup>45</sup> The first step of such a model suggest interventions that should be tried initially, while interventions in the later steps are reserved for those with persisting pain and disability whose condition was not controlled by lower step treatment options.

In OA management, there have already been some initiatives to develop tools to support the decision making. An Australian integrative toolkit describes the diagnostic procedures and treatment,<sup>46</sup> but it lacks recommendations regarding the timing for treatment. In Sweden, nationwide population-based information registers are used to assist the implementation of guidelines, i.e. inform physicians about the treatment options and offer feedback about their management.<sup>47</sup> Moreover, in the UK a SCS for older adults in primary care with knee pain or knee OA has been developed.<sup>39</sup> However, a comprehensive protocol to guide timing and indication of non-surgical management for hip or knee OA is not available.

Therefore, our first aim was to develop a SCS to manage hip or knee OA that gives recommendations regarding the timing of and the indication for non-surgical treatment. We presumed that this strategy should include evidence-based treatment modalities in such order that it presents modalities in the first step that should be offered to all patients with hip or knee OA and presents modalities in the subsequent steps that should only be considered in patients with persisting pain or disability despite the use of interventions of the lower steps. The strategy did not have to give explicit statements regarding the involvement of specific professionals as some treatment options can be delivered by different health care providers. Even more, the strategy did not have to give recommendations regarding intensity and content of the interventions as these are already described in existing guidelines, such as the dosage, assessment of contra-indications, and prevention of side effects.

## Implementation of the SCS into clinical practice

Similar to guideline recommendations, a SCS is not self-implementing.<sup>48</sup> A treatment strategy would be helpful to facilitate guideline implementation. Clearly, before we start implementation on a large scale, the implementation process should be tested and evaluated on a limited scale first.<sup>49</sup> Implementing is a step by step process in which views from various disciplines should be taken into account.<sup>50</sup> Therefore, effective guideline implementation strategies involve a synergy of strategies at multiple levels, including the patient. As patients with hip or knee OA are treated in primary health care for a long period of time and since the GP plays a gatekeeper role in Dutch health care<sup>25</sup>, we decided to target our main implementation interventions on GPs and patients.

Consequently, factors at each of these different levels can influence the success of the implementation and, thus, should be identified.<sup>49</sup> Grol and Wensing have provided a clear overview of these potential barriers and facilitators.<sup>51</sup> They distinguish patient-related factors into knowledge (insight in the treatment options), skills (e.g. educational level), attitude (e.g. being self-active), and compliance (e.g. being adherent). Furthermore, provider-related factors were categorized into awareness and knowledge (e.g. insight in the problem), attitude (e.g. towards the guideline recommendation), motivation (e.g. personal characteristics), and behavior (e.g. actually following the recommendations). Factors regarding the social and organizational context included the setting (e.g. practical possibilities) and modelling factors (e.g. influences from other health care providers).

Our second aim was to get more insight in these barriers and facilitators at the level of the patient, the provider, and the organization in order to improve the implementation of the SCS into clinical practice. Therefore, we performed a pilot study in the region Nijmegen in the Netherlands, to identify factors that can influence the success of the implementation. These results can be used to adjust the implementation activities for a nationwide implementation.

## Outline of this thesis

To improve the management of hip or knee OA, a stepped care model that gives recommendations about the indication for and timing of treatment options seems necessary. This thesis describes the development and content of such a SCS and evaluates its implementation in clinical practice. The results of this pilot implementation can be used to give recommendations for a nationwide implementation. The content of the chapters in this thesis is outlined below.

In **chapter 2**, a study regarding the development and content of a SCS for the management of hip or knee OA is described. This strategy is developed using a consensus procedure by a national steering group.

In **chapter 3**, attitudes of GPs regarding the SCS are described to assess potential barriers and facilitators at the level of the GP. Their agreement with the SCS-recommendations is evaluated in a cross-sectional study among a sample of GPs in the Netherlands.

In **chapter 4**, patients' views are described regarding the use of a tailored-made tool for patients, i.e. the self-management booklet "Care for Osteoarthritis" (in Dutch: "Zorgwijzer Artrose®"). This booklet was developed to educate patients about their disease and treatment options and to stimulate self-management and patient-doctor communication.

In **chapter 5**, health care use of patients with hip or knee OA is described and its determinants are identified. Targets for a nationwide implementation are suggested. In this prospective cohort-study, data is collected from GPs in the city-region Nijmegen and their consecutive patients. Several tailored implementation activities were developed and executed in this region.

In **chapter 6**, consistencies between clinical practice and the SCS-recommendations, regarding the three aspects of care, i.e. the timing of radiological assessments, the sequence of non-surgical treatment, and the prevalence of advice to make follow-up consults, were identified. This article suggests other targets for a nationwide implementation.

In **chapter 7**, the effect of receiving SCS-consistent care on the outcome of care is described. Primary outcome measures were pain, limitations in functioning, self-efficacy, and pain coping.

In **chapter 8**, we discuss the overall findings and its implications for further research, and the consequences for further nationwide implementation in clinical practice.



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