Physiotherapist as primary assessor of knee osteoarthritis in primary care

Evaluation of patients' self-assessment, preferences, quality of life, and health economy

Chan-Mei Ho-Henriksson

Department of Health and Rehabilitation

Institute of Neuroscience and Physiology

Sahlgrenska Academy, University of Gothenburg

UNIVERSITY OF GOTHENBURG

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chan-mei.ho@gu.se, chan-mei.ho@vgregion.se

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It is freedom to feel that your body carries you

(Participant)

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ABSTRACT

Aim: The purposes with this thesis was to evaluate the feasibility of 30-second chair stand test as a self-test, and to investigate the effects of direct access to physiotherapist on costs and health in people with knee osteoarthritis, as well to investigate experiences of care among these individuals when physiotherapists serve as the primary assessor.

Methods: This thesis consists of four papers: Paper I investigated intra- and inter-rater reliability and the diagnostic ability of 30-second chair stand test to function as a self-test for people with knee osteoarthritis (n=114); Papers II-III investigated differences in health outcomes (Paper II) and the cost-effectiveness (Paper III) of a randomised controlled pragmatic trial using a physiotherapist assessment compared with physician's assessment in people with knee osteoarthritis in primary care (n=69); and Paper IV used a qualitative interview study to explore the expectations and experiences of a care pathway initiated with a physiotherapist assessment in people with knee osteoarthritis (n=15).

Results: The 30-second chair stand test seem feasible as a self-test with excellent intra-rater reliability and moderate to good inter-rater reliability when comparing self-test results with a physiotherapist assessment. The differences between physiotherapists and physicians as primary assessors on health outcomes were not significant, and both healthcare pathways resulted in

significant improvements in health-related quality of life. Direct access to a physiotherapist could lead to cost savings with a marginal quality adjusted life-year (QALY) loss. People seeking care for knee osteoarthritis reported that they expected to be "taken seriously" and receive a proper examination so that they can get the help they need to get back to their normal physical activities. The informants viewed physiotherapist and exercise-based treatment as a natural first option. The knowledge gained from the physiotherapist and the supported osteoarthritis self-management programme were seen as important factors in learning how to self-manage knee osteoarthritis and informants were hopeful that they could return to their normal physical activity level.

Conclusion: The results of this thesis imply that a 30-second chair stand as a self-test is a reliable instrument that can be useful in digital healthcare and self-assessment and that direct access to a physiotherapist could lead to cost savings without significant differences in health outcomes for individuals suffering from knee osteoarthritis. However, larger studies are needed. Informants who were assessed by a physiotherapist first felt they were understood and gained the knowledge they needed to self-manage their knee osteoarthritis. They reported feeling hopeful that they could return to their normal physical activities.

Keywords: knee osteoarthritis, physiotherapist, physiotherapy, direct access, self-assessment, reliability, physical function, experience, person-centred care

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EN SAMMANFATTNING PÅ SVENSKA

De flesta får värk i muskler och leder någon gång i livet och besvär i rörelse- och stödorganen är en vanlig anledning att söka primärvård. En av de vanligast förekommande diagnoserna bland de som söker primärvård är knäledsartros. Kunskaper om sjukdomen, om träning, fysisk aktivitet och om egenvård är de viktigaste hörnstenarna för att personer med knäledsartros ska kunna hantera sin livslånga diagnos. Enligt rekommendationerna i Sverige ska man först bedömas av en fysioterapeut vid misstanke om knäledsartros. Att bli bedömd av en fysioterapeut utan att ha bedömts av en läkare innan kallas för direkt access. Det är enbart i 22% av alla världens länder som har direkt access till fysioterapeut. Det saknas kunskap om hur livskvaliteten och kostnadseffektiviteten påverkas, och hur vården har upplevts med fysioterapeuter som förstabedömare för personer med knäledsartros. Den ökade förekomsten av digital fysioterapi tydliggör att det saknas tillförlitliga tester i den kliniska vardagen som individer kan göra själva i hemmet.

Syftet med detta avhandlingsarbete var att utvärdera effekterna på livskvalitet, hälsoekonomi samt upplevelsen av fysioterapeuternas vård som förstabedömare för personer med knäledartros. Vi ville dessutom utvärdera tillförlitligheten av funktionstestet 30 sekunders stolstest som ett självtest för personer med knäledsartros. Avhandlingsarbetet innehåller fyra delstudier med olika studiedesign för att besvara dessa syften. Totalt har 213 personer deltagit i delstudierna. Den första delstudien undersökte skillnader mellan 30 sekunders stolstest som självtest jämfört med när personen är testad av en fysioterapeut. Personer med misstänkt knäledsartros lottades i delstudie II mellan att först bedömas och behandlas av antingen fysioterapeuter eller läkare för att utvärdera skillnaderna i hälsoeffekter. Därefter utvärderades hälsoekonomin mellan de två bedömarna i delstudie III. Slutligen, i delstudie IV, blev personer med knäledsartros intervjuade om sina upplevelser av fysioterapeuter som förstabedömare.

Resultaten visar på att funktionstestet 30 sekunders stolstest är tillförlitligt som ett självtest. Direkt access till fysioterapeut kan leda till kostnadsbesparingar utan betydande skillnad i hälsoeffekter för personer med knäledsartros. Vården med fysioterapeut som förstabedömare har motsvarat personer med knäledsartros förväntningar om att bli sedda och tagna på allvar samt att de fått verktyg för att fortsätta sin egenvård med hopp om att återgå till sin tidigare fysiska aktivitetsnivå.

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Ho-Henriksson CM, Thorstensson CA, Nordeman L. Self-assessment using 30-second chair stand test for patients with knee osteoarthritis – an intra- and inter-rater reliability study. *Submitted.*

II. Ho CM, Thorstensson CA, Nordeman L. Physiotherapist as primary assessor for patients with suspected knee osteoarthritis in primary care – a randomised controlled pragmatic study. *BMC Musculoskeletal Disorders 2019; 20: 329.*

III. Ho-Henriksson CM, Svensson M, Thorstensson CA, Nordeman L. Physiotherapist or physician as primary assessor for patients with suspected knee osteoarthritis in primary care – a cost-effectiveness analysis of a pragmatic trial. *BMC Musculoskeletal Disorders 2022; 23: 260.*

IV. Ho-Henriksson CM, Thorstensson CA, Nordeman L, Zidén L. "I want to be physically active as long as I live" – Patients' experiences of primary assessment and treatment of knee osteoarthritis by physiotherapists in primary care. *In manuscript.*

THESIS AT A GLANCE

Paper I

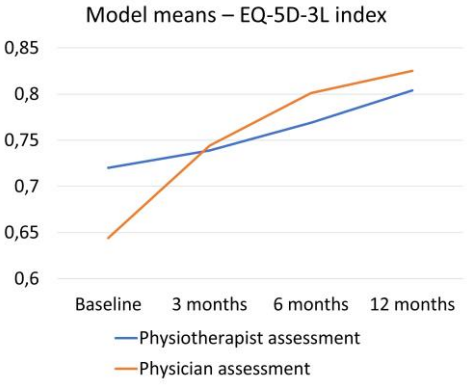
Intra-rater reliability of 30-second chair stand test as a self-test, and inter-rater reliability of a self-test and physiotherapist assessment.

Participants: 114 individuals with knee osteoarthritis.

Methods: Study of intra-rater reliability of a 30-second chair stand test as self-test and inter-rater reliability of self-test and physiotherapist assessment. Analysis of minimal detectable change and classification ability.

Conclusions: The 30-second chair stand test is feasible as a self-test for people with knee osteoarthritis. Individuals performing less than 13 stands are likely to have reduced physical function.

Paper II



Physiotherapist or physician as primary assessors in primary care*

Participants: 69 individuals with suspected knee osteoarthritis.

Methods: Randomised controlled pragmatic trial of physiotherapist as primary assessor compared with physician as primary assessor in primary care. Evaluation of the effects on health-related quality of life at 3-, 6- and 12-month follow-up.

Conclusion: When physiotherapists are the primary assessors, results for people with knee osteoarthritis are comparable with physicians in primary care. Both care pathways resulted in significant health effects, and there was no difference between the groups.

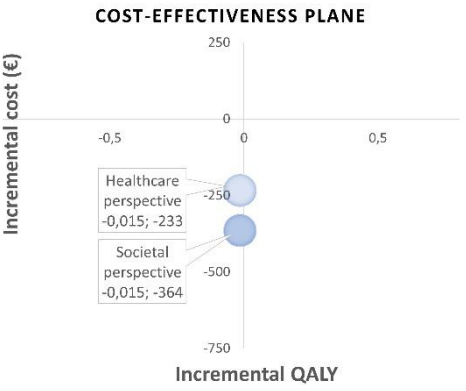
*Modified figure from Paper II. Reprinted with kind permission from BMC Musculoskeletal Disorder, Volume 20, Ho CM, Thorstensson CA, Nordeman L. Physiotherapist as primary assessor for patients with suspected knee osteoarthritis in primary care – a randomised controlled pragmatic study, 329, Copyright 2019, with permission from Springer Nature.

Participants: 69 individuals from paper II.

Methods: A cost-effectiveness study comparing individual health outcomes and costs in people with suspected knee osteoarthritis with physiotherapists as primary assessors versus physicians as primary assessors in primary care.

Conclusions: Direct access to physiotherapists resulted in fewer physician visits and referrals for radiography examinations. In terms of total costs, physiotherapist as primary assessor led to cost savings with a marginal loss in health outcomes.

Paper III



Cost-effectiveness of direct access to physiotherapist

Participants: 15 individuals with knee osteoarthritis.

Methods: Qualitative interview study exploring the expectations and experiences of direct access to a physiotherapist. Semi-structured interviews were conducted and analysed with qualitative content analysis.

Conclusions: Individuals with knee osteoarthritis expected to be "taken seriously" and to get a proper examination. They wanted to get back to their normal physical activities, and they believed that a physiotherapist and exercise treatment were the natural first option.

Paper IV

Expectations and experiences of direct access to physiotherapist

CONTENTS

ABBREVIATIONS

30 CST	30-second Chair Stand Test
AUC	Area Under the receiver operating characteristic Curve
BMI	Body Mass Index
CEAC	Cost-Effectiveness Acceptability Curve
CI	Confidence Interval
EQ-5D-3L	EuroQol 5 Dimensions 3 Levels
EQ-VAS	EuroQol Visual Analogue Scale
HrQoL	Health-related Quality of Life
ICC	Intraclass Correlation Coefficient
ICER	Incremental Cost-Effectiveness Ratio
ICOAP	Intermittent and Constant Osteoarthritis Pain
KOA	Knee Osteoarthritis
KOOS-PS	Knee injury and Osteoarthritis Outcome Score - Physical function Short form
MDC	Minimal Detectable Change
NRS	Numeric Rating Scale
OA	Osteoarthritis
QALY	Quality Adjusted Life-Years
RCT	Randomised Controlled pragmatic Trial
ROC curve	Receiver Operating Characteristic curve

SD	Standard Deviation
SEM	Standard Error of Measurement
SOASP	Supported Osteoarthritis Self-management Programme
VAS	Visual Analogue Scale

DEFINITIONS IN SHORT

Area under the (ROC) curve	The area under the receiver operating characteristic curve (AUC) gives an indication of how well a model can distinguish between two groups. The value range between 0 to 1, where 1 reflects perfect classification ability and values less than 0.5 are interpreted as equal to random classification (2).
Bootstrapping	A statistical non-parametric method to generate multiple replicates of original data into a larger sample size to assess sampling uncertainty (3).
Cost-effectiveness	Cost-effectiveness reflects the comparison of the costs and effects of two or more treatments or interventions (4).
Cost-effectiveness acceptability curve	A graph illustrating the probability of an intervention to be cost-effective given a threshold of willingness to pay for a treatment to gain the effect (4).
Cost-effectiveness plane	The cost-effectiveness plane illustrates the differences in costs and health outcomes between two interventions (5).
Direct access	Direct access, or self-referral, means that people can seek or refer themselves directly to the healthcare service that is needed without recommendation by another health professional (6).
Disability-adjusted life-years	Abbreviated as DALY. A measure of the overall burden of a disease, that combines lost life-years due to premature mortality and loss of life-years due to disease or disability. One DALY is the loss of one year of full health (7).

Exercise	Defined as “physical activity that is planned, structured, repetitive and purposive in the sense that improvement or maintenance of one or more component of physical fitness is an objective” (8).
Health-related quality of life	Can be described as how an individual perceives their wellbeing in physical, mental and social health and how well the individual is able to perform activities in their daily life (9).
ICER	Abbreviation for incremental cost-effectiveness ratio. A method for comparing the cost and effect of two treatments by presenting the cost per each QALY earned or lost (4).
Intraclass correlation coefficient	Reflects both the agreement and the consistency in a reliability index. The intraclass correlation coefficient varies from 0 to 1, where values closer to 1 correspond to higher reliability (10).
Physical activity	Defined as “any bodily movement produced by skeletal muscles that results in energy expenditure” (8).
Physical function	Physical function is defined as “the capacity of an individual to carry out the physical activities of daily living. Physical function reflects motor function and control, physical fitness and habitual physical activity” (11).
Physician	A medical professional, also called general practitioner, that “treat all common medical conditions and refer individuals to hospitals or other medical services for urgent and specialist treatment” (12).

Physiotherapist	Also called physical therapist. A professional that identifies and enhances the potential in individuals to achieve a high quality of life and functional movement in individuals through the promotion, prevention or, maintenance of quality of life or through rehabilitation (13).
Physiotherapy	Or physical therapy. The services delivered by physiotherapists to develop, maintain or regain functional abilities and movement in individuals (13).
QALY	An abbreviation of quality adjusted life-years. The QALY combines life length and quality of life in one single measure. Usually having a range between 0 (death) and 1 (perfect health) (4).
Qualitative content analysis	A qualitative method to analyse data. A method where the analysis is both near the originally spoken words and the content is abstracted into categories and themes (14).
Reliability	Reliability describes how well measurements can be repeated. Similar terms for describing precision are repeatability, stability, consistency, reproducibility and agreement (15).
ROC curve	Abbreviation of receiver operating characteristic curve. A statistical method to illustrate the amount of true positives (sensitivity) and false positives (1-specificity) in a diagnostic test (2).
Self-care	“Self-care interventions are tools which support the ability of individuals, families and communities to promote health, prevent disease, maintain health and cope with illness and disability with or without the support of a health worker” (16).

Self-management	An individual task including medical, role and emotional management of their chronic disease or condition in order to live well (17).
Standard error of measurement	The margin of error of a score due to systematic and random errors that is not related to the true change (18).

1 INTRODUCTION

"Why didn't this patient come to me earlier?" I often thought when I assessed people with knee osteoarthritis (KOA). The first time this thought crossed my mind was during my first years as a physiotherapist in primary care. Individuals were referred to a physiotherapist from a primary care centre, and it was common for the individuals to be treated with painkillers and/or anti-inflammatory drugs. Typically, these individuals had already undergone a radiographic examination to confirm the suspicion of KOA. Individuals sought out a physiotherapist to participate in a patient education called the "Supported Osteoarthritis Self-management Programme" (SOASP) and to get started with physical exercise. The entire care process up to the first meeting with the physiotherapist took about 2-3 months. This healthcare process felt unnecessary, and individual access to the recommended treatment was being delayed. Would it be possible to improve an individual's pathway to a more evidence-based healthcare process? With that question in mind, I started my first research project. This thesis is a summary of a long journey to determine how the osteoarthritis (OA) care can be improved.

1.1 OSTEOARTHRITIS

OA is a type of joint failure (19) where there is an imbalance in the normal process of cartilage break down and repair (20). It involves changes in all joint structures – not only the cartilage, but in subchondral bone, ligaments, capsule, synovium and muscles surrounding the knee (21). The most common site of OA is the knee, followed by the hand and then the hip (22). Typical symptoms of KOA are activity-related knee pain, while more severe KOA can cause nocturnal pain and pain at rest. The joint may become stiffer with reduced range of motion, and the individual may report symptoms of stiffness after a long period of physical inactivity (e.g. morning stiffness). Crepitus, joint instability and swelling are other common joint-related symptoms (23). The symptoms may come in flare-ups (24), which is defined as a worsening of symptoms for a period of time, with swelling, warmth over the knee, stiffness and/or increased pain followed by a period with milder or no symptoms. In this thesis, the focus will be on KOA, though general descriptions of OA could also include hip and hand OA.

1.1.1 ETIOLOGY AND PREVALENCE

Worldwide, it is estimated that more than a fifth of all people over 40 years of age suffer from KOA (25) and 14% of the Swedish population over 45 years of age (26). The global incidence of KOA among people aged over 20 years has been estimated to be 203 individuals per 10,000 individuals each year (25). In 2019, over 360 million people suffered from KOA, which is an increase of 122% compared to 1990 (22); see ***Figure 1***.

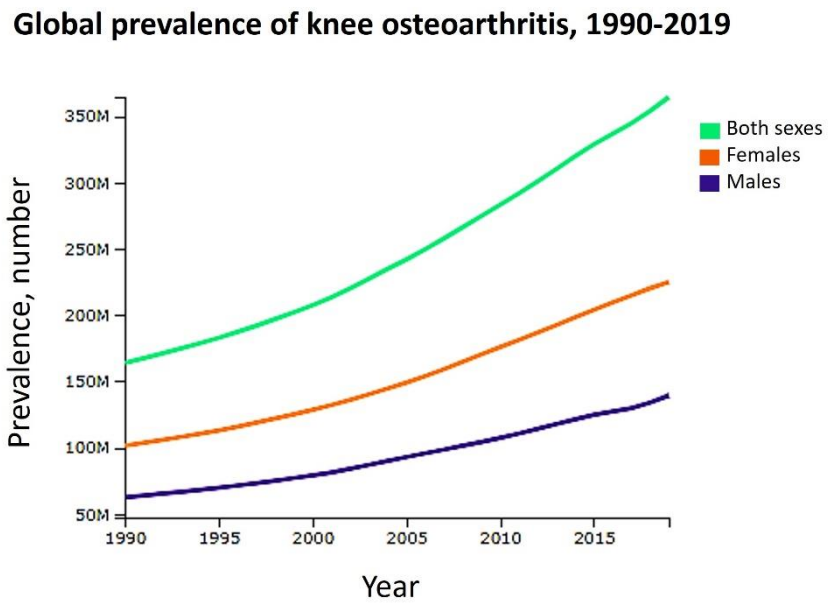


Figure 1. Global prevalence of knee osteoarthritis – (1990-2019). Screenshots from the Institute for Health Metrics and Evaluation's database were reproduced with permission using data from the Global Burden of Diseases study 1990-2019.

The causes of KOA are not yet fully understood, although several risk factors have been identified. Heritability along with other risk factors, such as injury and its related avoidance, body weight, muscle mass, and bone and cartilage structures account for approximately 40% of KOA (27), though the strongest risk factors are previous knee injury (odds ratio (OR) 2.83) followed by overweight and obesity (OR 1.98 and OR 2.66, respectively) (28). High Body Mass Index (BMI) explained 25% of new onset knee pain (28, 29); a 5% weight loss has been demonstrated to lead to a decrease in knee disability (30). Another risk factor is female gender (OR 1.68) (28); KOA is more prevalent and more severe among women (31).

Ageing-associated changes, such as reduced muscle mass; increased fat mass; metabolic changes, degenerative processes in cartilage, meniscus and ligaments; and mitochondrial dysfunction could contribute to the development of OA (32). Also, lifestyle changes, such as changes in physical activity levels (33) and overweight and obesity (34), are more prevalent in older people, which could increase the risk of developing KOA.

Although the disease is most prevalent among the elderly population, KOA is present in younger adults too (35). Even though most young adults have a healthy weight, only 20% have a normal BMI in late midlife. It has been suggested that almost one third of all knee replacements could be prevented if young adults (18-21 years old) delayed weight gain (of 8-12 kg) until they are 62 years old (36). Overweight and obesity have the potential to initiate knee joint changes due to mechanical overload or metabolic factors, such as increased fat mass and metabolic syndrome (37). Younger people with a history of sports-related joint injury have an increased risk of developing KOA (38), and high levels of high-intensity sports are also associated with an increased risk of developing KOA (hazard ratio=1.13, 95% CI: 1.07-1.19) (39).

1.2 DISEASE BURDEN

KOA is considered to be one of the most common causes of disability in musculoskeletal disorders (40) and one of the leading and increasing causes of global disability (41). The estimated disability-adjusted life-years (42) have increased among people with OA by 35% between 1990 and 2015 (43). The number of people with obesity is growing fast and by 2030, it is estimated that over one billion people will be overweight or obese worldwide, meaning that 24% of all women and 19% of all men will have obesity (44). In addition to the expected demographic shift globally, where older people aged 65 years or older have outnumbered children under the age of five, it is estimated that by 2050, older people will be twice as many than children under five years of age (45) thus increasing the disease burden (43). Another global challenge concerns the need to educate enough healthcare professionals to respond to the expected demographic shift (46). It is estimated that 2.4 billion people worldwide would benefit from rehabilitation services, 14% of which suffer from OA (47).

People with KOA are twice as likely to be on sick leave compared to the general population (48). KOA accounts for 1.3% percent of all sick leave costs in Sweden and is one of the largest drivers of sick leave costs (49).

1.2.1 IMPACT ON THE INDIVIDUAL

OA has a negative impact on health-related quality of life (HrQoL), and people with OA have significantly lower HrQoL than the general population, with physical health being affected more than mental health (50). Most people with KOA have at least one comorbidity (72%) and have more comorbidities than the general population (51). The most common comorbidities are low back pain (46%), cardiac disease (45%), diabetes (24%), and depression (14%) (52). However, cardiovascular diseases and diabetes may be present before the KOA diagnosis, and these diseases share two of the same risk factors, physical inactivity and overweight (52).

KOA pain can lead to activity limitations if individuals avoid painful activities (53-55). This can lead to a downward spiral of physical deconditioning, where muscle weakness occurs due to pain avoidance (54, 56) and results in further limitations in daily activities (55, 56). Previous study report that 79% of people with OA had quit or reduced their physical activities because of their symptoms (57). Lower physical activity level is associated with increased risk of mortality, cardiovascular disease, cancer and diabetes mellitus (58). Overweight and obesity lead to a higher concentration of adipose cells between the muscle cells. These adipose cells can increase the levels of pro-inflammatory hormones, which can cause joint and cartilage damage (59). Among people with KOA, the continuation of physical activity is seen as essential (60). In previous studies, people have requested more time for consultation and more information about OA. Persons with KOA reported that they received unclear explanations or gained insufficient knowledge about KOA (61, 62) and need help to return to physical activity (60).

The mean number of days on sick leave for people with KOA is 81 days (63, 64), and more than half (53%) have a sick-leave period longer than three months (63). For this group of individuals, there is a high rate of recurrence, where 33% had another sick leave period due to KOA and 71% for another musculoskeletal disorder (65). Further, women working in the healthcare, childcare and cleaning sectors had a higher risk of sick leave and disability

pension due to KOA (65). Disability pension is slightly higher for women with KOA than for men with KOA (relative risk (RR) 1.54 and 1.36, respectively) compared with the general population (48). Similar sick leave rates and work loss have been reported in another study (66), and it is estimated that costs associated with productivity loss will increase by 46% from 2010 to 2031, where 38% of the increase is explained by an increase in OA and demographic shifts (66). One in six individuals with KOA have work adaptations, and those who are able to remain at work have significantly better health status than non-workers (67). It is estimated that 24% of people with OA leave work prematurely, but it is not significantly higher than the number for people without OA (68).

According to the International Classification of Functioning, Disability and Health (ICF), KOA affects body function, activities and participation (69); see the potential impact of KOA as described with ICF in ***Figure 2***.

1.2.2 HEALTHCARE PERSPECTIVE

OA is one of the most common reasons for seeking primary care (70). It is estimated that by 2032, almost 30% of all Swedes aged 45 years or older will have contacted primary care for OA symptoms and half of these contacts will be for KOA (26). The burden increases as the risk for all-cause mortality increases (71), and this group of people has more comorbidities than the general population (51). Costs increase twofold when managing 2-3 comorbidities versus 0-1 comorbidities, and three-fold when comparing three or more to zero comorbidities for people over 55 years of age (72). Despite the contradiction against using strong opioids in OA care (73, 74), the consequences of the widespread use of opioids has resulted in increased societal costs (75). When people with OA use strong opioids, there is a significantly higher healthcare cost but only a modest pain reduction, along with an increased burden of comorbidities, cognitive impairment and drug addiction (76).

The medical costs of OA have been estimated to account for about 1.0-2.5% of national gross domestic product (77), with knee joint replacements being the most costly (78), at 87% of all OA related costs in Sweden (79). Costs for OA care in Sweden are estimated to be SEK 2 842 million per year (79).

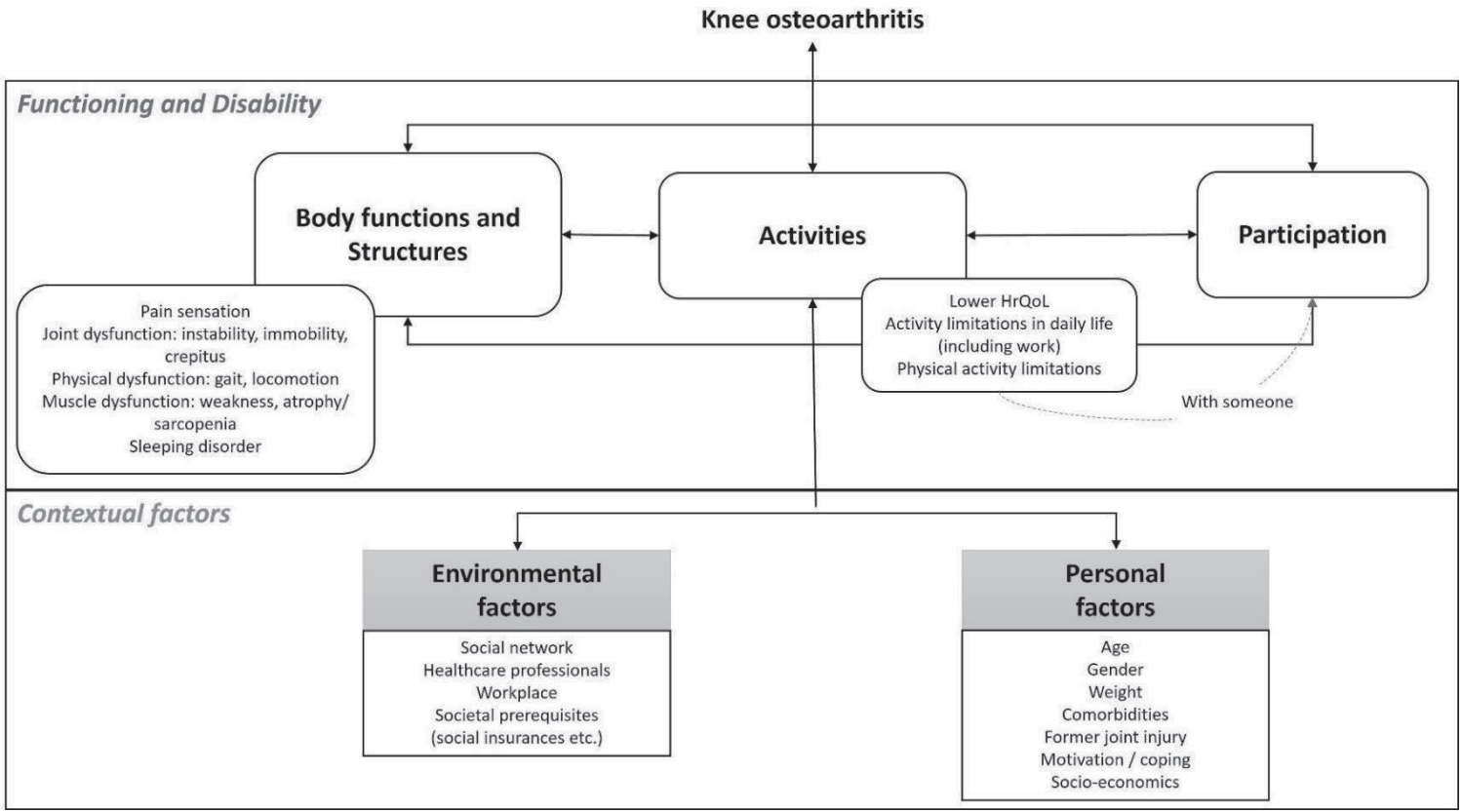


Figure 2. The possible impact of knee osteoarthritis described with the International Classification of Functioning, Disability and Health (ICF). HrQoL=Health-related quality of life.

Guidelines do not recommend diagnostic radiography in typical presentations of OA (80). However, according to data from the Swedish Osteoarthritis Registry from 2019, two out of three people stated that they underwent a radiographic examination before seeing a physiotherapist, which corresponds to costs of approximately SEK 10 million annually (79).

1.2.3 CARBON FOOTPRINT

The carbon footprint of care is defined as the total greenhouse gas emissions for clinical pathways, products or services, where emissions are calculated as carbon dioxide equivalents (CO_2e) (81). A sustainable healthcare system is defined as a system that works with available environmental and social resources to improve current health and the health of future generations. To achieve this, healthcare needs to work to reduce carbon emissions, minimise waste and pollution, increase resource efficiency, strengthen community and its assets, and build resilience to climate change (81).

The healthcare system's carbon footprint represents 5.5% (range 3.3-8.1%) of a country's total emissions, and the Swedish healthcare system generates emissions corresponding to 4.5% of total national emissions (82). Pharmaceuticals represent about a tenth of the total emissions in healthcare (82). The use of magnetic resonance imaging (MRI) and computed tomography (CT) scanners account for 0.77% of global carbon dioxide emissions, and emissions are expected to increase (83).

In total, a single surgical procedure is estimated to lead to 35 kg CO_2e, where energy and consumables account for 62% of emissions (84). In KOA care, first-line treatment could postpone surgery by two years or more (85), and fewer knee replacement surgeries could decrease the ecological footprint through a reduction in surgical waste (86). Also, changing the manufacturing methods used for the production of knee prosthetics so that less waste material is generated can reduce carbon emissions by 75% compared to conventional methods (87). A total of 20,533 knee arthroplasties were performed during 2023 in Sweden (88), which corresponds to total emissions of 718,655 kg CO_2e. Further, more than 80% of people with hip and KOA received pharmacological interventions before starting core treatment with SOASP (89). Based on the estimated emissions from self-management in healthcare (1.6 CO_2e) (90), creating clinical pathways with less pharmacological

interventions, radiography and surgery would reduce the ecological footprint of OA care.

1.3 ASSESSMENT AND DIAGNOSIS

Most often, people seek care when they are unable to do the same activities as before (i.e. their physical function has worsened) (91) or when pain becomes unbearable (57). Depending on a country's healthcare system, the primary assessor can differ. Usually, the first assessment is in primary care (79, 92, 93).

Sweden has guidelines stating that a physiotherapist should assess people with suspected KOA (94). Based on the results of a survey, it appears that most people who seek care for knee pain in Swedish primary care meet with a physiotherapist first, but a physician was also the first assessor in a great extent. The results also show that it is the physiotherapist who makes the diagnosis, but that in most cases, a physician also assessed the individual before the diagnosis was entered in the medical record (79). In this thesis, I describe the clinical assessment of KOA in primary care; therefore, radiography assessment and the associated diagnostic criteria are not described here.

Guidelines recommend an overall assessment that includes individual history, reported symptoms (e.g. knee pain, morning stiffness, functional and activity limitations, and participation restrictions) and clinical findings (e.g. decreased joint range of motion) (95-97). Radiology is indicated when serious pathology or malignity is suspected (80) or as a basis for deciding whether surgery is indicated (98). Diagnostic criteria differ as described in ***Table 1***. Skou et al. (99) evaluated the three most common classification criteria for KOA and concluded that among the individuals included in their cohort (n=13,459), most met the criteria for KOA according to the National Institute for health and Care Excellence (NICE) criteria (89%) (97). This can be compared to 48% of individuals when the European League Against Rheumatism (EULAR) criteria was applied and 52% when the American College of Rheumatology (ACR) criteria was applied (96, 100). The ACR criteria seem to reflect later stage OA (101), and diagnostic criteria for early KOA is in development (102) (***Table 1***).

Potential differential diagnoses are meniscal tears, ligament lesions, tendinosis/itis, bursitis, inflammatory arthritis, other inflammatory/systemic conditions (e.g. polymyalgia rheumatica, rheumatoid arthritis), or malignancy.

Table 1. Comparison of three most common classification criteria for knee osteoarthritis

		NICE	ACR		EULAR
Symptoms	Knee pain	●	●		●
	Age	≥ 45 years	≥ 38 years	≥ 50 years	≥ 40 years
	Morning stiffness ≤ 30 minutes	●	●	○	●
	Functional limitations				●
	Crepitus		●	○	○
Clinical findings	Restricted range of motion				○
	Bony enlargement			○	○
	Bone margin tenderness			○	
	No palpable warmth			○	

● Necessary criteria

○ Conditional criteria, ACR: at least 3 of 6 except knee pain, EULAR: plus one or more except necessary criteria.

NICE=National Institute for health and Care Excellence's classification criteria for knee osteoarthritis.

ACR=American College of Rheumatology's classification criteria for knee osteoarthritis.

EULAR=European League Against Rheumatism classification criteria for knee osteoarthritis.

It is worth noting that meniscal tears may be the first sign of KOA or may be caused by existing KOA (103). Either way, treatment is not likely to differ between KOA and meniscal tears.

There are several questionnaires that can be used to evaluate patient-reported outcomes, where the Knee injury and Osteoarthritis Outcomes Score – Physical function Short form (KOOS-PS) can be used to assess knee function and the EuroQol 5 Dimensions 3 Levels (EQ-5D-3L) for HrQoL and Visual Analogue Scale (VAS) or Numeric Rating Scale (NRS) can be used to assess pain, and are some of the suggested tools in the standard set of outcome measures (104).

Additional testing of physical performance can be used as a complement to patient-reported outcome measures, where the 40m fast paced walk test, stair climb test and 30-second chair stand test (30 CST), are the recommended minimal core sets of performance tests according to Osteoarthritis Research Society International (OARSI) (105).

The 30 CST can be used for older people and is a performance test used to evaluate lower body strength and body function (106). The test could be useful as a self-assessment (e.g. in digital physiotherapy). Previous studies have evaluated different technical solutions used to facilitate the use of the 30 CST as a self-test in healthy individuals, and individuals with multiple sclerosis, cancer or OA (107-110). It appears that in these studies, evidence in support of reliable self-tests that measure physical function in people with KOA without the use of technical devices is lacking. In addition to a reliable self-test, the identification of a cut-off value for reduced physical function could make it easier for clinicians to interpret test results without checking reference values.

KNOWLEDGE GAP

Is the 30-second chair stand test a reliable self-test for people with knee osteoarthritis?

What is the cut off value for reduced physical function using 30-second chair stand test as self-test for people with knee osteoarthritis?

1.4 TREATMENT GUIDELINES

There are several treatments used for people with KOA, and in this thesis, I will describe the core treatments, that is, non-pharmacological and non-surgical treatments provided by physiotherapists.

1.4.1 CORE TREATMENT

The core treatment for KOA is patient education, exercise and weight loss, if necessary. The aim is to achieve symptom relief through continued self-care of lifelong joint disease. For some people, complementary drug treatment and assistive devices are needed. For more severe symptoms or cases where core and additional treatment have insufficient treatment effects, surgery may be a treatment option (73, 74). Treatment guidelines (74, 95) are illustrated in ***Figure 3***.

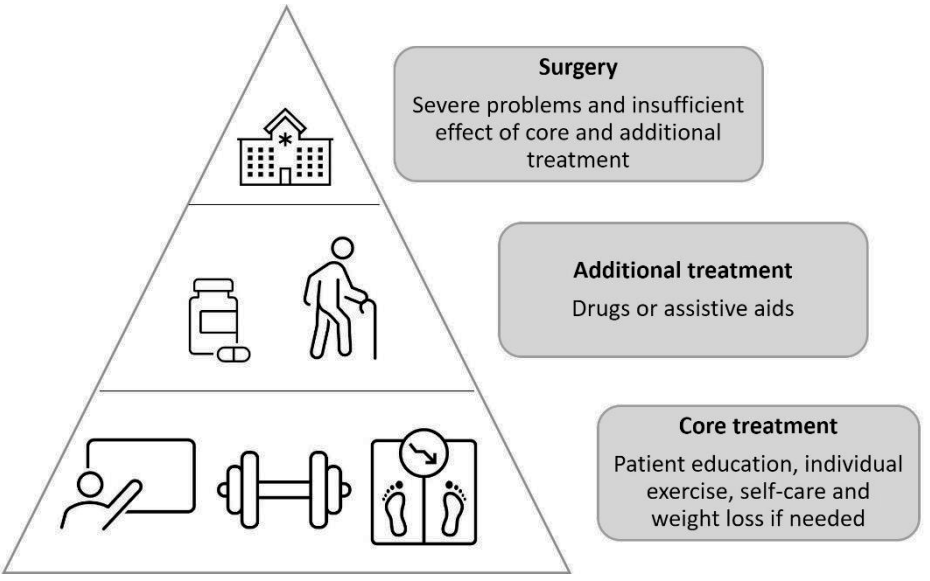


Figure 3. Treatment guidelines for typical presentation of knee osteoarthritis

Due to the gap between recommended evidence-based OA treatment and current clinical practice (111), new models of care have been developed (112). Eighteen years ago, the evidence-based SOASP was developed in Sweden (113). This concept included patient education about OA, emphasized the importance of exercise and physical activity and offered recommendations to self-manage symptoms. Thereafter, individualized exercises were introduced and practiced on-site under the supervision of a physiotherapist or at home. The treatment was evaluated after three and 12 months (113). Although research shows that exercise reduce pain regardless of the severity of OA (114), results from the 2023 national evaluation of OA care in Sweden show that only 38% of people with OA receive physiotherapist-led exercise and 63% receive some form of exercise (physiotherapist-led, self-managed exercise or digital exercise). This is far from meeting the target, where the goal is for 80% of all people with OA in Sweden to receive physiotherapist-led exercise (79).

Inspired by the Swedish concept, a similar approach has been developed in Denmark (Good Life with osteoArthritis Denmark – GLA:D) (115). In this programme, 80% of all participants receive evidence-based supervised physical exercise twice a week for 6-8 weeks (115). The difference between the procedures used in Sweden and Denmark is that the Swedish SOASP allows the individual to choose which form of exercise they prefer (79), while

the Danish model also offers home exercise, but strongly recommends supervised exercise as it increases adherence to the exercise programme and has a greater effect (115).

Globally, a recent study found 37 different models of OA care from 13 countries, where the majority (62%) were self-management programs. There is some evidence that these models of care improve individual patient outcomes and quality of care, but the long-term effects of these programmes need to be evaluated (116).

1.4.2 DIGITAL TREATMENT

Several years ago, a Swedish digital KOA treatment was introduced as a mobile application (117), consisting of a digital physiotherapist assessment, exercise programme and patient education. Of all people registered in the Swedish Osteoarthritis Registry in 2023 (n=25,367), 64% were registered through this digital platform (118), indicating that there is a high demand for digital healthcare.

During the COVID-19 pandemic, digital healthcare emerged as an option for people with KOA who could not be assessed face-to-face because of the infection risk (119). Individuals with KOA were largely forced to use technical solutions to get access to healthcare, since most of these individuals were members of a risk group. In the aftermath of the pandemic, the evidence regarding digital physiotherapy shows that more studies are needed to evaluate the reliability of common physiotherapy tests in a digital setting (120).

1.5 TRADITIONAL CARE PATHWAY IN PRIMARY CARE

Traditionally, physicians act as primary assessors for all people seeking healthcare and refer individuals for further assessment or treatment as needed. It is estimated that a primary care physician would need 27 hours per day to provide guideline-recommended primary care (121). Primary care physicians assess a large number of people with musculoskeletal disorders that can be treated in physiotherapy, yet the referral rate is low and the likelihood that an individual with OA will be referred to a physiotherapist is only 5% (122). Given the multiple diagnoses a primary care physician encounters daily, it has

been shown that physicians down-prioritize OA relative to other diseases (123). In addition, physicians express that it is difficult for them to know how to manage OA (61, 124), and prescribing exercise was perceived as beyond a primary care physicians' area of expertise (123). Before 2010, the most common non-pharmacological KOA treatment offered by physicians was referral to an orthopaedic surgeon (less than 3% of individuals were referred to a physiotherapist). Only 4% of people with KOA received exercise treatment and 15% received patient education (125). More recent studies of physician managed OA care show that people with KOA still receive low value care, where individuals continue to receive recommended treatments at a low rate, and pharmacological treatments, imaging and referral to surgery were still at high levels (92, 126).

Healthcare managers and decision makers are challenged by the ongoing need to increase the number of physicians (127, 128). As mentioned earlier, the situation will be more difficult to solve due to demographic changes (45). Despite an increase in the number of physicians in Sweden in recent years, there is still a shortage in primary care (127), and similar problems have been reported in other countries (128, 129).

1.5.1 INDIVIDUAL PERSPECTIVES OF CARE

Individuals often report that they have not been taken seriously and that healthcare providers see OA as part of aging (60, 61, 130, 131). A previous study indicated that people with OA feel a sense of hopelessness and lack the knowledge they need to self-manage OA symptoms. The informants in the study perceived that surgery was the only solution. While waiting for surgery, individuals mostly received passive treatments, and exercise was seen as beneficial only after surgery (60). Although, only 65% of all referrals to orthopaedic surgeon are considered relevant for knee replacement (132). Further, it was previously believed that exercise in people with OA would only increase pain (60), and due to the belief that KOA is caused by "wear and tear", individuals feared that further loading could harm the joint (133). Individuals with KOA call for a more holistic perspective on the individual, with a reduced focus on the joint and drug treatment (61). They want more knowledge about their disease (61, 62) and need help to get started on an exercise regimen, not just a general recommendation (60).

Studies exploring experiences of KOA care are mainly about the healthcare processes initiated by physicians or other aims rather than the experiences of individuals or impact when physiotherapists are the primary assessors (60-62, 130, 131, 133). Little research has been done on the experiences and expectations of people with KOA when they have direct access to a physiotherapist. Furthermore, research has yet to explore how a physiotherapist as primary assessor could affect individuals' perceptions of their own health and the impact on self-care.

KNOWLEDGE GAP

What expectations do people with KOA have before initial assessment by a physiotherapist first?

How do people with KOA experience the first visit and subsequent care when they have direct access to a physiotherapist?

What impact does direct access to a physiotherapist have on individual perceptions of health and self-care?

The traditional care pathway with physicians as first assessors may mean that individuals receive additional examinations and treatments (e.g. radiography and drugs) at an earlier stage than is needed. The recommended treatment of patient education and exercise can also be delayed if the physician does not feel confident in the use of these treatments; see ***Figure 4*** for an example of a traditional care pathway.

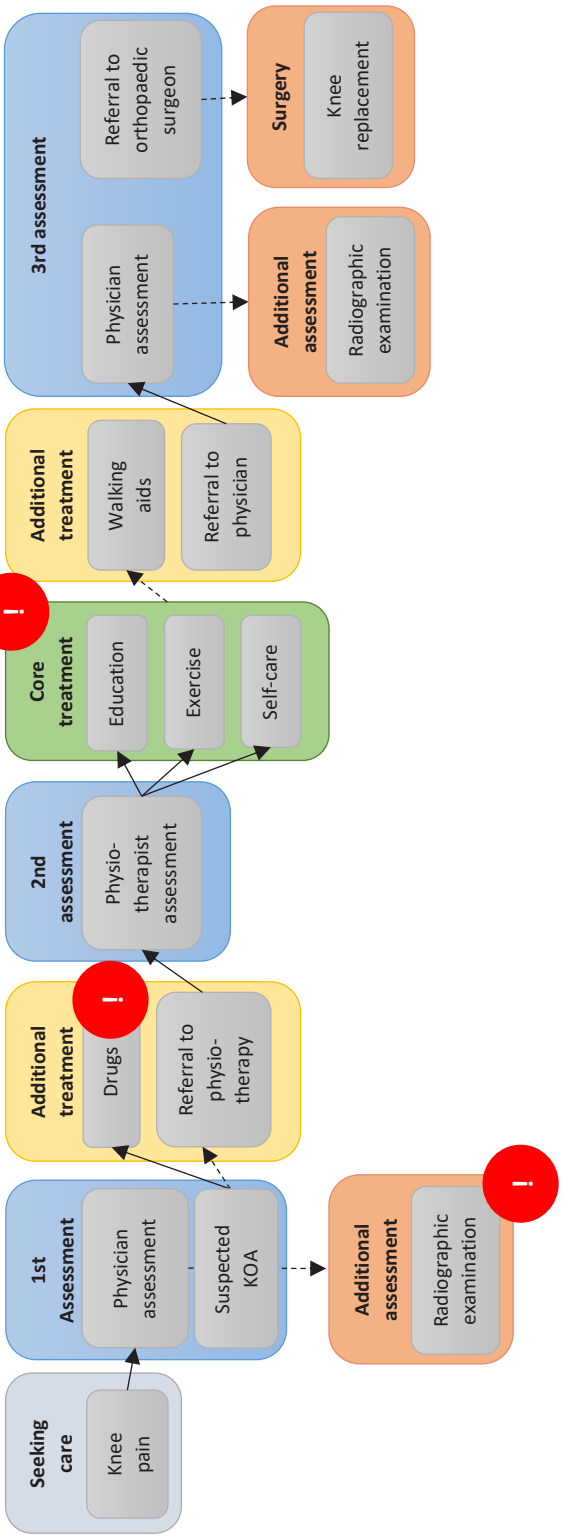


Figure 4. Flow diagram of traditional care pathway of knee osteoarthritis care

1.6 TASK SHIFT IN CARE PATHWAY WITH THE PHYSIOTHERAPIST AS THE PRIMARY ASSESSOR

Considering the diagnostic criteria and core treatments of KOA, physiotherapists can diagnose and provide recommended treatments. Physiotherapists are well-acquainted with the guidelines and feel confident in the role as primary assessor and in giving first-line OA treatment (134). A task shift in the care pathway for KOA could make the healthcare process more efficient and individuals may get direct access to recommended treatment faster. Direct access, or self-referral, means that people can seek care or refer themselves directly to the healthcare service that is needed without a referral by another healthcare professional (6). Direct access to physiotherapists was first introduced in 1957 in the state of Nebraska in US (135), and in 2023, 66 years later, 21 states have unrestricted direct access, 27 states have direct access with provisions and two states have limited direct access. In Sweden, direct access to physiotherapist was fully implemented in 2009 (136). Globally, 48% of all countries have some type of direct access.

Table 2. Overview of direct access globally

Continent	Direct access	Private only	Public only	No	Unknown*
Africa (n=54)	26%	15%	6%	6%	50%
Asia and Western Pacific (n=61)	23%	11%	2%	15%	49%
Europe (n=45)	17%	53%	-	28%	2%
North America and the Caribbean (n=23)	18%	18%	-	26%	39%
South America (n=12)	18%	37%	-	37%	8,3%
Global (n=195**)	22%	24%	2%	18%	35%

n=number
*Not members of the confederation World Physiotherapy, on which this data is based (1).
**Number of sovereign states according to the United Nations.

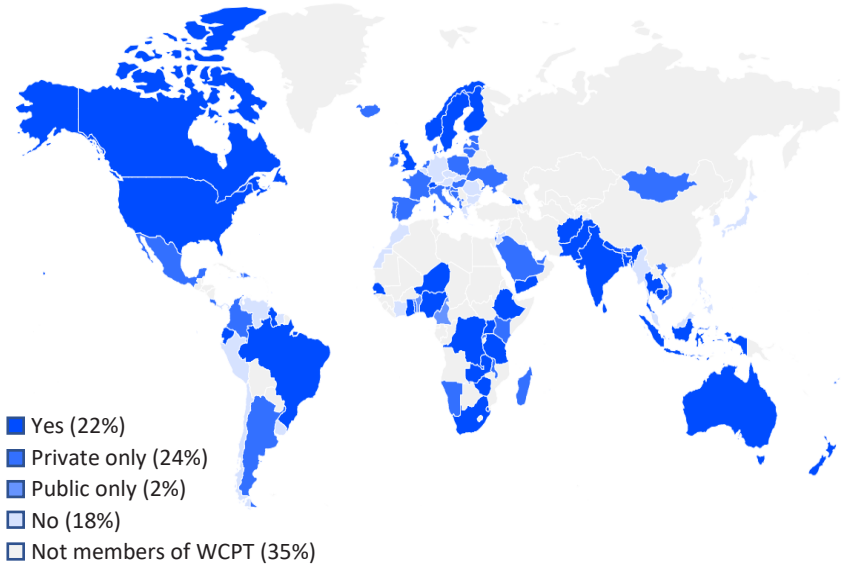


Figure 5. Direct access to physiotherapist globally for member organizations of World Physiotherapy (WCPT) (1). With the kind permission from World Physiotherapy to reuse the screenshot from their website.

Twenty-two percent of countries have stated they have direct access to physiotherapists, 24% direct access to private practitioners only and 2% to public only; see ***Table 2*** and ***Figure 5***. Even though Sweden and its Nordic neighbours use this care pathway, only 17% of European countries offer direct access to physiotherapist. This is the lowest rate compared to other continents (1) (***Table 2***). Previous study has shown that knowledge about direct access to physiotherapist varies, and this knowledge combined with positive views of physiotherapy treatment may lead more people to seek direct care through a physiotherapist (137). Previous consultation with a physician for musculoskeletal disorders could make people more likely to consult a physician first (138).

1.6.1 DIAGNOSTIC COMPETENCE

Even in countries where it is possible to consult physiotherapist directly, individuals sometimes feel that a physician consultation provides reassurance before a physiotherapist assessment (137-139). This was true even for individuals who worked in healthcare and knew the role of the physiotherapist (137). On other hand, one of these studies showed that people with musculoskeletal disorders were accepting physiotherapists as primary

assessors (138). Vervaeke et al. concluded that the essential competencies needed to assess and evaluate musculoskeletal disorders and rule out serious differential diagnoses, such as fracture or malignity, where broad skills in planning and performing an individual assessment, and clinical reasoning (140). A common concern that arises when discussing direct access to a physiotherapist is the risk that the physiotherapist will fail to detect serious pathology. In previous studies that have examined adverse events, most studies reported that there were no adverse events (141-146). One study reported that there were mild adverse events associated with a physiotherapist assessment (3%), but no difference was seen when compared to physician assessment (6%) (147). Overall, people report high levels of satisfaction when assessed by a physiotherapist first (148-151).

It is important that a physiotherapist as primary assessor has the ability to refer individuals to other healthcare providers as needed (140). In some regions, Swedish physiotherapists are able to refer individuals to radiology if needed (146). In addition to this, the competence needed to plan and motivate the use of suitable treatments were seen as essential for a primary assessor (140).

Assuming that radiographic examination is the control assessment for musculoskeletal disorders, physiotherapists have a 75% accuracy rate, which is comparable to the accuracy for orthopaedic surgeons of 81%. The accuracy rate of physicians when diagnosing musculoskeletal disorders is 35% (152). When it comes to assessing knee-joint related injuries including OA, similar study show a high inter-rater agreement between physiotherapists and orthopaedic surgeons or physicians who specialise in sports medicine (kappa coefficient=0.89), and the diagnostic inter-rater agreement regarding surgical candidates was good (kappa coefficient=0.73) (153). Furthermore, a study that evaluated people with musculoskeletal disorders has shown that 85% of individuals did not visit a physician within three months after being assessed by a physiotherapist in primary care (149), and direct access to a physiotherapist resulted in a reduction in physician visits compared to physicians as primary assessors (154-157).

1.6.2 HEALTH OUTCOMES AND COST-EFFICIENCY

Overall, several studies show when physiotherapists are the first assessors of individuals with musculoskeletal disorders, an improvement or no difference in health outcomes is seen when comparing to physicians as first assessors (145, 158, 159). From a sick-leave perspective, the care pathway with a physiotherapist as the first assessor results in a lower number of individuals on sick leave, and individuals who are on sick leave who receive an assessment from a physiotherapist first have fewer days or a shorter period of sick leave compared to people who consult a physician first (144, 154, 155, 160, 161).

Previous reviews have concluded that direct access to a physiotherapist could be a cost-effective care pathway for individuals with musculoskeletal disorders (159, 160, 162-165). Overall, direct access to a physiotherapist has been shown to lower the costs per individual (141, 142, 155, 161, 166, 167). Even though musculoskeletal disorders in lower extremities are represented in few cost-effectiveness studies, the cost-effectiveness of only KOA care have not been evaluated yet.

1.6.3 USE OF DIRECT ACCESS

Individuals who have previously sought care from a physiotherapist are more likely to seek direct care from a physiotherapist (157, 168). Individuals may also choose to see a physiotherapist first as it is a lower cost option compared to the fees charged by a physician (137). One obstacle to seeking direct care from a physiotherapist is that people are often unaware that it is possible to seek direct care (137, 139, 150). Other factors that may have an impact are condition-related characteristics (e.g. low back pain and neck pain) (156, 157), and education level (157).

1.6.4 LACK OF KNOWLEDGE ABOUT DIRECT ACCESS FOR KNEE OSTEOARTHRITIS

In recent decades, several reviews have been published about direct access (158-160, 162-165) including 73 articles, of which 43 were published over the last ten years. Most studies have evaluated direct access to physiotherapist for people with musculoskeletal disorders in general. Lower extremity musculoskeletal disorders are represented in several of the studies that have evaluated the “physiotherapist-first” model, but not as a homogeneous group.

Clinically, the care process for individuals with transient problems may differ from the process for those with chronic problems, where greater focus should be given to the individual's motivation for continued self-care after the rehabilitation period. There is a lack of knowledge about whether the treatment effect of the first assessor differs in chronic disorders such as KOA compared to other musculoskeletal disorders. There is also a knowledge gap of whether a physiotherapist as a first assessor is a cost-effective care pathway for KOA.

KNOWLEDGE GAP

Would the positive effects in health outcomes and costs seen when individuals with musculoskeletal disorders have direct access to physiotherapist be applicable for a chronic disease such as knee osteoarthritis?

1.7 KNOWLEDGE GAPS

Although both international and national KOA guidelines are well established, compliance with guidelines is insufficient. There is thus a potential to refine the care process; see ***Figure 6*** for a proposed new care pathway. One solution to make OA care more accessible is the use of digital health, where an individual could be examined remotely without needing to go to the rehabilitation centre. Before this approach can be implemented, the feasibility of existing outcome measures from self-testing instead of on-site testing needs to be evaluated. Another solution could be direct access to a physiotherapist who is confident providing first-line OA treatment. However, it is not yet known how patient-reported outcome measures would be affected by direct access to a physiotherapist or if this care pathway would be a more cost-effective alternative to the traditional physician-first care process. Also, there is a lack of knowledge of individuals' expectations before their first visit with a healthcare provider and their experiences of treatment when physiotherapist is the first assessor. Further, the knowledge about how this care pathway affects the individual's self-care and health is limited.

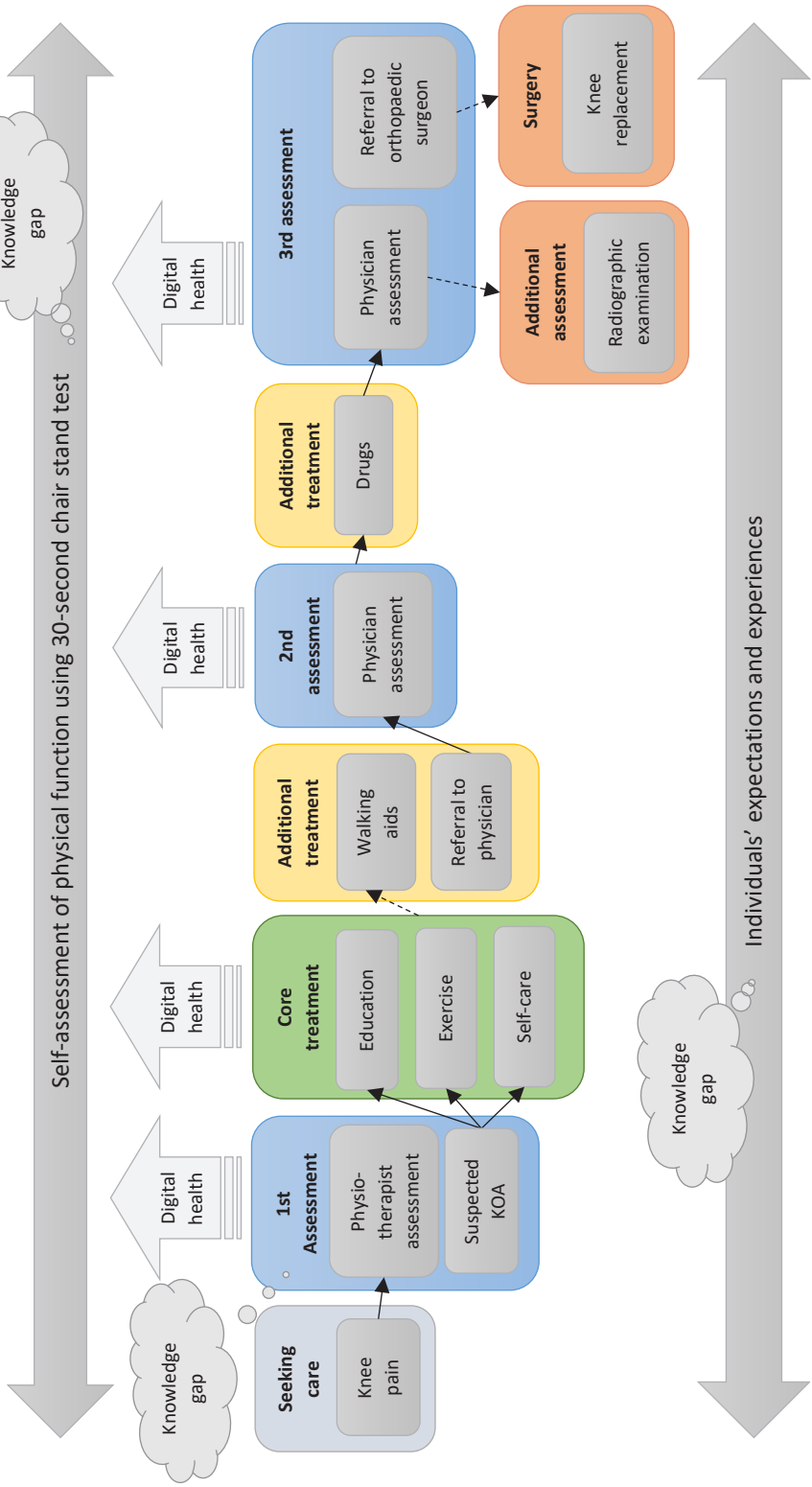
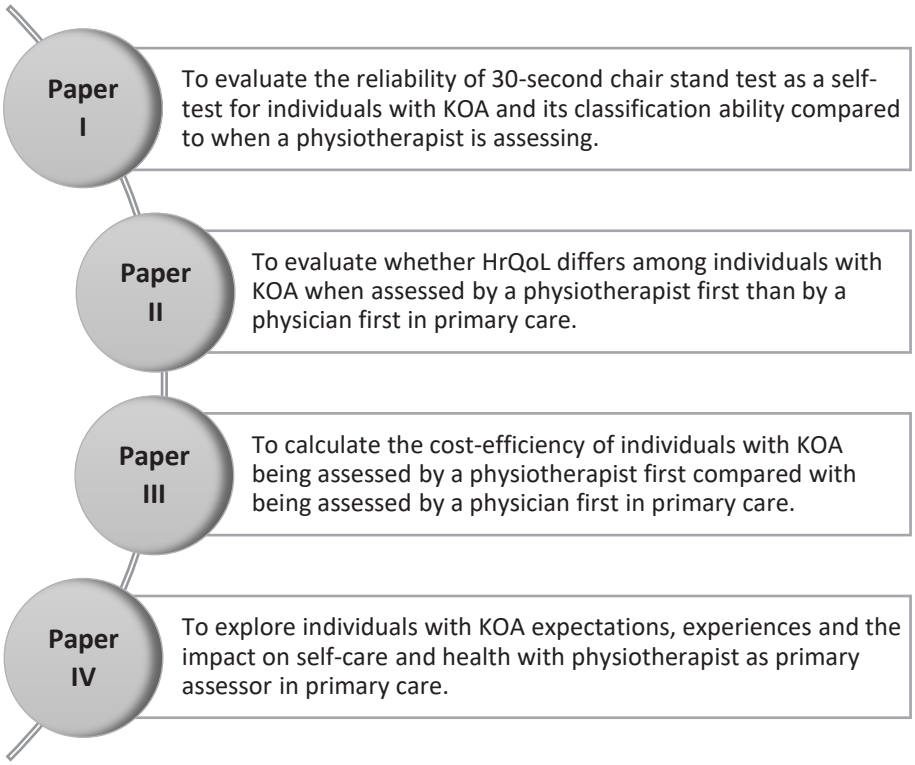


Figure 6. Knee osteoarthritis care pathway with physiotherapist as primary assessor

2 AIM

The overall aim of this thesis is to evaluate how physiotherapists as primary assessors are perceived among individuals with KOA compared to physicians as primary assessors when seeking care in primary care and how this shift in care pathways affects HrQoL and health economics. Another purpose was to evaluate whether the 30 CST is feasible as a self-test for this group of people.

Specific aims



3 METHODS

People with suspected or confirmed KOA were recruited to this doctoral project. Four different study designs, both quantitative and qualitative, were conducted to evaluate the method, individual perspective, healthcare perspective, and cost perspective in healthcare development. Due to the variety of perspectives, the data collection and analysis methods included reliability analyses, comparative analyses and qualitative content analysis.

3.1 STUDY DESIGNS

In Paper I, we designed a reliability study to evaluate a self-test that could be used by individuals for self-monitoring and in digital settings. The effects of direct access to physiotherapists for people with KOA were evaluated from multiple perspectives in three studies with different study designs. In Paper II, a randomized controlled pragmatic trial (RCT) was conducted to compare the effects on HrQoL with physiotherapists as primary assessors and physicians as primary assessors. In Paper III, the next step was to evaluate whether this new care pathway could be a cost-effective alternative. To this end, a health economics study was conducted based on Paper II. Lastly, to gather knowledge about the individual's perspective when the physiotherapist is the primary assessor, a qualitative study was conducted in Paper IV. See ***Table 3*** for an overview of all study designs.

The different papers were reported according to the following guidelines:

- Paper I – COSMIN reporting guideline for measurement properties of patient-reported outcome measures (169) and Guidelines for Reporting Reliability and Agreement Studies (GRRAS) (170).
- Paper II – CONSORT Statement (171).
- Paper III – Consolidated Health Economic Evaluation Reporting Standards (CHEERS) (172).
- Paper IV – COnsolidated criteria for REporting Qualitative research (COREQ) (173).

Table 3. Overview of all study designs

	PAPER I	PAPER II	PAPER III	PAPER IV
Design	Reliability study	Randomized controlled pragmatic trial (RCT)	Cost-efficiency study	Qualitative study with inductive approach
Study sample	(n=129)	All individuals in the RCT (n=69)		(n=15)
Enrolment units in primary care	5 rehabilitation centres	Rehabilitation centres (n=3) Primary healthcare centres (n=5)		5 rehabilitation centres
Enrolment period	February 2019 to July 2023	May 2013 to October 2017		January 2023 to July 2023
Outcome measurements	30 CST, NRS, ICOAP, KOOS-PS, pain drawing	EQ-5D-3L index, EQ-VAS, pain VAS, 30 CST	QALY, costs	Semi-structured interviews, NRS
Outcome assessments	Baseline, 2 days and 14 days	At baseline, 3, 6 and 12 months		One occasion between 1–12 months of treatment
Data analysis	Descriptive statistics. ICC, SEM, MDC, ROC curve, AUC	Descriptive statistics. Spearman's correlation rank, Chi-square test. Mixed effects models.	Descriptive statistics. ICER, linear regression analysis, independent samples t-test, bootstrapping, CE-plane, CEAC	Qualitative content analysis

30 CST=30-second chair stand test; AUC=Area under the receiver operating characteristic curve; CE=cost-effectiveness; CEAC=Cost-effectiveness acceptability curve; EQ-5D-3L=EuroQol 5 Dimensions 3 Levels; EQ-VAS=EuroQol Visual analogue scale; ICC=Intraclass correlation coefficient; ICER=Incremental cost-effectiveness ratio; ICOAP=Intermittent and Constant Osteoarthritis Pain; KOOS-PS=Knee injury and Osteoarthritis Outcome Score – Physical function Short form; MDC=Minimal detectable change; n=number; NRS=Numeric rating scale; QALY=Quality-adjusted life-years; ROC curve=Receiver operating characteristic curve; SEM=Standard error of measurement.

3.2 PARTICIPANT RECRUITMENT

The thesis included participants from primary care centres and rehabilitation centres in remote cities in southwestern Sweden in Region Västra Götaland. The population size ranged between 14,500 and 59,000 inhabitants. Most of the participants were recruited through physiotherapists at rehabilitation centres, and in Papers II and III, participants were also recruited from primary care centres. Recruitment in Paper IV was complemented with a search in the patient medical record database conducted by operations managers at the recruiting centres to identify individuals with KOA that had been treated within the past year. Thereafter, a physiotherapist from the rehabilitation centre contacted and asked the individuals whether they were interested in participating in a research study.

Screening forms based on inclusion and exclusion criteria were used in all papers; forms for Papers I-III were on paper, while forms for Paper IV were available digitally via esMaker. All papers included people with suspected or confirmed KOA. In Paper II, inclusion criteria were based on one of ACRs clinical diagnostic criteria (100):

- 38 years or older
- Pain most days of the last month
- Morning stiffness less than 30 minutes (later removed)
- Crepitus on active motion (later removed)

Due to low participant rates, the eligibility criteria morning stiffness and crepitus were removed after 20 participants were included. Potential participants who were pregnant or who suffered from severe somatic or psychiatric disorders, such as unstable heart disease, neurologic disorders, widespread pain or mental illness, were excluded due to the potential impact on outcome measurements. Also, due to the risk of further confounding individuals who had contact with the doctoral student as a physiotherapist were excluded in Papers II-IV. Because of the fall risk, people with insufficient balance were excluded in Paper I. For inclusion, participants needed to be able to understand Swedish both orally and in writing.

3.2.1 SAMPLE SIZES

All of the quantitative papers (I-III) included power analysis with power set to 80% and a significance level of 0.05. The power analysis for Paper I was conducted to detect an intraclass correlation coefficient (ICC) of 0.8. Power analyses for Paper II and III were based on a minimal clinical difference of 0.12 for the EQ-5D-3L index in people with KOA (174, 175) and a standard deviation (SD) of 0.2. With an expected dropout rate of 20% and 14% respectively, 147 participants were planned to be recruited for Paper I, and 100 participants for Papers II-III. For Paper IV, it was estimated that 12-15 participants would be sufficient plus pilot interviews. A purposeful sampling procedure was used to get as rich a variation in socio-demographic factors and treatments as possible. The socio-demographic characteristics were gender, age, origin (born in Sweden or abroad), single household or not, education level, pain duration, pain intensity, comorbidities, and treatment. See the overview of the participant flow in ***Figure 7***.

3.3 DATA COLLECTION

Data were collected through assessments, questionnaires, registers, medical records and interviews. Socio-demographic data were collected through questionnaires. In Papers I-III, age was calculated using participants social security numbers. Participants were asked to indicate their age in Paper IV. Information about KOA duration was collected in Paper I. In all papers, the participants were asked whether they were born in Sweden or abroad, and if they had a parent that was born abroad. Information about participants' education level was collected in all papers with pre-specified alternatives: primary school, high school, or college/university. In Papers I and II, BMI was assessed by measuring weight and height to calculate weight x height^2. The BMI was categorized into four different groups (176):

- underweight <18.5,
- healthy weight 18.5-24.9,
- overweight 25-29.9 and
- obese >30.

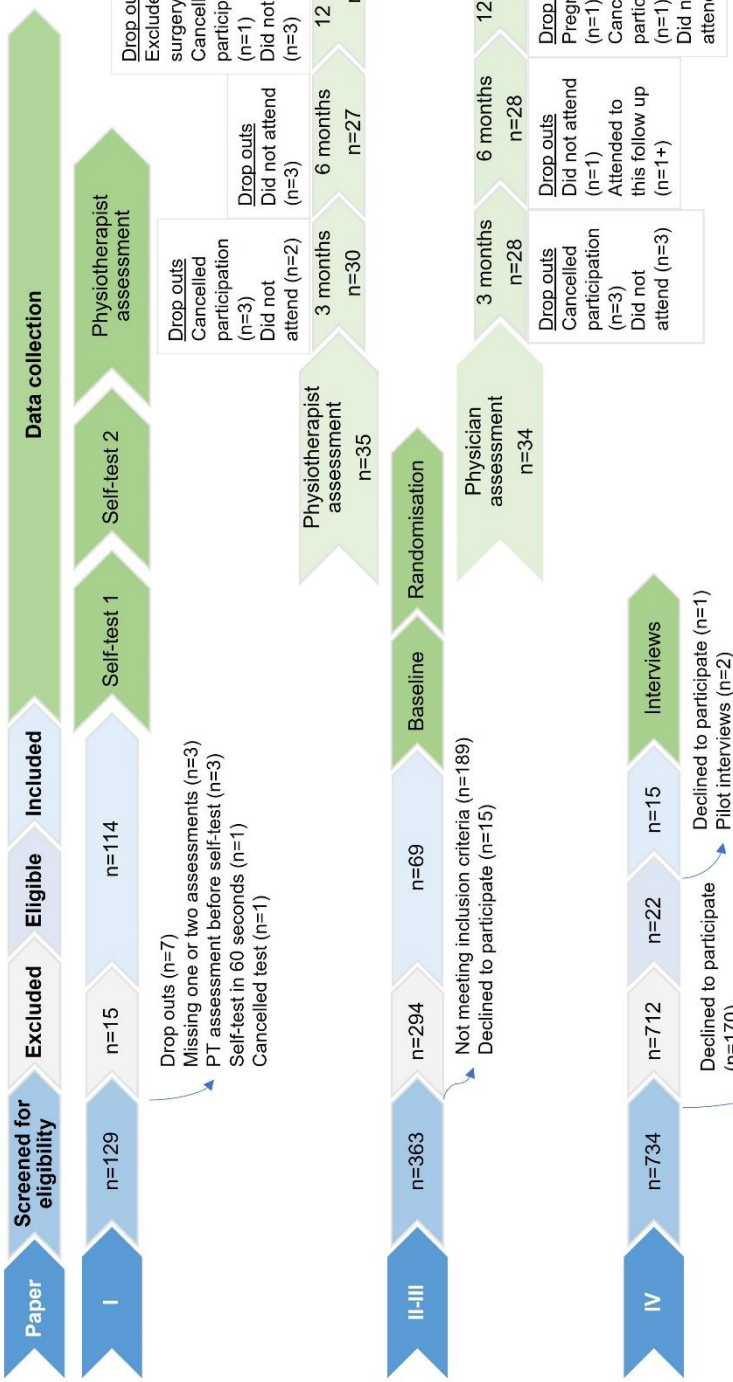


Figure 7. Flow chart over all papers I-IV

3.3.1 TEST OF FUNCTIONAL PERFORMANCE

Physical function can be evaluated using self-reported forms or performance-based tests (177), where the latter are usually assessed by healthcare personnel. Results from self-reported questionnaires tend to differ compared to performance-based tests (178).

In this thesis, physical function was measured with 30 CST in Papers I-II. This is a recommended performance test for the assessment of physical function and lower extremity muscle strength in people with KOA (105). The intra-rater reliability for 30 CST is excellent and the test is useful for individuals with KOA, with an ICC over 0.9 (179-181) and a standard error of measurement (SEM) of one repetition (181, 182). However, the construct validity and responsiveness of this instrument is lacking (182). The individual minimal detectable change (MDC_{ind}) is 2.3-2.8, and 0.25-0.36 for group level (MDC_{group}) (181).

In Paper I, the 30 CST was performed two times as a self-test at home a maximum of two days apart. Participants received an envelope with instructions for the 30 CST. They were informed before the self-tests to place a chair against the wall and, if possible, a table or similar in front of them in case they lost their balance. A chair with an approximate height of 45 cm was recommended, with or without an armrest. The start position was sitting with arms folded across the chest or on the armrests, if needed. The arms were to be kept folded in this position during the entirety of the test ***(Figure 8)***. In the written instructions, the participants were then asked to do as many stands as possible for 30 seconds (106). A full stand was counted if the participant stood with straight hips and knees and returned to the sitting position. The self-tests could

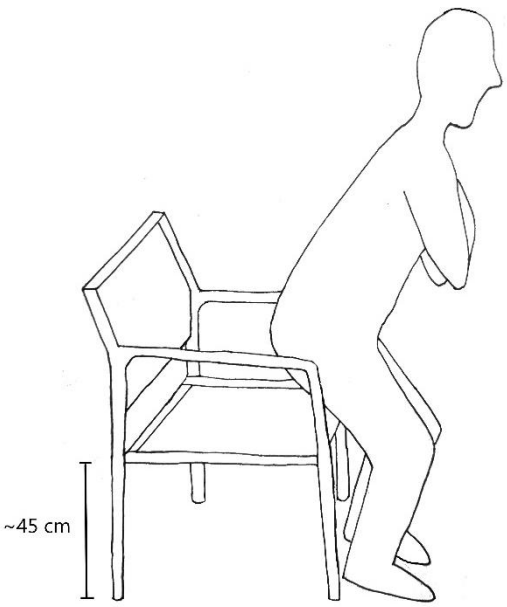


Figure 8. 30-second chair stand test. Illustrated by Chan-Mei Ho-Henriksson.

be conducted anytime of the day. The results from the self-tests were returned to the physiotherapist in a sealed envelope to ensure that the physiotherapist was blinded to the self-test results before the third test with the physiotherapist. The third 30 CST was performed on-site under the supervision of a physiotherapist within one week after the second self-test, using the same manual. All physiotherapists were instructed and trained by the PhD student (CH) according to the protocol, 30 CST and safety routines for fall prevention.

In Paper II, the 30 CST was evaluated by the PhD student (CH) who was responsible for the data collection. Participants were assessed at baseline, 3 months and 6 months after baseline. At the 12-month follow-up, the 30 CST was conducted as a self-test.

3.3.2 PATIENT-REPORTED OUTCOME MEASURES

The patient-reported outcome measures in this thesis evaluate three areas that affect the daily lives of individuals with KOA: pain, physical function and HrQoL. See the overview of patient-reported outcome measures used in Papers I-IV in ***Table 4.***

In all papers, self-reported knee pain duration was registered. In Paper I, participants marked the number and location of pain sites on a mannequin with 18 pre-specified body areas (183). In Paper I, the pain intensity was assessed with NRS (184) in order to evaluate pain intensity before the 30 CST, as well as directly after the test to evaluate pain during the test (184). The NRS ranged from 0-10, with 0 being no pain and 10 being the worst pain imaginable. The NRS was also used in Paper IV in the digital screening form, where the individuals stated their current, mean, lowest and highest knee pain intensity over the past week. In Papers II and III, the participants estimated their pain intensity over the past month. Pain intensity was evaluated with VAS 0-100 mm (185), where 0 corresponded no pain at all and 100 to the worst pain imaginable. Values from 1-99 were anchored as follows:

- 1-20: light pain
- 21-40: moderate pain
- 41-60: moderately severe pain
- 61-80: severe pain
- 81-99: unbearable pain

Table 4. Overview patient-reported outcome measures

Instrument	ICF	Paper	Description	Psychometrics
Health-related quality of life				
EQ-5D-3L index (191)	Body function, activity, and participation	II-III	Self-administrated questionnaire about HrQoL. The index is a score ranging between -0.594 and 1. A score of 0 corresponds death, and below 0 worse than death, and 1 full health.	ICC: 0.7 [CI: 0.58-0.80]. Significant rank correlations with WOMAC and SF-36. Discriminates accurately within the domains compared to SF-36. Construct validity, significant associations with other similar questionnaires. Binomial distribution and 4% of all health states accounted for 82% of the results (186). Minimal important difference: 0.12 (SD 0.32) (187).
EQ-VAS (191)	Activity, participation	II	Self-administrated questionnaire about health status. Anchored with worst imaginable health state at 0 and best imaginable health state at 100.	ICC: 0.73 [CI 0.61-0.82]. Significant association with EQ-5D-3L index (186).
Physical function				
KOOS-PS (192)	Body function, activity	I	Knee-specific questionnaire assessing physical function in daily activities. The total score ranges from 0-100, where 0 represents severe difficulties and 100 no difficulties.	Pooled Cronbach's alpha 0.85. Pooled ICC 0.81 [CI 0.67-0.87]. Measurement error indeterminate due to inconsistent results. Construct validity is insufficient (188). Cross-cultural validity: High internal consistency 0.75-0.91 with WOMAC function (189). Insufficient responsiveness (188). Minimal clinical important difference 2.2 (190).

Pain				
NRS (0-10) (184)	Body function	I, IV	Pain assessment where 0 corresponds to no pain and 10 to the worst pain.	Good correlation with VAS and simple descriptive scale (184). ICC: 0.95 [CI: 0.93-0.96], SEM 0.48 and MDC 1.3 (193).
Pain VAS (0-100 mm) (185)	Body function	II-III	Pain assessment where 0 corresponds to no pain and 100 to the worst pain.	ICC: 0.97 [CI: 0.96-0.98], SEM 0.3 and MDC 0.8 (193).
Pain duration	Body function	I-IV	Self-reporting pain duration in months.	Not tested.
Pain locations (183)	Body function	I	Self-reporting pain assessment, pre-defined locations on a pain drawing.	Not tested.
ICOAP (196)	Body function, activity, and participation	I	Disease-specific pain assessment consisting of questions about constant and intermittent osteoarthritis pain. Total score 0-100 where 0 corresponds to no pain and 100 to extreme pain. The subscales can be presented separately, 0-24 for intermittent pain and 0-20 for constant pain. Higher scores indicate more pain.	Construct validity: the subscales can be used separately (194). Internal consistency is good, Cronbach's alpha 0.86 for total score, 0.80 for constant score and 0.84 for intermittent score. Moderate construct validity (195). Cross-cultural validity: Moderate to high correlations (0.43-0.84) with WOMAC pain and function subscales (189). Reliability: ICC 0.63-0.65 (CI 0.34-0.83) (190, 195). Minimal clinical important difference is 19 on the total score, 3.8 and 3.6 on the subscales constant and intermittent pain, respectively (190).

CI: Confidence interval; EQ-5D-3L-index: EuroQol 5 Dimensions 3 Levels index; EQ-VAS: EuroQol Visual analogue scale; ICC: Intraclass correlation coefficient; ICOAP: Intermittent and Constant Osteoarthritis Pain; KOOS-PS: Knee Osteoarthritis Outcome Score - Physical function Short form; MDC: Minimal detectable change; NRS: Numeric rating scale; SEM: Standard error of measurement; SF-36: Short form health survey 36; VAS: Visual analogue scale; WOMAC: Western Ontario McMaster Universities' Osteoarthritis Index.

The Intermittent and Constant Osteoarthritis Pain (ICOAP) – Swedish version, was used to assess pain experience. The questionnaire contains two subscales with question areas about intermittent and constant pain. The total score for the intermittent pain subscale ranges from 0-24 points and from 0-20 points for constant pain. The total score from 0-44 is usually recalculated to a scale from 0-100 (total score/44 x 100), where 0 corresponds to no pain and 100 to extreme pain (196). To capture experiences of difficulties in physical function in knee related activities, the Swedish version of KOOS-PS was used. The total score ranges between 0 and 100 where 0 represents severe difficulties and 100 no difficulties (192).

HrQoL was assessed with EQ-5D-3L (191, 197). The questionnaire consists of five areas: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants were asked to estimate their level of problems, where 1 indicates no problem, 2 some problems and 3 extreme problems. The results consist of a combination of the levels in each dimension, which is expressed as a number. For example, 11111 will result in an index of 1 and corresponds to perfect health. The EQ-5D-3L index ranges from values less than 0 to 1, where 0 means death and negative values are health states worse than death. The index is based on a tariff, and the health state can differ depending on which tariff is used. In Paper II, the index was calculated using the United Kingdom (UK) tariff (198). The Swedish tariffs (199) were not available when designing the study and the UK tariff was widely used, which enhanced the generalizability. The questionnaire also consists of a VAS (EQ-VAS), where the participants were asked to indicate their current health state on a scale from 0-100, where 0 corresponded to worst imaginable health and 100 to best imaginable health.

3.3.3 COSTS AND HEALTH EFFECTS

Data for the health economics evaluation were retrieved from medical records and databases to calculate total costs. The prices for each visit were recalculated from Swedish Krona (SEK) to present the costs in Euro (€) using annual exchange rates for the years 2013-2017 when the research in Paper II was conducted. See the overview in ***Table 5***. The total costs were presented from a healthcare perspective and a societal perspective. The difference is that the societal perspective includes healthcare costs, productivity loss and unpaid work compensation.

Table 5. Data collection of health and cost outcomes

Outcome	Description	Data collection
QALY	The QALY combines life length and quality of life in one single measure. One corresponds to full health and 0 to death.	Calculated from data collection of EQ-5D-3L index in Paper II.
Visits	Physiotherapy: individual, group and telephone calls. Physician: individual, telephone calls, drug prescriptions only, letter. Nurse: individual, telephone calls.	Review of medical records and register data from VEGA.
Costs per visit	The cost of different visits with a physiotherapist, physician, nurse and orthopaedic surgeon and radiographic examination. Depending on the type of visit, i.e. telephone call, on-site visit, administrative; the costs differed based on the duration. Duration was based on clinical estimations from physiotherapists, physicians and nurses.	Calculated using standard costs for primary care in 2013-2017.
Referrals	Referrals to physiotherapist, radiography and orthopaedic surgeon.	Number of referrals was retrieved from medical records.
Prescribed drugs	Drugs belonging to the Anatomical Therapeutic Chemical Classification groups: M01 anti-inflammatory and anti-rheumatic products, M02 topical products for joint and muscular pain, M03 muscle relaxants, M09 other drugs for disorders of the musculoskeletal system, N02A opioids, N02B other analgesics and antipyretics.	Retrieved from the regional drug database Digitalis: collected drugs, substance, strength, amount, total cost, benefit cost and patient charges for drugs.
Productivity loss	Productivity loss included time for healthcare visits plus travel and waiting time for each visit and sick leave. The productivity loss was calculated using mean gross salary, including social fees; net mean salary was used if the individual was retired or on sick leave.	Number of visits was retrieved from medical records and register data from VEGA. Sick leave notes were collected from medical records.

EQ-5D-3L=EuroQol 5 Dimensions 3 Levels
QALY=Quality adjusted life-years
VEGA=Regional healthcare database of Region Västra Götaland.

3.3.4 INTERVIEWS

Semi-structured interviews were carried out to explore individual expectations and experiences of physiotherapists as primary assessor. An interview guide was used, and minor changes were made after the pilot interviews. The changes included a more open initial question. The questions about the impact on health and self-care were revised to be open-ended questions rather than close-ended questions. Also, additional prompts were added to the interview guide. The question areas were about expectations and experiences of the first visit and continued contact with healthcare providers, as well as the impact on perceived health status and self-care.

All of the interviews were recorded using an MP3-player or through a secure video conference call (Cisco Webex). All interviews were conducted at a location decided by the participant. Six of the interviews were conducted by video call, five interviews on-site at a rehabilitation centre, and four interviews by telephone. The interview data was transcribed verbatim; most were transcribed by the PhD student (CH) and the remainder by an R&D coordinator.

3.4 INTERVENTIONS

The 30 CST as a self-test was evaluated as the intervention in Paper I and used as a secondary outcome in Papers II-III. This physical performance test is recommended in the OARSI test battery for assessing physical function in people with KOA (105). The 30 CST was first described in 1999 by Jones et al. (106) and was developed to assess a wider range of functional level since the former sit-to-stand tests, such as the five and ten chair stand tests had a floor effect when participants were unable to perform the amount of stands required.

Papers II-IV evaluated the intervention with a physiotherapist as primary assessor for people with KOA in primary care. In Papers II and III, the intervention was compared to assessment, diagnosis and treatment by a physician. Participants in the study were only obliged to attend the first visit, which they were randomly assigned to. Thereafter, they could choose to continue or change to the other group, regardless of whether they received a referral. Paper IV explored the experiences of individuals who received an

initial assessment from a physiotherapist without a physician referral. Individuals in Paper IV did not participate in the RCT.

3.5 DATA ANALYSIS

All quantitative papers (I-III), present descriptive analyses of demographic data and patient-reported outcome measures. Descriptive data were presented with mean and SD, median and interquartile range, and number and percent. The first paper consisted of reliability and ROC curve analyses. In Papers II-III, a healthcare process initiated by different primary assessors for people with KOA and the long-term impact one year after assessment were evaluated. Assessment was conducted at baseline and follow-up at 3, 6 and 12 months after baseline. Comparative analyses were used since we were interested in how the outcomes changed over time between the groups. In Paper II, mixed effects models were used to analyse both individual changes over time and between groups, while Paper III included health economic analyses. To analyse the interview data in Paper IV, a qualitative content analysis was performed. See the overview of all analyses in ***Table 6.***

3.5.1 PAPER I – RELIABILITY, SENSITIVITY AND SPECIFICITY

Reliability describes how well measurements can be repeated. Similar terms for describing precision are repeatability, stability, consistency, reproducibility, and agreement (15). Inter-rater reliability represents the variation of two or more raters who test the same group of participants. Another term used is test-retest reliability which reflects how much the measurements vary when the same instrument is used on the same participant and under the same circumstances. Intra-rater reliability shows the variation of two or more measurements conducted by the same rater (200).

$$\frac{True\ variance}{True\ variance\ +\ Error\ variance} = Reliability\ (index\ 0-1)$$

Common reliability analyses are the Pearson correlation coefficient, ICC, analysis of variance, paired t-test, coefficient of variance and Bland-Altman plot (10). ICC are a measure of reliability that evaluates both the degree of correlation and agreement between measurements; ICC was used in Paper I.

Table 6. Overview of analyses

Type of statistics	Paper I	Paper II	Paper III	Paper IV
Descriptives				
Number (%)	●	●	●	
Mean (SD)	●	●	●	
Median (IQR)	●	●	●	
Correlations				
Intraclass correlation coefficient	●			
Spearman's correlation rank		●		
Regression				
ROC curve	●			
Mixed effects models		●		
Linear regression			●	
Comparative analyses				
Chi-square test		●		
Independent samples t-test			●	
Health economic evaluation				
Incremental cost-effectiveness ratio			●	
Sampling uncertainty				
Bootstrapping			●	
Cost-effectiveness plane			●	
Cost-effectiveness acceptability curve			●	
Qualitative analysis				
Qualitative content analysis				●

IQR = Interquartile range
ROC curve = Receiver operating characteristic curve
SD = Standard deviation

There are different forms of ICC calculations (201), and the choice of ICC is based on the set of raters and whether they are randomly selected or not. The models that can be used are the one-way random-effects model, two-way random effects models and two-way mixed-effects models (200). The one-way random-effects model is used when the participant is rated by different randomly picked raters from a large population of possible raters. The two-way random-effects model is used when the study consists of a random sample of raters with similar characteristics, and the two-way mixed-effects model is

used in test-retest situations or for intra-rater reliability (200). Both the two-way mixed model and random-effects model are based on the same equation, and the differences between these models are in the study design and the interpretation of the results (200).

In Paper I, we measured the intra-rater reliability of the self-tests, which means that the participant was both the rater and the one being assessed. The two-way mixed-effects models was used to evaluate the intra-rater reliability, and the two-way random-effects models was used to evaluate the inter-rater reliability between the self-test 2 and the physiotherapist assessment.

Absolute agreement reflects how much the results of rater 1 agree with the results from rater 2. The consistency shows how much the raters' results differ over time. In Paper I, results of absolute agreement and the ICC of average measures are presented (i.e. the mean reliability index of the different raters). The ICC was interpreted according to Portney et al. (202):

- < 0.5 poor reliability,
- 0.5-0.74 moderate reliability
- 0.75-0.89 good reliability, and
- ≥ 0.9 excellent reliability

The results were considered a floor effect if the number of participants scoring 0 on the 30 CST exceeded 15% (203). The SEM was calculated using the equation:

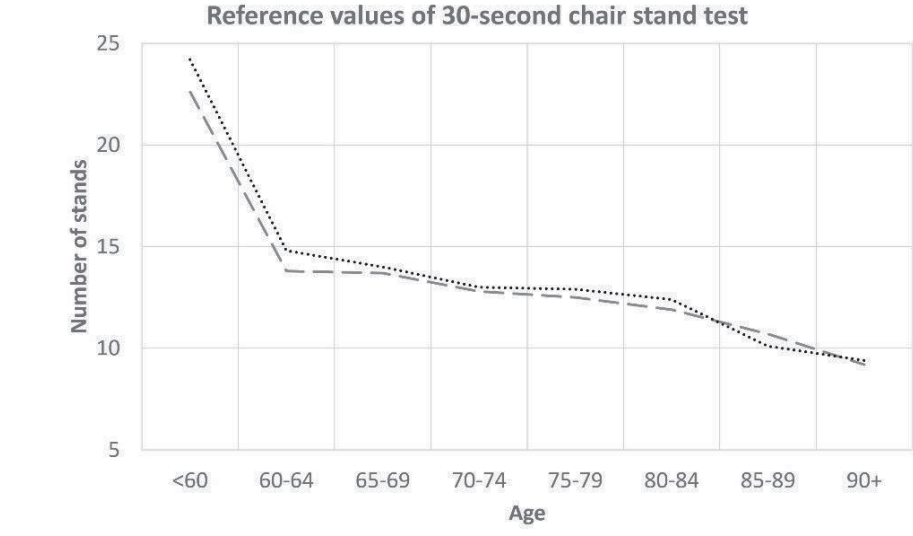
$$SEM = SD\sqrt{(1 - ICC)}$$

The SD in this equation was retrieved from the mean SD from the two tests included in the ICC analyses. Post-hoc analyses were made to use SEM in a calculation of MDC for self-tests and between the self-test and physiotherapist assessment. The MDC is presented on an individual level and group level (MDC_{ind} and MDC_{group}). The following equations were used (203):

$$MDC\ ind\ =\ 1.96\ x\sqrt{(2)}\ x\ SEM$$

$$MDC\ group\ =\ MDC\ ind\ /\ \sqrt{(n)}$$

In Paper I, a logistic regression analysis was conducted to determine whether the 30 CST as a self-test was able to detect reduced physical function to the same extent as an in-person assessment with a physiotherapist. A receiver operating characteristic (ROC) curve illustrated the trade-off between true positive answers (sensitivity) and false positive answers (1-specificity) in 30 CSTs as a self-test. In this analysis, the results from the 30 CSTs were dichotomized into normal physical function if equal to or above the reference value and reduced physical function if below the reference value (204, 205) (***Figure 9***), which meant that the ROC curve was adjusted for age and gender. The ROC curve represents the relation between the test's sensitivity and 1-specificity, meaning that the curve consists of cut off values with different levels that indicate how well the self-test can detect physical dysfunction when it is present and the probability of a finding of reduced physical function in individuals with normal physical function. There is a trade-off where either the sensitivity or the specificity is prioritized; see illustration in ***Figure 10***. The ROC curve analysis resulted in the presentation of the sensitivity and specificity of different cut-off values.



		<60	60-64	65-69	70-74	75-79	80-84	85-89	90+
— -	Women	22.6	13.8	13.7	12.8	12.5	11.9	10.7	9.2
·····	Men	24.2	14.8	14.0	13.0	12.9	12.4	10.1	9.4
		Number of stands per age interval							

Figure 9. Reference values of 30-second chair stand test

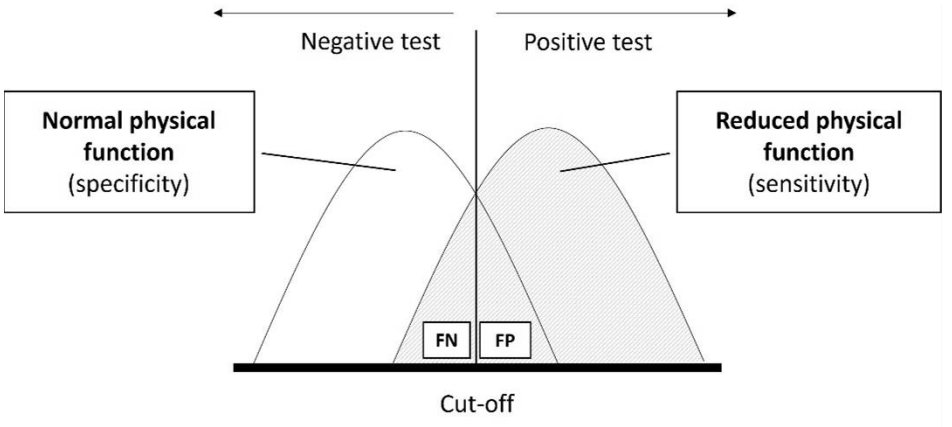


Figure 10. Sensitivity and specificity in diagnostic tests. FN=False negative. FP=False positive.

Along with the ROC curve, the area under the ROC curve (AUC) showed the classification ability, that is, how well the self-test can distinguish between reduced physical function and normal physical function compared to an in-person physiotherapist assessment with the 30 CST. The AUC can range from 0 to 1 and is interpreted as:

- < 0.5 random classification
- ≥ 0.5-0.59 fail,
- ≥ 0.6-0.69 poor,
- ≥0.7-0.79 fair,
- ≥0.8-0.89 good, and
- ≥ 0.9 excellent classification ability (206).

3.5.2 PAPER II – MIXED EFFECTS MODELS

In Paper II we compared the intervention (physiotherapist as the primary assessor) with the control group (physician as the primary assessor) for individuals with suspected KOA. The analyses from the mixed effects model were used to evaluate the effects over time, taking the individual differences into account.

Preparatory analyses were conducted before entering variables into the mixed effects model. The first step was to use Spearman's rank correlation to check the collinearity coefficient ($r \leq 0.7$), where all potential variables of the mixed effects models were included: group, EQ-5D-3L index and EQ-VAS, age,

gender, BMI, educational level, pain intensity and physical function. Further, the Chi-square test was used to check each category variable against another category variable if >80% of observations in diagonal and cells contained values with more than five observations; see ***Table 7***.

Table 7. Example of preparatory analyses before mixed effects models using Chi-square-test

			Men	**Women**	**Total**
Group	**Physiotherapist assessment**	Count	14	21	35
		% within Group	40%	60%	100%
	Physician assessment	Count	11	23	34
		% within Group	32%	68%	100%
Total		Count	25	44	69
		% within Group	36%	64%	100%

Example of interpretation of the Chi-square results:

- ☑ All cells contain values of more than five observations.
- ☑ Sum diagonally A: 40% + 68% = 108%
- ☑ Sum diagonally B: 32% + 60% = 92%

These results showed that the variables fulfilled one of the conditions to enter the mixed effects model. Lastly, all category variables were analysed against continuous variables with boxplots to ensure overlap and not too many outliers.

After the preparatory analyses, the mixed effects models were conducted using the following steps:

1. **Model 1**
   a. Group variable
   b. Time variable
   c. Group * Time (group interacted with time).

2. **Model 2 – testing confounding variables**
   Group * Time * confounding variable 1
   Group * Time * confounding variable 2…

   Significant variables with $p<0.2$ were added to the final model.

3. **Model 3 – final**
   Group * Time * all significant variables from model 2.

The primary outcomes were EQ-5D-3L index and EQ-VAS. The results are presented with p-values with a significance level of 0.05 and estimated model means.

3.5.3 PAPER III – HEALTH ECONOMICS EVALUATION

There are several different types of health economics evaluations, of which the four most common are cost-benefit analysis, cost-effectiveness analysis, cost-utility analysis and cost-minimisation analysis. In Paper III, we conducted a cost-effectiveness analysis of a care pathway with a physiotherapist as the primary assessor versus a physician as the primary assessor.

Quality adjusted life-years (QALY) is a measure of how long an individual will live with a health status, taking quality of life into account. The QALY is calculated by using a generic measure for improvement in health. In Paper III, the EQ-5D-3L index was used with data retrieved from Paper II. Due to missing data, we performed analyses of mean QALY differences on complete case data sets with no imputation, imputation using the last observation carried forward and multiple imputation. The last observation carried forward used the last observation of the EQ-5D-3L index and imputed that observation at every follow-up that had a missing value of the index. The multiple imputation was conducted with linear regressions to generate random numbers of the EQ-5D-3L index where data was missing. The analysis was performed in the Statistical Package for Social Science (SPSS) Windows, version 25.0 (207). Before the multiple imputation, the missing values were checked for random patterns. The baseline values of group, age, gender, BMI, education level, pain intensity and 30 CST, were used as predictors to generate the imputed values. The QALYs for each dataset were then calculated separately using linear interpolation

between each measurement and the trapezoidal rule (area under the curve) with following equation:

$$\left(\frac{(Health\ effect\ A + health\ effect\ B)}{2}\right)\ x\ (Time\ point\ B - time\ point\ A)$$

Example from ***Table 8***, with results of estimated model means from Paper II:

QALY baseline to 3-month follow up =

$$((0.72 + 0.74))/2\ )\ \times\ (0.25\ year - 0\ year) = 0.18$$

Results: The QALYs gained between baseline and the 3-month follow-up for the physiotherapist group were 0.18.

Table 8. Example of how the QALY was calculated

	Physiotherapist group		**Physician group**	
Time point	EQ-5D-3L index	Area under the curve	EQ-5D-3L index	Area under the curve
Baseline = 0	0.72		0.64	
3 months = 0.25	0.74	(0.72+0.74)/2* (0.25 y-0 y) = **0.18**	0.74	(0.64+0.74)/2* (0.25 y-0 y) = **0.17**
6 months = 0.5	0.77	(0.74+0.77)/2* (0.5 y-0.25 y) = **0.19**	0.80	(0.74+0.80)/2* (0.5 y-0.25 y) = **0.19**
12 months = 1	0.80	(0.77+0.80)/2* (1 y- 0.5 y) = **0.39**	0.82	(0.80+0.82)/2* (1 y - 0.5 y) = **0.41**
Total	**0.76 QALYs**		**0.77 QALYs**	

EQ-5D-3L index=EuroQol 5 Dimensions and 3 Levels.
QALY=Quality adjusted life-years.
y=year

The independent samples t-test was used to analyse the differences between each cost item and QALY. The differences in total QALYs and total costs were calculated with linear regression with a significance level of $p<0.05$ and presented with a 95% confidence interval (CI). The regression analyses were adjusted for baseline differences in the EQ-5D-3L index in the QALY analysis. To analyse the cost-effectiveness of direct access to physiotherapist for people with KOA, the incremental cost-effectiveness ratio (ICER) was calculated (i.e.

the ratio between the incremental costs and the incremental effects of the two clinical pathways on QALY). The ICER was calculated using following equation:

$$ICER = (Cost\ A - Cost\ B) / (QALY\ A - QALY\ B) = \Delta Cost/\Delta QALY$$

The results of the cost-effectiveness analysis were illustrated in a cost-effectiveness plane, where the results are categorized into four areas in a graph. The upper left corner represents a less effective intervention at a higher cost, the upper right corner represents a more effective intervention at a higher cost, the third quadrant in the lower left corner represents a less effective intervention at a lower cost, and the results in the lower right corner reflect a more effective intervention than a traditional intervention at a lower cost. Non-parametric bootstrapping was used to evaluate the uncertainty of the sample and was performed in the statistical programme STATA 17 (208). The bootstrap analyses were conducted with multiple imputation by using "nearest neighbour matching" and with the same predictor variables as in the multiple imputation analyses for missing values of the EQ-5D-3L index mentioned above.

The probability that the estimated cost-effectiveness ratio would be below the value of willingness to pay was illustrated with a cost-effectiveness acceptability curve (CEAC). The willingness to pay was based on the Swedish National Board of Health and Welfare's lower informal threshold of 100,000 SEK/QALY (209).

3.5.4 PAPER IV – QUALITATIVE CONTENT ANALYSIS

A qualitative content analysis was conducted according to the method described by Graneheim et al. (14, 210). To get a sense of the whole, the interviews were read through several times by the interviewer (CH) and co-author (LZ) separately. The written interviews were transferred to the analytic programme NVivo 14. The first step in the analysis was to extract meaning units (i.e. parts of the text that corresponded to the purpose of the study). The next step was to condense the meaning units without losing the content. The condensed meaning units were then coded and sorted into subcategories with the aim of creating homogeneous data within the subcategories that was as

heterogeneous as possible. The final steps were sorting the subcategories into categories and deriving a theme from these to describe the results as a whole. The analysis was conducted back and forth between the different steps of the content analysis and discussed within the research team until consensus was reached. The authors' contributions in the analysis process are illustrated in ***Figure 11***, and the transition from low to high abstraction level is described in the modified ***Figure 12*** based on Lindgren et al.'s figure of abstractions levels in a two-dimensional model of different epistemological approaches (211).

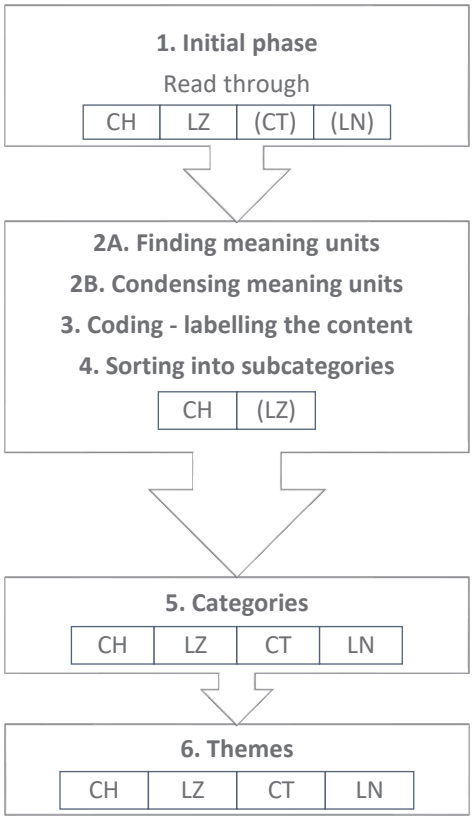


Figure 11. Overview of author contributions in the qualitative content analysis. Authors: CH=C. Ho-Henriksson, LZ=L. Zidén, CT=C. Thorstensson, LN=L. Nordeman.

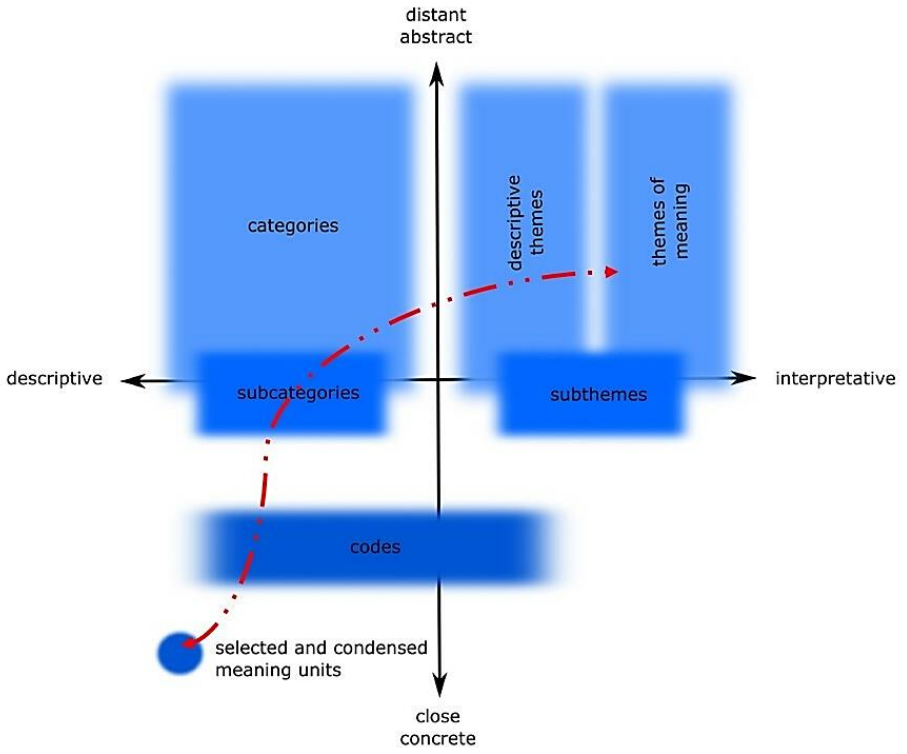


Figure 12. The transition between abstraction levels in the content analysis. Reprinted from International Journal of Nursing Studies, Volume 108, Lindgren BM, Lundman B, Graneheim UH, Abstraction and interpretation during the qualitative content analysis process, 103632, Copyright 2020, with permission from Elsevier. Modified with the red arrow to illustrate the transitional process in the analysis.

3.6 ETHICAL APPROVAL

The study protocols and methodological changes made to all papers after study start have been approved. The Swedish Ethical Review Authority approved the study protocols for Papers I and IV. The study protocols for Papers II-III were approved by the Regional Ethical Review Board in Gothenburg. All participants provided informed consent and could withdraw at any time without stating a reason. The protocols for Papers I and IV were prospectively registered in ClinicalTrials.gov, while the protocols for Papers II-III were retrospectively registered. Data storage practices are in accordance with the

General Data Protection Regulation (GDPR) and former Swedish Personal Data Act (Personuppgiftslagen) has been applied and approved by Närhälsan in Region Västra Götaland for completed and ongoing studies. The ethical approvals and registered study protocols in ClinicalTrials.gov were:

- Paper I: 2019-00784/1236-18, amendment: 2022-05340-02. Prospectively registered: NCT03855813.
- Papers II and III: 979-12, Amendments II-III: T674-13, T497-14, T791-15. Amendment only Paper III: 2020-00432. Paper II: Retrospectively registered, NCT03715764. Paper III: Retrospectively registered, NCT03822533.
- Paper IV: 2022-03479-01. Prospectively registered, NCT05566925.

4 SUMMARY OF RESULTS

This thesis will be available digitally. The results from Paper IV are presented briefly to avoid any problems with future publication. The theme, categories and subcategories will be described in detail in the printed thesis.

The papers included in this study have evaluated the feasibility of self-assessment of physical function using the 30 CST and the effects of direct access to a physiotherapist from an individual, healthcare and health economics perspective; see an overview of the potential of this thesis to improve different parts of the healthcare process for people with KOA in ***Figure 13***.

A total of 213 participants were recruited for the studies in this thesis. A large proportion of the participants were women (61%), mean age was 66 years and the average BMI was 29, which corresponds to overweight. Mean pain duration was more than two years, and pain intensity was light to moderate (mean NRS range 2.3-4.1, VAS 49 mm). In Paper I, 40% (45/114) of participants had a KOA diagnosis for more than one year. Thirty-seven percent of the same study population had bilateral knee pain, with the right knee being the most frequently reported pain site (69%) followed by the left knee (63%) and lumbar spine (41%). The participants had an average of four pain sites (SD 3): more than half had three or more pain sites (67%) and nearly half had at least four pain sites (48%). Participants scored 39/100 (SD 20) on the ICOAP total score, indicating moderate pain: 10 (SD 4.7) out of 24 had an intermittent pain score, and 6.9 (SD 4.2) out of 20 had constant pain.

Overall, physical function was good (30 CST=13 stands) and self-reported physical function was moderate at 59/100 (SD 14). The HrQoL was 0.67 on the EQ-5D-3L index and 71 on the EQ-VAS. See participant characteristics in ***Table 9*** including a comparison with data from individuals with hip and KOA from the Swedish Osteoarthritis Registry.

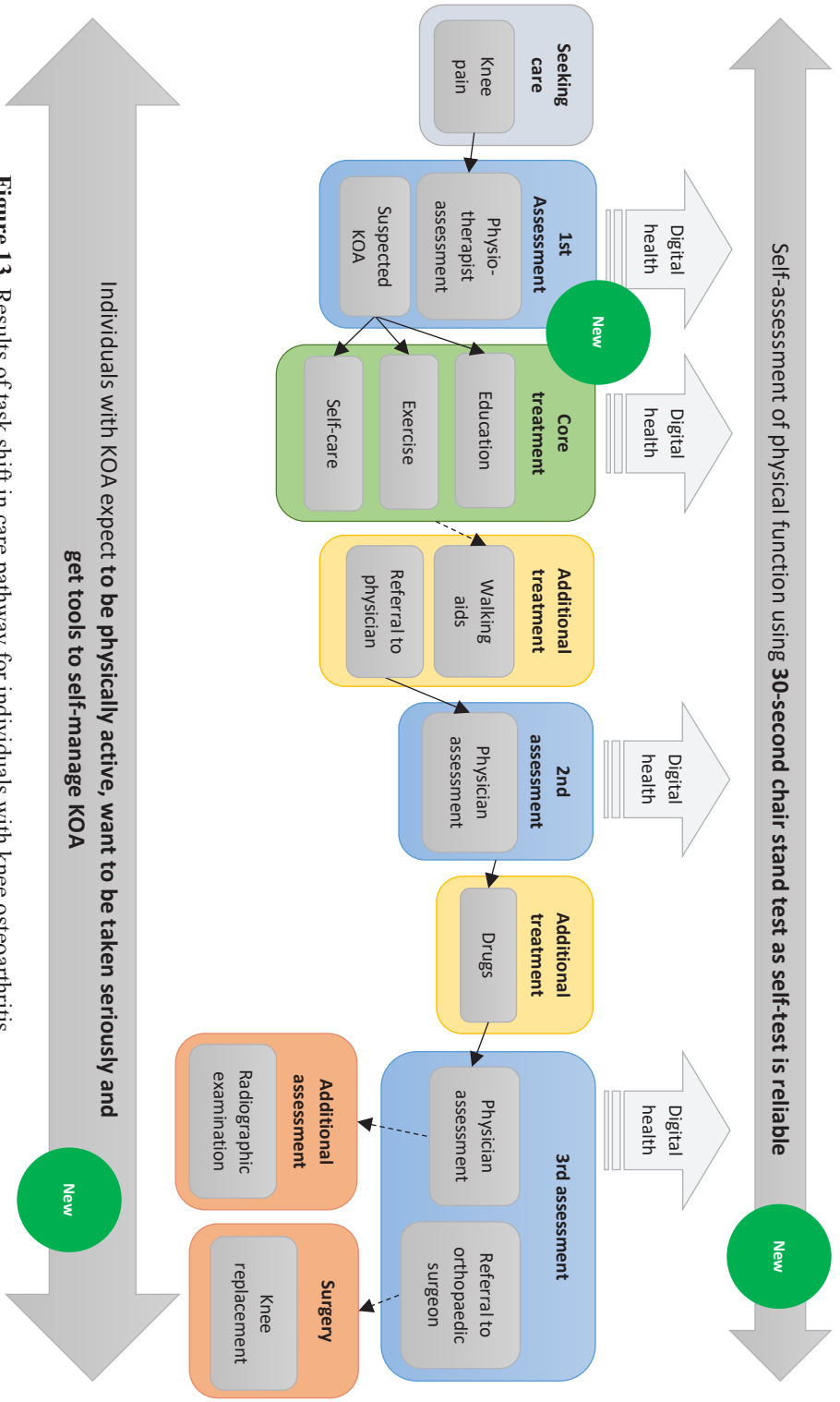


Figure 13. Results of task shift in care pathway for individuals with knee osteoarthritis

Table 9. Participants' characteristics

	Paper I n=114	Papers II-III n=69	Paper IV n=15	Total n=198	SOAR 2012-2015 n=19,750
	Mean (SD) or n (%)				
Age	69 (8.7)	60 (12)	64 (9.1)	66 (11)	67 (8.9)
Gender, females	66 (58%)	44 (64%)	11 (73%)	121 (61%)	14,329 (73%)
BMI	29 (4.6)	29 (5.6)	*No data*	29 (5.0)	28 (4.8)
Born in Sweden	107 (94%)	62 (90%)	15 (100%)	184 (93%)	*No data*
Education level					
Primary school	38 (33%)	12 (17%)	2 (13%)	52 (26%)	4,331 (22%)
Secondary school	43 (38%)	35 (51%)	7 (47%)	85 (43%)	9,843 (50%)
University/college	32 (28%)	22 (32%)	6 (40%)	60 (31%)	5,525 (28%)
Social status, single household	*No data*	12 (17%)	1 (7%)	13 (16%)	7,754 (39%)
EQ-5D-3L index	*No data*	0.67 (0.18)	*No data*	0.67 (0.18)	*No data*
EQ-VAS	*No data*	71 (20)	*No data*	71 (20)	66 (19)
Pain duration, months	39 (48)	12 (19)	14 (7.9)*	27 (40)*	*No data*
Pain intensity (VAS 0-100 or NRS 0-10)	NRS 2.3 (2.2)	VAS 49 (17)	NRS 4.1 (1.8)	NRS 3.3 (2.4)**	NRS 5.3 (1.8)
Physical function (30 CST)	14 (5.2)	12 (4.1)	*No data*	13 (4.9)	*No data*
Comorbidities	67 (59%)	*No data*	3 (20%)	70 (55%)	*No data*

*Maximum 24-month duration in Paper IV; pre-defined >2 years.
** Merged data; recalculated VAS-values to 0-10.
EQ-5D-3L=EuroQol 5 dimensions 3 levels questionnaire. Resulting in an index, where 1 means perfect health and 0 death. Values below 0 are health status worse than death.
EQ-VAS=EuroQol Visual analogue scale, presenting values between 0 and 100, where 0 corresponds to worst imaginable health and 100 best imaginable health.
n=number
NRS=Numeric rating scale, where 0 was no pain and 10 the worst imaginable pain.
30 CST=30-second chair stand test. A higher score indicates better physical function.
SD=Standard deviation
SOAR=Data retrieved from Battista et al. (212) using Swedish Osteoarthritis Registry data, including people with both hip OA and KOA.
VAS=Visual analogue scale. Measures pain intensity where 0 corresponded to no pain at all, and 100 the worst pain imaginable.

4.1 SELF-ASSESSMENT

The mean number of days between self-test 1 and 2 was two days (SD 0.9) and 4.7 days (SD 5.6) between self-test 2 and physiotherapist assessment. The results of the 30 CST were similar across the three assessments, 13.6 (5.0) and 14.3 (SD 5.3) on the self-tests, and 14.0 (SD 5.2) when supervised by a physiotherapist. Participants rated their pain intensity lower on the NRS when reporting to a physiotherapist compared to ratings recorded at home. The chair heights during the self-assessments were 1 cm higher than for assessments conducted on-site (46 cm (SD 1.4); 45 cm (SD 0.7)). A few participants used hand supports to perform the test, and only one discontinued the test due to severe knee pain ***(Table 10)***.

Table 10. Descriptives of 30-second chair stand test

	Self-test 1 (n=114)	**Self-test 2 (n=114)**	**Physiotherapist assessment (n=114)**
	Mean (SD); median 25th to 75th percentiles or n (%)		
Days after previous test		2.1 (0.9); 2.0 [2.0,2.0]	4.7 (5.6); 3.0 [2.0,5.0]
Number of stands	13.6 (5.0); 12.0 [10.0,16.0]	14.3 (5.3); 13.0 [10.0,16.0]	14.0 (5.2); 13.0 [10.0,16.0]
Chair height (cm)	46 (1.4); 45 [45,46]	46 (1.4); 45 [45,46]	45 (0.7); 45 [45,45]
Pain before test (NRS 0-10)	2.9 (2.1); 3.0 [1.0,4.0]	2.9 (2.1); 3.0 [1.0,4.0]	2.3 (2.2); 2.0 [0.0,3.0]
Pain during test (NRS 0-10)	3.8 (2.4); 4.0 [2.0,6.0]	3.7 (2.4); 3.0 [2.0,6.0]	3.1 (2.5); 3.0 [1.0,5.0]
Folded arms across the chest	110 (97%)	109 (97%)	111 (97%)
Hand support	3 (2.6%)	2 (1.8%)	1 (0.9%)
Performed 0 on the test	0 (0%)	0 (0%)	0 (0%)
Discontinued	0 (0%)	1 (0.9%)	1 (0.9%)
Reduced physical function	73 (64%)	63 (55%)	63 (55%)

n=number of participants analysed; NRS=Numeric rating scale, ranging between 0-10 where 0 corresponds to no pain and 10 to the worst imaginable pain; SD=standard deviation.

No floor effect was present for the self-tests nor the physiotherapist assessment. More than half (55-64%) of participants were classified as having reduced physical function. The 30 CST as self-test had excellent intra-rater and moderate to good inter-rater reliability. ICC for intra-rater reliability was 0.97, with a CI of 0.95-0.99 and a SEM of 0.89, and for inter-rater reliability the ICC was 0.81, CI 0.72-0.87 and SEM of 2.3. The agreements are illustrated in ***Figure 14***.

The 30 CST self-test had fair to good classification ability in the detection of reduced physical function (AUC=0.79-0.80); the ROC curves are illustrated in ***Figure 15A and B.*** The dashed lines in each curve show the sensitivity and 1-specificity values of cut-off values which were interpreted to have reasonable sensitivity and specificity. With a cut-off value of 13.5 for self-test 1 and for self-test 2, there is a 75-79% probability (sensitivity) that physical dysfunction will be detected with the self-test and 62-72% probability (specificity) that normal physical function will be classified correctly, regardless of age and gender. Further, the MDC_{ind} was 6.4 stands for the individual comparison of self-test results with physiotherapist assessment, and 0.59 on group level. The MDC_{ind} was 2.5 stands when comparing between individual self-test results and 0.23 stands when comparing between groups. The mean difference between self-tests 1 and 2 was -0.73 stands (SD 1.5) and +0.33 (SD 4.3) between self-test 2 and physiotherapist assessment.

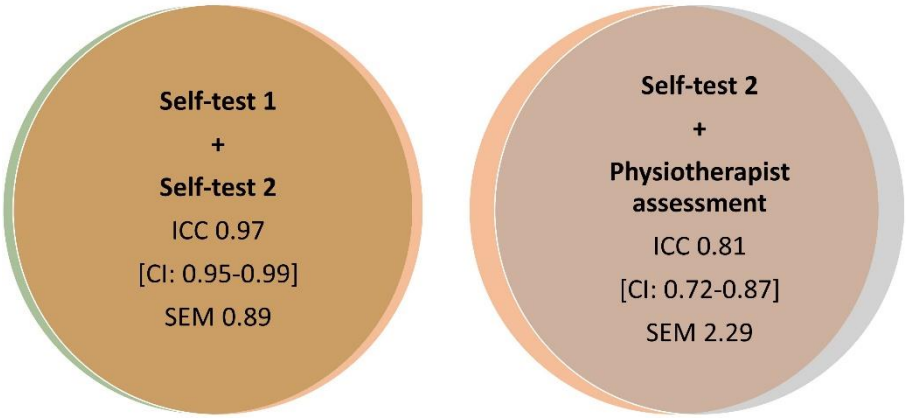


Figure 14. Venn diagrams of intraclass correlation coefficients (ICC). The left Venn diagram illustrates the ICC of intra-rater reliability between the self-tests, and the right Venn diagram illustrates the inter-rater reliability between self-test 2 and the physiotherapist assessment. CI=Confidence interval. SEM=Standard error of measurement.

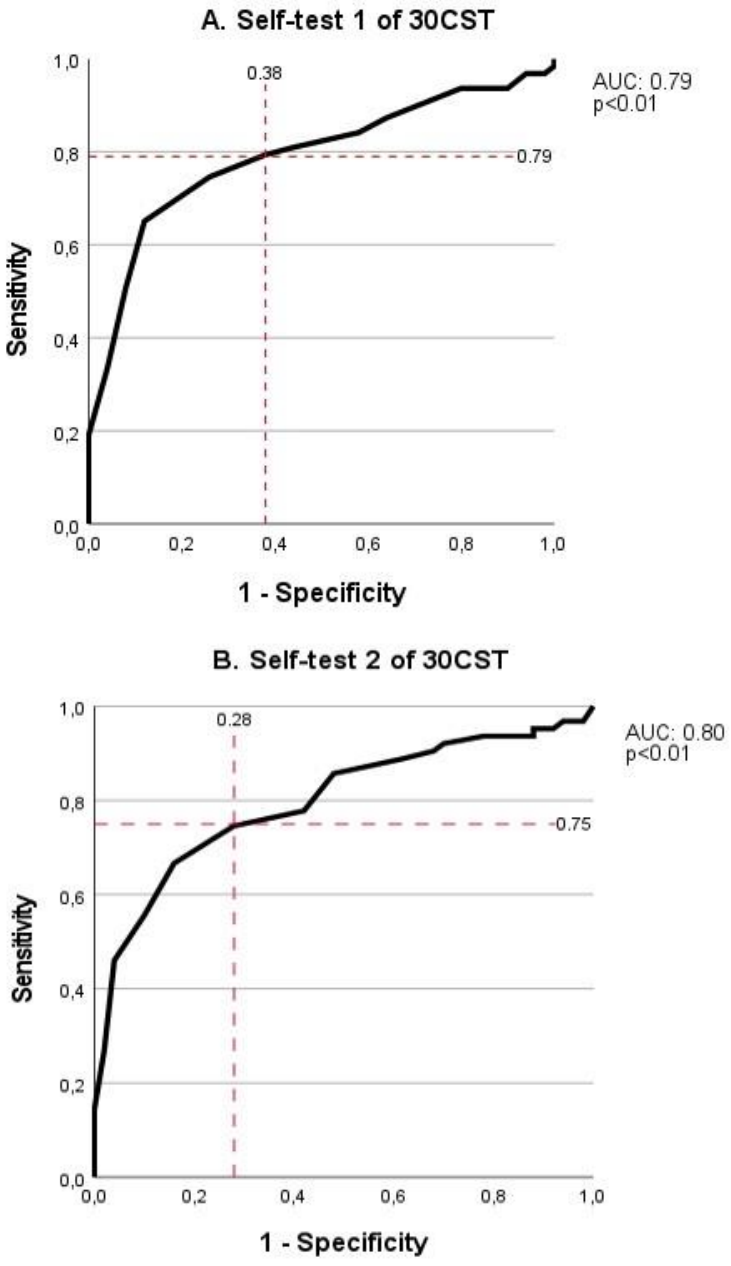


Figure 15A and B. ROC curves of self-test 1 and 2. The dashed lines show the cut-off value of 13.5 stands.

4.2 DIRECT ACCESS TO PHYSIOTHERAPIST

Individuals with KOA who were assessed by a physiotherapist in primary care reported that the experience met their expectations, that they were taken seriously and perceived that they received proper examinations. Participants reported that the physiotherapist assessment and exercise programme was a natural first option to maintain or regain their ability to perform normal physical activities. Being physically active was essential for the participants, at least in relation to their perceived well-being. The participants felt relieved to learn that physical activity was not harmful for KOA, rather the opposite. The knowledge the participants gained from the SOASP was an important factor in their return to exercise and initiation of self-management. Most participants understood that they had control over their own improvement and found it useful to have a physiotherapist coach them until they could exercise independently.

Over the long term, individuals who received their first assessment from a physiotherapist showed significant improvements in HrQoL one year after the assessment (time, $p<0.001$), which was a similar effect compared to individuals who were assessed by a physician first (group $p=0.087$; group interacted with time $p=0.18$). Total gained QALYs did not differ significantly, regardless of whether imputed data sets were used, with mean differences ranging between -0.009-0.015 QALY and $p>0.05$.

Direct access to a physiotherapist could reduce costs without affecting long-term health outcomes for people with suspected KOA compared to the traditional care pathway with a physician as the first contact. Most participants referred to physiotherapists directly were treated by a physiotherapist alone (26/35), and 14 individuals in the physician group were referred to a physiotherapist (14/34); see ***Figure 16***. The total cost savings were 233-364 €/person for the physiotherapist-led pathway, and the differences were not statistically significant ($p=0.17$). The physician-led pathway led to significantly higher costs, which were associated with physician visits ($p<0.001$) and radiography ($p=0.01$). Participants assessed by a physician first had five times more physician visits than participants in the physiotherapist group. The number of individual physiotherapist visits was similar in both groups.

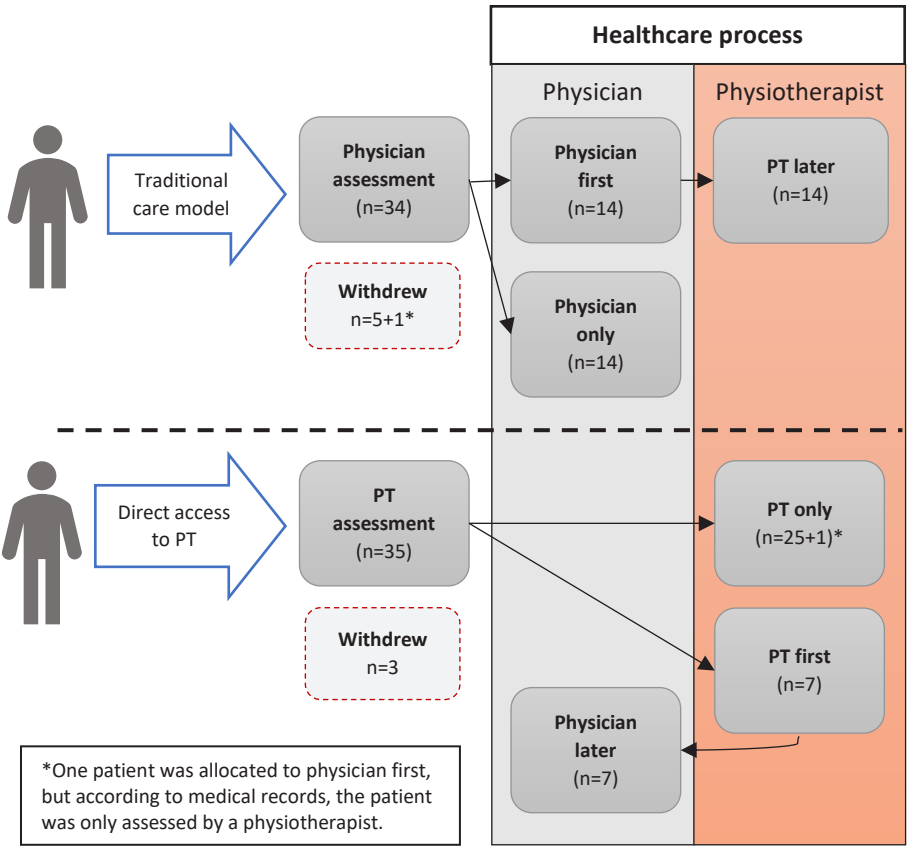


Figure 16. Healthcare process evaluated in paper III. Reprinted with kind permission from BMC Musculoskeletal Disorder, Volume 23, Ho-Henriksson CM, Svensson M, Thorstensson CA, Nordeman L. Physiotherapist or physician as primary assessor for patients with suspected knee osteoarthritis in primary care – a cost-effectiveness analysis of a pragmatic trial, 260, Copyright 2022, with permission from Springer Nature. Modified with larger font size and relocated explaining box. n=number. PT=Physiotherapist.

The results of the ICER showed that the physiotherapist-led pathway could save €24,266 for each QALY lost from a societal perspective and €15,533 from a healthcare perspective. The health consequences presented in Paper II were not statistically significant, and these are the results Paper III is based on. The majority (72-80%) of the bootstrapped replicates were in the range of ±0.05 QALYs for a lower cost with physiotherapists first, where the mean ICER indicated lower costs for less effect; see ***Figure 17***. The results from the CEAC showed that the care pathway where individuals with KOA received a physiotherapist assessment first was 40% likely to be cost-effective.

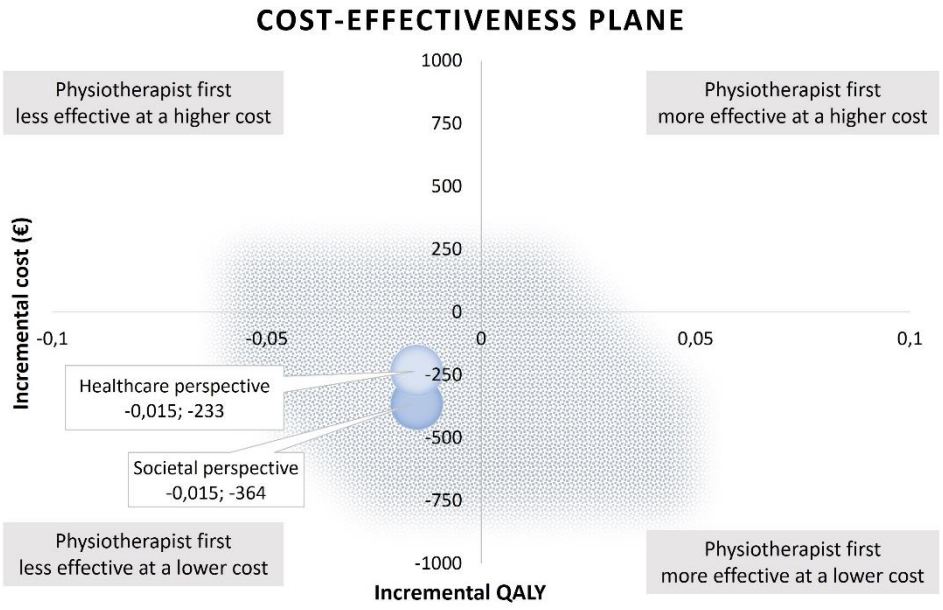


Figure 17. Cost-effectiveness plane for direct access to a physiotherapist. The large circles represent the incremental cost-effectiveness ratio (ICER) of the healthcare perspective and societal perspective. The darkened background illustrates the results where most of the bootstrapped ICERs fell.

The care pathway with a physiotherapist as the primary assessor seems to have a lower carbon footprint, with less drug prescriptions (12% versus 43%) compared to the physician group and about one third (11/28) of participants were referred for a radiographical examination in the physician group compared to 9% (3/33) in the physiotherapist-led group.

5 DISCUSSION

This thesis aimed to evaluate the reliability of the 30 CST as a self-test for individuals with KOA and to evaluate differences in health outcomes in people with KOA and health economics, when a physiotherapist is the primary assessor. The thesis also aimed to evaluate the experiences of individuals with KOA when they have direct access to physiotherapists. Most participants reported that they felt that they were taken seriously and understood. The participants reported that a proper examination was important, and their expectations were met when they were assessed by a physiotherapist. When individuals with KOA had direct access to physiotherapists an equally positive effect on HrQoL was seen at a lower cost compared to the traditional care pathway with a physician as the first contact. The reliability study showed that the 30 CST as a self-test has excellent intra-rater reliability and moderate to good inter-rater reliability.

5.1 THE FEASIBILITY OF SELF-ASSESSMENT

It is of great importance to have reliable measurements to evaluate the effects of treatments or diagnostic tests, both in clinical settings and in research. In this thesis, it was found that the 30 CST as a self-test is reliable for individuals with KOA.

A strength of Paper I is the generalisability of the study, as participants were recruited in a pragmatic setting. The participants showed a variety of symptoms, from knee pain only to multiple pain sites. Some had comorbidities, which reflects the variety of people with KOA encountered in primary care. Most of the participants had at least one comorbidity (67%), and 21% had OA in another joint. Compared to previous study, the comorbidity rate is similar, but fewer participants had multi-joint OA in Paper I (51). About two thirds (67%) of participants had at least three or more pain sites. Although, the variance in participants' characteristics probably attributed less to the ICC than how the 30 CST was conducted, since the ICC for inter-rater reliability was lower than for intra-rater reliability. Another factor affecting the ICC in inter-rater reliability could be the individual variation in typical KOA symptoms. However, pain intensity rated before the 30 CST was similar. Pain intensity for self-tests 1 and 2 (NRS 2.9) was rated somewhat higher compared to the

physiotherapist assessment (NRS 2.3). Yet, the results of the 30 CST did not differ between self-test 2 and the physiotherapist assessment.

The ICC for inter-rater reliability was lower compared to previous reliability studies of 30 CST in individuals with KOA (179, 213, 214). One factor could be the pragmatic setting, as the high number of assessors could affect the results. Another factor could be the wide range of clinical experience. However, to reduce variability in the way the 30 CST was conducted by the physiotherapists, they received instructions from the PhD student. The ICC value may also have been affected by the extended gap between self-test 2 and physiotherapist assessment (mean 4.7 days (SD 5.6)). Even though some individuals may have received exercise treatment between the tests, it seems unlikely that the treatment would have improved their physical function in such a short period of time. The results show that the number of stands did not differ between the self-tests (14.3 stands) and the physiotherapist assessments (14.0 stands). Other factors that could have affected the results include the brief instructions, where no standard description was given for feet position (width) or whether it was mandatory to lean against the back of the chair. Further, instructions did not stipulate the type of chair that should be used (height, soft or hard surface), counting or timing problems could have affected the results. These factors would likely have a greater effect on the inter-rater reliability in settings other than the home setting, where one can assume that individual variations would be the same for the self-test. However, the ICC of inter-rater reliability was moderate to good with an ICC of 0.81 [CI 0.72-0.87].

Post-hoc analyses of the MDC with the SEMs were conducted, and the results showed that MDC_{ind} would be over six stands between the self-test results and physiotherapist assessment when interpreting on an individual level. While comparing the results between self-tests the MDC_{ind} were over 2.5 stands. The MDC_{ind} for intra-rater reliability was similar to previous study (181). When comparing individual results within self-tests, and especially between self-tests and physiotherapist assessments, clinicians should be aware that 2.5-6.4 stand difference is within the normal range. Based on the post-hoc analysis of the MDC_{group}, the mean difference in the self-tests exceeded the threshold of 0.23 on a group level, but not between the self-test and physiotherapist assessment (0.59). The mean was 0.7 additional stands and the median was 1.0 additional stands in self-test 2 compared to self-test 1. This may be explained by the fact

that the participants were not blinded to their previous results in self-test 1, and they may have strived to achieve equal or better results in the second self-test.

There is a trade-off in terms of prioritising the sensitivity or the specificity when interpreting the results from the ROC curve analyses. In performance tests, it is important to detect deficiencies when they are present. The sensitivity was therefore considered to be a higher priority. However, in a clinical setting, the self-test needs to be reliable as the 30 CST is used to evaluate treatment effects over time. Previous study have found a lack of responsiveness in the 30 CST (182). Although it does not affect the results in Paper II, further research is warranted to evaluate whether the 30 CST as a self-test is valid over time, since it is recommended to evaluate people with KOA annually (104).

The results of the ROC curves should be interpreted with caution for individuals under 60, as the number of stands required for normal physical function rapidly decreases for those over 60. An individual in their late 50s needs to perform at least 22 stands. Compare this to an individual who has just reached the age of 60, who needs to perform 9 stands less than a 59-year-old. Hence, reference values with shorter intervals of 5-10 years are warranted and would be more applicable for clinicians and in research analyses. We performed additional analyses that excluded participants 59 years of age or younger. The AUC increased to 0.84 and when using the same cut-off value for the self-tests (13.5), the sensitivity increased (82-88%), while the specificity was similar (60-70%).

In the emerging field of digital physiotherapy, more studies evaluating the reliability of self-assessment tests of pain, range of motion and patient-reported outcome measures and physical function are needed (120). Paper I contributes by providing a reliable self-test that can be used in self-monitoring or during a digital health meeting. Further, a reliable self-test of physical function could reduce carbon emissions as the need to travel is reduced when people can be assessed digitally. The test may be suitable for use as a safe self-test for several groups of individuals, such as people without balance deficiencies. However, the reliability of the self-test for people with other diagnoses needs to be evaluated in future studies.

5.2 INDIVIDUALS' EXPERIENCES OF DIRECT ACCESS

The results of this thesis showed that individuals with KOA expect to continue physical activity. They sought care to access an exercise programme and were prepared to take responsibility for self-management. Most participants were hoping to find an explanation for their symptoms and a proper examination to assess the cause of their pain. The participants reported that the physiotherapist took their needs seriously, that they felt heard and received the tools they needed to self-manage their KOA.

Similar to the findings in Hurley et al. (215), most participants were seeking answers to determine the root cause of their pain and their pain was an obstacle to normal physical activities. The participants in Paper IV were a physically active group of individuals, and this is in line with previous studies showing that the physical and intellectual ability of today's 70-year-olds are similar to 50-year-olds five decades ago (216). The participants in Paper IV were all physically active and many had expectations of getting back to their normal activities. In Paper IV, many participants reported long waiting times for continued care and felt that they were a lower priority because of their advanced age. Most participants did not see themselves as "old". As more and more people are reaching old age with preserved cognitive and physical function, the healthcare system needs to review the way it treats individuals in this age group. Healthcare providers also need to change their view of OA as an inevitable symptom of old age (60, 61, 130, 131, 217), as it is important that individuals do not just accept their symptoms but take action to regain or maintain a healthy level of physical activity to prevent comorbidities, especially considering the negative consequences of physical inactivity in people with KOA.

The results of Paper IV highlighted the importance of ensuring that the individuals feel understood and that they are taken seriously. The participants reported that these needs were met through the physiotherapist assessment. The results show that physiotherapists provided the recommended patient-centred care (218) to individuals with KOA, meaning that care should be individualised based on the individual's needs and wishes (219). Another related concept is person-centred care, where the individual is in the centre

together with the individual's background, family and prerequisites, and the individual is an active decision-maker in his or her care (220). Person-centred care aims for a meaningful life, while patient-centred care focuses on achieving a functional life (221). Our results reflect both aspects, as the participants needed a functional life to have a meaningful life.

In SOASP, the purpose is self-management of KOA after the treatment period, which could be a big challenge for physiotherapists if individuals are not set up for self-management. Physiotherapists need to have the competence to motivate (140) individuals with KOA to be physically active, where an important factor is informing individuals so that they understand that physical activity could increase their health and lower mortality risk (222). Health literacy could affect compliance, which is the knowledge, competence and motivation to find, understand, value and use health information in healthcare, to prevent disease and promote health (223). Even though most individuals (71%) with knee pain have sufficient health literacy, it does not appear to be enough for individuals to make lifestyle changes (224). It is suggested that person-centred care should be used to evaluate whether individuals are likely to take an active role in their care, as well as what is needed to motivate the individual to act on the information provided by healthcare professionals (224). This is in line with the results of Paper IV, where some participants expressed that their mind-set seemed to play an important role in self-care during and after a rehabilitation period, and this determined whether the individual was capable of using the health information or treatment.

5.3 HEALTH IMPACT AND COST SAVINGS WITH DIRECT ACCESS

The HrQoL for people who received treatment for KOA in primary care showed a statistically significant improvement over time, but the improvements did not differ between the groups. The total change in both groups in the EQ-5D-3L index did not exceed the minimal clinical difference of 0.12 (174, 175). Yet, the large variation in baseline values could have been a result of the pragmatic design (225), and a larger sample size could have evened out this variation. Further, if an EQ-5D with more levels was used (e.g. 5 levels (5L)), the index score may have been distributed in a larger variation (226). Another aspect that could affect the EQ-5D-3L index would be the

scoring of the index using Swedish tariffs (199) instead of the commonly used UK tariffs (198), as the study is based on conditions in Sweden. When Swedish tariffs are used, scores tend to be higher than when the UK tariffs are used, and the results may not be comparable due to the different scoring (199).

A healthcare process with a physiotherapist as primary assessor could reduce healthcare costs at a slight reduction in QALYs. The referral rate to physiotherapist was high, which indicated that most participants received the recommended core treatment. The physician group had significantly higher costs for physicians' visits ($p<0.001$) and radiography examinations ($p=0.01$). Even though it is not necessary to use radiography as a diagnostic tool when typical OA is present (80), 39% (11/28) of the participants in the physician group were referred to radiography. The Swedish Osteoarthritis Registry shows that 68% of all registered individuals had a radiography examination before a physiotherapist assessment, which amounts to more than SEK 10 million per year for radiography costs (79). It is estimated that Sweden could save 63% in radiography costs if the proportion of these people that are referred for a radiography examination is reduced to under 25% (79). These savings could then be spent on supervised physiotherapist-led exercise, which is estimated to increase costs four-fold if the goal for 80% of all individuals with OA to receive supervised exercise is reached (79). However, it is estimated that the total cost of OA care would decrease by 10% in Sweden if 80% of individuals receive supervised physical exercise, less than 25% receive imaging diagnostics and no knee arthroscopies are performed (79). When applying the rate of 9% radiography referrals for individuals assessed by physiotherapists first from Paper III, costs would be SEK 1.4 million compared to the goal of SEK 3.9 million if under 25% of individuals are referred to radiography before core treatment. This indicates that the care pathway with direct access to a physiotherapist could be a solution to reduce healthcare costs. With a reduction in radiography referrals and prescribed drugs, the ecological footprint would also be reduced as the carbon dioxide emissions decrease when individuals have direct access to physiotherapist (83, 90).

The results of the ICER showed the costs per lost QALY, and the CEAC showed a low likelihood that direct access would be cost-effective. The results are in contrast with a pervious Swedish study, which showed that triaging people with musculoskeletal disorders directly to physiotherapist had a

probability of 85-93% to be cost-effective at a higher threshold value of €20,000 (161). As the willingness to pay could differ between different countries (227), the costs should be calculated based on conditions in different countries and interpreted based on their cost-effectiveness thresholds. Another method to compare the costs and effects of an intervention is the net monetary benefit (NMB), where the intervention is considered to be cost-effective when the ICER is less than the willingness to pay (or NMB > 0). This means that the results of the intervention with direct access to a physiotherapist as the primary assessor could be interpreted as a cost-effective alternative to a threshold of €15,533 from a healthcare perspective and €24,267 from a societal perspective. In ***Figure 18*** and ***Figure 19***, we have calculated the NMB for different cost-effectiveness thresholds.

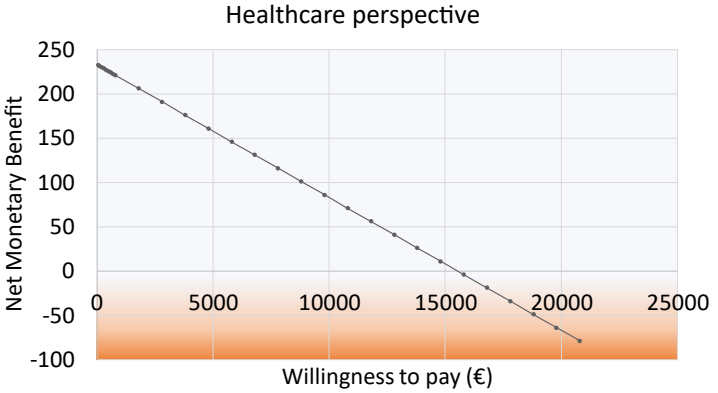


Figure 18. Net monetary benefit (NMB) for different cost-effectiveness thresholds from a healthcare perspective.

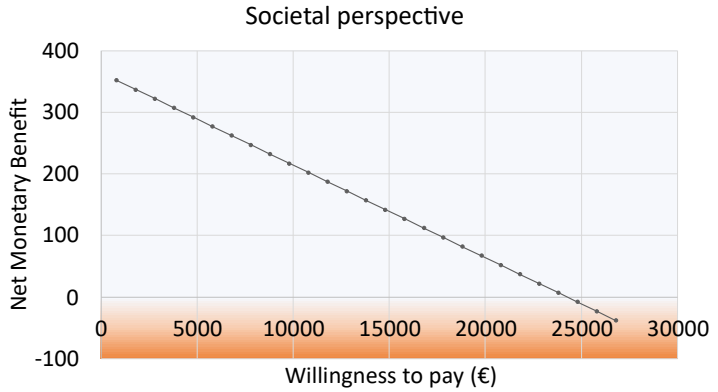


Figure 19. Net monetary benefit (NMB) for different cost-effectiveness thresholds from a societal perspective.

5.4 METHODOLOGICAL CONSIDERATIONS

5.4.1 PAPER I

There are several different performance tests and chair stand tests to choose from (228). The 30 CST was chosen since it has been recommended in international guidelines (105). The longer version, the 60-second chair stand test, seemed to be more common in studies involving lung diseases or endurance, where the 30 CST is likely too short to test physical fitness (229). The shorter version, with five repeated chair stands, measures lower limb muscle strength (230) and could lead to floor effects (231). Individuals who perform five stands or fewer on 30 CST will be categorized as having a physical dysfunction in the lower extremities regardless of age (204). Similarly, five stand test performed in 30 seconds or more also indicates physical dysfunction, where normal values are below 5.8 seconds in individuals younger than 60 years (232) and 8.6-12 seconds for individuals over 60 years (232, 233). Previous study has reported the ability of impaired physical function (tested with one-leg rises) to predict radiographic KOA within five years in people aged 35-54 years (234). Unfortunately, the one-leg rises may be too difficult for elderly individuals to perform due to balance difficulties and/or low muscle strength, and an easier test, such as a chair stand test, could be a safer alternative.

Most reliability studies use a design that assumes that the rater and the test subject are two different individuals. The difficulty with self-tests is that the rater and the test subject are the same person. Hence, it is difficult to decide which ICC form to choose. Since the present study was a multicentre study, the one-way random-effects model could have been conducted, where one can argue that the same set of raters applies to all participants in one centre and another set of assessors at the other centre. Here, it was decided that the two-way random-effects model would be suitable as the physiotherapist raters were randomly chosen from all physiotherapists working at the rehabilitation centre at the time the study was conducted. This model is suitable for studies that aim to generalize the results to any raters who possess the same characteristics as the selected raters (200), which in this paper were people with KOA and physiotherapists in primary care.

5.4.2 PAPERS II-III

Due to organizational changes in primary care that needed to be prioritized during the study period of Paper II, the participant flow for the study was impacted and was very low. Clinical trials in Swedish primary care have historically encountered obstacles due to low participant flow (145, 235). It can be difficult to create the right conditions for a clinical trial in Sweden due to low participant flow as the country has more than 2,000 cities, but only ten cities with a population over 100,000 (236). And it may become even more challenging to conduct clinical trials in the future because of the ongoing organizational shift in the Swedish healthcare system, where specialized care is being moved out of hospitals to primary care and healthcare is being made more accessible to people seeking care. This shift puts a tremendous strain on primary care, since it is expected that more healthcare should be provided at this level of care. Hence, it may become even more difficult to conduct clinical trials due to time constraints, and researchers may need to re-evaluate which study design is appropriate for each individual study. On the other hand, it is of great importance that research studies are conducted and that new working methods are systematically evaluated, of which time needs to be set aside to be able to conduct studies.

The 12-month follow-up was conducted remotely with the 30 CST used as a self-test. The results of the 30 CST from the 12-month follow-up were not included in the mixed effects models. From the start, the statistical analyses included group comparisons using independent samples t-test or Mann-Whitney U-test. After consultation with a statistician, the statistical analysis plan was changed to use a mixed effects model, as it takes individual changes over time into account.

Different factors that could affect the ICER include the use of the EQ-5D-3L instead of the 5L, which increases the risks of a ceiling effect from 30% with 5L to 46% in the 3L (237). If the 5L was selected, it could have lowered the incremental QALY loss (238, 239), as the 5Ls can discriminate better between milder health problems and are able to detect small changes in health status (226). Another aspect is the prices used in Paper III, where the higher costs of medical locum were not accounted for.

5.4.3 PAPER IV

An inductive content analysis was chosen as it was deemed suitable for the purpose of the study, which was to describe the variation and similarities in expectations and experiences among individuals with KOA who were assessed by physiotherapists. Inductive content analysis, as described by Elo and Kyngäs could have also been an option (240), but due to the authors' previous experience with Graneheim's approach to content analysis, this method was chosen as it also works well for the purpose of the study. In the method described by Granheim et al. (14), it is important to abstract the data without losing its content, and the results should reflect the participant's voice. The manuscript contains accounts from the participant's point of view, where the text describe their experiences and perceptions with manifest content. Further, many of the subcategories and categories were close to the actual texts. Also, the quotations help the reader interpret whether the results are the participants' voice or the researcher's narrative.

To increase trustworthiness, the entire process was described – from sampling to analyses and results. For each subcategory, at least one quotation to support the results was provided. The analysis, its results and the potential effect of the researchers' pre-understanding on the process were discussed regularly. Prolonged engagement was applied through follow-up questions to test for misinformation and get richer data. The interviews were read several times by the main author and the last author to get a sense of the content as a whole, and the data was analysed back and forth between the different stages of coding and categorization. The results were discussed regularly between all four authors, and consensus was reached. A limitation was that the transcripts were not sent back to the participants for a check.

A challenge with saturation is that it is difficult to predict, and sample sizes are normally stated beforehand. The estimation of the number of interviews needed has been a topic of discussion and can differ depending on the theory (241). The concept of saturation, was developed in 1967 as part of the grounded theory approach in which theoretical saturation is used to address the point where no additional insights have emerged (242). Other terms are data saturation or thematic saturation, which describe the point in data collection where data have become redundant and no further information is added (243). Previous studies of code saturation have reported that saturation is reached

between 7-16 interviews (244-246), and Paper IV included 15 interviews. However, reaching meaning saturation would require 16-24 interviews (244), where a sample size of nine would only give a comprehensive understanding of concrete perceptions, and subtle issues could be missed. Meaning saturation is defined as the point where the researcher fully understands the subject that is being studied and no further dimensions, nuances or insights can be gleaned from the research (244). However, one also have to keep in mind that too much data can lead to superficial analysis, where data can be difficult to grasp and abstract (247).

Guest et al. have developed a method for calculating the saturation of the collected data in thematic analysis as a basis for deciding whether to close the data collection or not (248). The first saturation analysis occurs after 4-6 interviews, and then 2-3 interviews are added at a time to analyse the saturation further. Analysing interviews before data collection has ended can increase the risk that the interviews will be biased, as researchers get a pre-understanding from the analyses and the categorization. In future research, it would be interesting to study whether the saturation calculation could be applied in qualitative content analysis, where, for example, the interviewer and the person calculating the saturation are different people.

The interviews were performed by one of the researchers, who is a physiotherapist with clinical experience in a primary care rehabilitation centre that includes the assessment and treatment of individuals with KOA. In addition to the interviewer's profession, interviewees could have been affected by the interviewer's senior position. Even though participants were not informed, they could have become aware of the interviewer's position due to signage in the waiting room. Also, the setting could have influenced the interviewees' answers, where one can assume that positive feedback is more likely when interviews are conducted in the same clinics where the rehabilitation services were received (n=5). This may have influenced participants to adapt their answers to what they believed they were anticipated to talk about. However, the interviews were carried out at a place chosen by the participant which could enhance the trustworthiness.

One can question the use of the inductive approach with a semi-structured interview guide that contained questions based on experiences the authors assumed were relevant. One could also question whether it was possible for

the authors to set aside their pre-understandings during the interviews and analyses. Yet, a deductive approach usually involves a model or theory on which the researcher bases the analysis. At the same time, the subcategories and categories were changed several times, where subcategories in an earlier version were sorted to a category such as person-centred care, which involves a partnership between the individual and healthcare provider based on the individual's history (220). Moving back and forth between empirical study and theory could rather be classified as an abductive approach to analysis (210).

Recruitment was also conducted at rehabilitation centres, where individuals were asked about participation in the study, which resulted in the two pilot interviews. Due to low participant inflow, it was decided to recruit via the medical record database. Another factor influencing transferability was non-respondents (233/734) and those who were not asked or screened for eligibility, which were those who may not be as computer savvy, where 12% (92/734) did not have the digital platform 1177.se. Although some of the non-respondents made an active choice not to answer, a total of 39% (325/734) were not reached due to the use of 1177.se in the recruitment process. A study evaluating the use of online questionnaires among older people, showed that online questionnaires were feasible for older people. Yet, the fact that a paper form was not offered as an option could lead to biased results as low educated, women, retired and non-married people could be underrepresented (249). In order to include older people with limited computer skills, telephone and mail could be alternative methods of contact. However, this procedure would have been difficult to apply in today's primary care due to time constraints and would have required significant resources in the research projects. In addition to age, potential participants with a foreign background could have been excluded due to difficulties making contact via 1177.se due to language barriers.

5.5 STRENGTHS AND LIMITATIONS

One strength of the thesis is the wide range of KOA participants, which included individuals from early KOA and participants with KOA duration of more than two years. The participants were recruited from a pragmatic setting, which enhances the implementation process as testing has already been done in the clinical environment (250). The breadth of the studies is another strength,

as this thesis evaluates how people with KOA can be managed more efficiently from several perspectives. As far as I am aware, the papers in this thesis provide new knowledge in relation to direct access to physiotherapist for people with KOA. This is accomplished through study designs that includes an RCT, a study of health economics and a qualitative study that evaluates the effects of direct access to physiotherapist. Also, the reliability study provides valuable new tools that people with KOA and physiotherapists can use to assess and monitor physical function (rather than just on-site), which can make healthcare more accessible. The thesis also provides tools that can be used to determine whether an individual with KOA should seek care to improve their physical function.

There are several patient-reported outcome measures to choose from when evaluating individuals with KOA symptoms and one strength of Papers I and II is that the international recommendation to use a standard set of outcome measures and data collection time points for individuals with KOA was followed (104).

A limitation of Papers I and II is the changes in study protocols. For Paper I, the project plan was revised to develop the analyses for the data collected; therefore, the ROC curve analyses and calculations of MCD were added. In Paper II, the eligibility criteria were changed to increase the participant flow to the study. This could affect the validity of the study as participants with diagnoses other than KOA were included. Yet, the aim was to recruit participants with suspected KOA, and Skou et al. recently demonstrated that it may be suitable to use fewer criteria in diagnosing KOA (99), since ACR diagnostic criteria seem to reflect symptoms of later OA (101).

Another limitation of the thesis is the fact that the required sample sizes were not reached in Papers I-III. However, the sample size in Paper I (with three fewer participants), increased the probability of type 1 error to 5.3% from 5.0% (i.e. the likelihood that we say there is a correlation, when it is no correlation). Due to the pragmatic design in Paper II, the data collection encountered several challenges due to organizational changes in primary care, which affected the motivation to screen for individuals with knee pain for participation in the study. The underpowered study increases the risk of type 2 error (i.e. the risk of false negative results). Further, the dropout rate of up to 40% is a limitation.

However, all enrolled participants, including those with missing data, could be used in the mixed effects models. Since the sample size is the same in Paper III, the same risks apply for that paper and the bootstrapping cannot compensate for that.

Only 7% of participants included in this thesis had a foreign background (i.e. if the participants themselves or their parents were born abroad), which is lower than the estimated rate of 15% in the Swedish population (251). To enable the inclusion of more individuals with a foreign background, one solution could be to include individuals who do not understand Swedish (orally or in writing). Some of the patient-reported outcomes measures used in this thesis are available in other languages, but they are not available in the most common languages spoken by among those with a foreign background in Sweden. If a researcher could translate into the most common foreign languages encountered by healthcare providers, such as Arabic, Serbo-Croatian and Somali, more participants with a foreign background could be recruited for participation from a Swedish primary care context. However, the translation to each language is a process in itself and should be evaluated scientifically for validity and reliability (252). Despite the fact that this thesis does not quite reflect the multicultural nature of the Swedish population as a whole, the results of this thesis could be transferred to middle-high income countries with similar conditions.

The main author's inexperience in conducting interviews is a limitation in Paper IV, where a more experienced interviewer may have investigated topics of interest in more depth. However, two pilot interviews were conducted and discussed, and the interviewer gained relevant experience and developed the skills needed to ask relevant follow-up questions, which could contribute to a deeper understanding of the studied area. It could also have been beneficial if another profession had been part of the analysis to reduce the risk that the authors' experience as physiotherapists would influence the results. Still, the aim of the study has always been to explore experiences of healthcare among individuals with KOA in general, not specifically to answer questions about physiotherapists or physicians. Since one inclusion criterion was direct access to a physiotherapist assessment and a question area about the expectations and experiences of the first assessment, it is natural to seek information about

participants' experiences of care and their perceptions when physiotherapists are the primary assessors.

5.6 ETHICAL CONSIDERATIONS

In all papers, the research group have had continuously ethical discussions about benefits for the participants in relation to risks and ethical dilemmas. In Paper I, participants were instructed to minimize the fall risk by placing a table in front of them. Also, due to the 30 CST in Papers I-II, participants were informed about potential pain increase during or after the test. Participants in Paper II were informed about eventual pain increase when starting exercising. Further, participants in Paper IV were referred to a professional if the interview resulted in emotional distress that the participant could not manage on their own.

When planning the studies, the research group have reflected on which information that needs to be collected to answer the research questions, and how data will be stored and presented to ensure the participants integrity. The participants could cancel their participation anytime without stating a reason. The research process has been transparent in terms of study protocols and any changes. The methodological changes in Papers I-II were made in response to a low participant flow. The data collection for Papers I-II lasted four years for each paper, which increases the risk that the study will not be completed, and that data will be out of date. This could lead to a lower probability of publication if similar results are published. It would be unethical to proceed with research that no longer evaluates a knowledge gap. Recruitment for Paper I started just before the COVID-19 pandemic and was paused involuntarily due to low or no participant inflow, since people over 60 were not allowed to visit rehabilitation centres. Hence, most participants recruited during that period were under the age of 60. The motivation to proceed with recruitment to the research project was low after the pandemic, and new rehabilitation centres were added to the study to increase the participant flow. Due to the lower participant flow after the second round of recruitment, the decision was made to end the data collection when the anticipated sample size of 117 had been reached. This was in line with the protocol that included two self-tests and one physiotherapist assessment. This sample size was reached after 129 participants were recruited. Changes in the study protocol were made to

increase the quality of the study and additional analyses were used to provide more valuable information to clinicians. Based on the same collected data, we added ROC curve analysis and post-hoc analyses of MDC to enrich the results of available data.

Paper II was conducted during a major organizational change in Sweden's primary care system, which led to de-prioritization of any commitments related to research studies. Changes in eligibility criteria were made to increase the participant inflow, since we assessed that individuals screened for eligibility did not fulfil all the specific criteria, such as crepitus and morning stiffness. Participants with new onset KOA were recruited, and it could be possible that not all typical symptoms of KOA were present in these individuals compared to individuals who had been diagnosed with KOA for several years. Thus, we submitted an amendment application to remove crepitus and morning stiffness from the inclusion criteria, which was approved. Also, changes were made in the statistical analyses of Paper II to increase the quality of the analyses and the credibility of the results, where the independent sample t-test or Mann-Whitney U test were changed to a mixed effects model analysis.

There is currently a challenge related to the requirement that data sets should be available in databases to be published in some journals. It is of great importance to secure the privacy of participants according to the GDPR, where data is de-identified before uploading material. In small cities like those included in this thesis, it is of great importance to consider whether the results could reveal an individual's identity, especially in Paper IV where we included the participant characteristics and quotations.

Good research practice also involves taking responsibility for publishing and implementing research. The results of the published studies will be and have been presented and discussed in scientific congresses and shared in clinical networks and social media.

6 CONCLUSION

The 30 CST is a reliable self-test that can be useful in digital health and in the self-assessment of people with KOA. We implicate that direct access to physiotherapist could be an equivalent clinical pathway to improve health effects and reduce costs for individuals with KOA. Individuals with KOA expected to receive access to an exercise programme to regain their normal physical activities and thought that a physiotherapist assessment and exercise treatment were a reasonable first option. Individuals perceived that they received person-centred care where they felt understood and gained knowledge on the self-management of KOA. People assessed by physiotherapists first were hopeful that they could return to an active life, despite their KOA diagnosis.

7 CLINICAL IMPLICATIONS

The results of this thesis could improve the healthcare process for people with KOA by encouraging direct access to physiotherapist for assessment and first-line treatment of KOA.

Primary care centres could benefit from:

- Access to or collaboration with physiotherapists to deliver evidence-based KOA care with a shorter clinical pathway.
- The considerations of a triage approach where all individuals with suspected KOA are referred to a physiotherapist in primary care.
- A policy where consultation with a physician is available if individuals with typical KOA and without comorbidities have received core treatments first.
- Pathways where referrals to an orthopaedic surgeon are possible if the individual has tried core treatments first.
- Direct access to physiotherapist for similar groups of individuals, such as people with hip OA and elderly individuals with reduced physical function in the lower extremities.

Physiotherapists in primary care can:

- Feel confident that physiotherapeutic interventions as the first line of treatment for people with KOA improve health effects significantly over time. The improvements do not differ significantly compared to a traditional physician assessment.
- Feel confident that individuals with KOA perceive the physiotherapist assessment as positive as they feel they are being taken seriously and understood when they seek healthcare for knee pain.
- Bear in mind that older people with KOA have expectations to regain or maintain their physical activity level.
- Consider to schedule follow-ups of self-care as it helps individuals with KOA feel more secure until they re-establish independence.
- Consider using the 30 CST as a self-test for individuals with KOA, which could be useful in a digital setting or in self-monitoring. However, there is an MDC of six stands when compared with traditional testing on-site supervised by a physiotherapist. It is important to keep this in mind when comparing the results of self-tests with physiotherapist testing.
- Interpret people with KOA who perform less than 13 stands on the 30 CST as a self-test as likely to have reduced physical function.

8 FUTURE PERSPECTIVES

The paradigm shift that was suggested several decades ago, where exercise and patient education were seen as the first choice instead of surgery for people with KOA (253), has played out in some countries. Even though high-income countries have the conditions to deliver high-value OA care, it is still underutilized (92, 111, 126). For individuals with KOA, previous contact with a physiotherapist and a referral from a physician seem to facilitate the use of physiotherapy services (254), where the recommended exercise treatment and patient education can be delivered.

The global disease burden of KOA is already high and is expected to increase with the demographic shift, where the proportion of elderly is expected to increase and more people will be overweight or obese. The lack of resources seen today will be an even bigger problem in the future, and we urgently need to determine how to deliver high-value KOA care for those who need it. Several decades after the above-mentioned paradigm shift the implementation process for direct access to physiotherapist is still ongoing. This is especially important for individuals with KOA, who traditionally have been referred for confirmative radiography before receiving a KOA diagnosis. The belief among people with KOA that this traditional care pathway is the best choice remains a barrier that healthcare providers need to overcome. In order to provide high-value evidence-based care for people with KOA, healthcare providers need to continue informing society about the current recommendations for OA care and that direct access to physiotherapist is available and should be the first option for this group.

However, there are a number of different barriers to the implementation of high-value OA care depending on the conditions in a particular country. Even though the results of this thesis could be applied to other high-income countries, low to middle income countries face other challenges, such as inequitable, unaffordable and uncoordinated healthcare. There is a lack of skilled and experienced OA clinicians, as well as a lack of education and support for self-management. Furthermore, individuals with OA consistently receive low-value care. Another barrier is that OA is considered an unimportant disease (255).

While Paper IV illustrates the implementation of a care pathway with physiotherapists as first assessors of KOA, there are still barriers among individuals and healthcare providers that need to be researched. In a national evaluation of OA care in 2023, many individuals were still assessed and diagnosed by physicians first (79). Healthcare needs to continue to implement the national care pathways that have already been established. Decision makers should consider focusing on enabling financial healthcare systems for the implementation of direct access to physiotherapist for individuals with KOA with consideration for the following:

- Direct access to physiotherapist increases the chances that people with KOA will receive the right care at the right time and healthcare resources can be used more efficiently.
- Physiotherapist initiated healthcare processes result in a lower rate of referrals to radiography and orthopaedic surgeon, which in turn lead to cost savings.
- Resources need to be redirected to hire more physiotherapists in order to manage the increasing number of individuals with KOA in need of rehabilitation.
- Resources to educate the society about when to seek care, direct access to physiotherapist and self-management of KOA.

Further, research should evaluate the health effects and cost-efficiency of direct access to physiotherapist on a larger scale. Ten years have elapsed since the first participant was recruited to Paper II. It would be interesting to evaluate the long-term effects of direct access to physiotherapist for people with suspected KOA. However, another study design would be appropriate since the sample size in Paper II was too small and there is a risk that further dropouts would occur due to the long period of time that has elapsed. This thesis evaluated direct access to physiotherapist from different perspectives, and it would be worthwhile for decision makers to also evaluate this aspect from a sustainability perspective.

The physiotherapist's competence in assessing individuals with KOA may also be applicable in a later phase of the healthcare process. Recent study has shown that individuals with OA who were referred to an orthopaedic surgeon reported that the physiotherapist assessment in orthopaedic wards was consistent with

a high quality of care (256). Since the healthcare system is moving away from specialist care in hospitals to a greater focus on primary care, it would be of value to investigate whether primary care physiotherapists can assess individuals that are referred to orthopaedic surgeon. Also, given the complexity related to comorbidities, it would be interesting to explore what physiotherapists together with other healthcare providers can improve the OA care by more preventive approach to detect possible comorbidities, such as hypertension or diabetes, in an earlier stage.

The World Health Organisation views digital care as a solution to the need for more accessible and equal care (257). Studies evaluating the 30 CST as a self-test for other diseases could be valuable, as this kind of test is needed in digital physiotherapy (120). Furthermore, the validity and reliability of digital assessments of KOA need to be evaluated.

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***

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