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Making Minds Matter



The Road to Recovery



Personalizing Physical Therapy After Total Hip and Total Knee Arthroplasty

Lichelle Groot

The Road to Recovery

Personalizing Physical Therapy After Total Hip and Total Knee Arthroplasty

Lichelle Groot

This thesis was primarily conducted at the department of Orthopaedic Surgery & Sports Medicine at the Erasmus Medical Center, Rotterdam, The Netherlands.
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The Road to Recovery: Personalizing physical therapy
after total hip and total knee arthroplasty

De weg naar herstel: personaliseren van fysiotherapie
na totale heup- en totale knieartroplastiek

Thesis

to obtain the degree of Doctor from
Erasmus University Rotterdam
by command of the
rector magnificus

Prof.dr.ir. A.J. Schuit

and in accordance with the decision of the Doctorate Board.
The public defence shall be held on

Tuesday 10 November 2026 at 10.30 hrs
by

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Propositions

1. Poorer recovery is associated with prolonged postoperative physical therapy in patients after total hip or knee arthroplasty (this thesis)
2. A personalized postoperative physical therapy strategy does not provide additional benefits over usual care in improving physical functioning after total hip- or knee arthroplasty (this thesis)
3. Variation in the range of the number, frequency, duration and delivery of post-operative physical therapy after total hip- or knee arthroplasty has decreased over time (this thesis)
4. The Animated Activity Questionnaire provides an accurate representation of physical function in patients after total hip- or knee arthroplasty (this thesis)
5. The COVID-19 pandemic had a limited impact on the number, frequency, duration and delivery of postoperative physical therapy (this thesis)
6. Total hip or total knee surgery should remain the preferred treatment for patients with end-stage hip osteoarthritis (supported by Talonpoika et al., The bone & Joint journal, 2026)
7. The effectiveness of prehabilitation in improving outcomes after total hip or knee arthroplasty remains unclear and requires further research to determine its potential benefit for patients undergoing total hip or knee arthroplasty (stated by Konnyu et al., the American Journal of Physical Medicine & Rehabilitation, 2023)
8. We cannot advance clinical care without learning from what does not work: negative and neutral studies are essential (supported by Bresee, The Canadian Journal of Hospital Pharmacy, 2017 OF inspired by Showell, The Cochrane database of systematic review, 2024)
9. Cluster randomization should only be used when truly necessary, as its added complexity and potential biases can undermine scientific validity if not carefully justified and rigorously applied (supported by Hemming and Taljaard, International Journal of Epidemiology, 2023)
10. Resilience is not just a helpful trait during a PhD—it is the foundation of turning setbacks into learning, uncertainty into growth, and persistence into achievement in life (inspired by Steel et al., BMC medical education, 2024)
11. All assumptions should remain open to questioning—a principle reinforced daily by those who dare to ask: "Why?" (inspired by Noah (5) and Lynn (3)).

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Aims and outline of the thesis

Chapter 1 describes the background and context of the research, outlining the key research questions, objectives, and the significance of the study. It also provides an overview of the current state of knowledge in the field and establishes the foundation for the subsequent chapters

Chapter 2 presents a study investigating the relation between recovery and PPT usage after THA or TKA, including the impact of comorbidities. This observational study uses data from a large, ongoing multi-center prospective cohort study of OA patients.

Chapter 3 describes the research protocol of a nationwide, cluster randomized controlled trial (RCT) comparing the effectiveness of a standardized, treat-to-target PPT strategy with usual postoperative care for patients undergoing THA or TKA.

Chapter 4 shows the results of the abovementioned RCT, with respect to the clinical effectiveness.

Chapter 5 presents the results of the economic analysis conducted alongside the trial.

Chapter 6 describes a study aimed to determine the validity and responsiveness of the AAQ in patients after THA or TKA included in the abovementioned RCT.

Chapter 7 includes a study examining the impact of the COVID-19 outbreak on postoperative physical therapy treatment in patients receiving THA or TKA in the Netherlands.

Chapter 8 presents a study evaluating the impact of the COVID-19 lockdown period on Dutch primary THA and TKA patients, using data from a the Dutch Arthroplasty Register.

Chapter 9 comprises a general discussion on the findings of this thesis and a summary.

Chapter 1

General introduction

Osteoarthritis (OA) is a common chronic, degenerative joint condition, primarily characterized by the breakdown of cartilage, along with other structural changes such as osteophyte formation and subchondral bone sclerosis and with synovial inflammation. OA leads to pain, stiffness, and impaired joint function. The disease progresses slowly and often results in functional disability and reduced quality of life (1). The annual prevalence of OA in 2023 was 1.653.100 people (605.500 men and 1.047.600 women) based on registries of general practitioners in the Netherlands. This corresponds to 68.1 OA patients per 1000 men and 116.5 per 1000 women (2).

OA commonly affects the hips and knees (1). In the Netherlands there were 185.600 men and 314.800 women with hip OA and 303.900 men and 500.700 women with knee OA in 2023(3). These large and increasing numbers are a result of the aging population and increased prevalence of risk factors such as obesity. Given the large impact of the symptoms of hip en knee OA on in particular mobility, it has become a major cause of disability worldwide (1).

While there is no cure for hip and knee OA, several treatment options can help alleviate symptoms and improve joint function. These approaches include pharmacological treatment comprising analgesics, non-steroidal anti-inflammatory drugs (NSAIDs) and intra-articular injections (4). Non-pharmacological management strategies include education and self-management strategies such as physical activity, exercise, weight management, optimization of sleep and the use of orthotics (4, 5). The appropriate use of non-pharmacological treatment strategies is, apart from the general practitioner or medical specialist, often supported by health care professionals, including e.g. a physical therapist, occupational therapist or dietician. When conservative treatment options fail, total hip arthroplasty (THA) or total knee arthroplasty (TKA) may be considered as the final treatment option (6-8). These procedures are effective surgical treatments which provide, in the majority of patients, significant pain relief and improvement of functional abilities and have a positive influence on the overall quality of life. THA and TKA are widely performed surgical procedures for end stage OA of the hip and knee. In the Netherlands, the number of primary THA or TKA procedures has steadily increased over the last decades. According to the Dutch Arthroplasty Register (LROI) in 2023, 36.684 primary THA and 36.351 TKA procedures were performed (9) and these numbers are expected to increase further in the upcoming years.

Physical therapy after Total Hip Arthroplasty and Total Knee Arthroplasty

Recovering from THA or TKA usually requires a combination of pain management, gradual reintroduction of movement to optimize joint function and muscle strength,

and the training of functional activities such as walking or climbing stairs (6-8). Physical therapy (PT) plays a crucial role in the recovery process following THA or TKA surgery. Postoperative PT (PPT), aiming to increase joint mobility, muscle strength, and overall function, is a recommended strategy to accelerate and improve the recovery process (10-15). Immediately after surgery, in the clinical phase, PT helps to manage postoperative pain and reduce stiffness, the latter especially after TKA (16-18). Early mobilization is key—not only to restore joint range of motion but also to prevent complications such as a joint contracture or deep vein thrombosis. Patients are encouraged to begin walking and practicing stair climbing shortly after surgery, as these basic activities are essential for regaining functional independence and enabling a safe return home (6, 7, 16-18). With hospital stays for THA or TKA becoming increasingly shorter and most patients being discharged to their homes, there is a growing emphasis on rapid functional recovery (19).

Regarding recovery after THA and TKA, irrespective of the discharge destination, PT is continued in the large majority of patients. Previous research in the Netherlands showed that almost 95% of the patients who received a THA or TKA used PPT in a primary care practice or at home (20). Just as in the direct postoperative phase, PPT that is continued after discharge from hospital includes range of motion exercises, muscle strengthening exercises and the training and practicing of activities of daily living (ADL) such as walking inside and outside, climbing the stairs and cycling (8). Another important aspect in this phase is to improve cardiopulmonary fitness, balance and gait, which can be affected by both the surgery and the preceding period of joint dysfunction. Balance and gait training is particularly important for the prevention of falls, which can lead to serious complications. Another important component in the recovery is education and self-management support regarding e.g. home exercises, the use of assistive devices (like walkers or crutches), and movements or activities that can best be avoided (6-8).

Current delivery of postoperative physical therapy

In the Netherlands, PT following THA or TKA is recommended in both the guidelines of the Dutch Orthopaedic Association (NOV) and the Royal Dutch Society for Physical therapy (KNGF)(6-8). Previous research shows substantial variation in the delivery of PPT treatment with respect to its timing (when to start and stop), content, dosage (intensity and frequency) and duration (20-23). Although existing guidelines on PPT (6-8) outline a general framework for postoperative rehabilitation, detailed recommendations for its optimal delivery are lacking, allowing considerable variation in clinical practice. From the health care and societal perspective, it is highly relevant that the most optimal PPT treatment strategy is used.

Regarding the duration of the current delivery of PPT, relatively little is known about whether or not, and to what extent, it is related to postoperative recovery. Apart from the duration of PPT, another key aspect is the appropriate timing of the start of the treatment. Current guidelines and treatment protocols do not always state explicitly when PPT should best be started after discharge from the hospital, and patients may need time to find a PT and/or make a first appointment. Research in THA/TKA populations showed that clear referral guidelines and timely therapy initiation can reduce complications, shorten hospital stays, and enhance both outcomes and patient satisfaction (24-27). Ideally, optimization of care after THA and TKA would be achieved through the implementation of a transmural care pathway, which integrates both acute (secondary care, either or not short-stay) and post-acute (primary care) services. In the context of recovery after THA and TKA, such pathways have been associated with fewer postoperative complications, reduced hospital stay duration, and lower costs compared to standard care (3–4 nights hospitalization)(25-27).

Another key aspect is related to the appropriate content and dosage, and the extent to which the treatment is personalized. Regarding content and dosage, it was found that PPT treatment usually includes muscle-strengthening, range-of-motion, aerobic, functional and neuromotor exercises (20), whereas it remains to be established if their dosage is sufficient to achieve health benefits. For personalization, it was observed that the application of individual goal setting, particularly with respect to specific functional milestones, appeared to be limited (28). A treat-to-target approach, which focuses on individualized milestones and sets clear criteria for discontinuing treatment once goals are met, has shown potential in enhancing treatment (24, 29).

In summary, whereas PPT is a proven effective strategy to enhance recovery after THA and TKA, currently no consensus exists on its optimal delivery. Knowledge on how the duration is related to postoperative recovery is scarce. Regarding the optimal timing and content, the literature suggests that a care pathway integrating PPT in the hospital and in primary care, with a standardized treatment that is yet personalized regarding its content and duration according to the individual patient's functional goals, might optimize its outcomes. Research into the effectiveness of such an optimized PPT approach for patients undergoing THA or TKA is lacking. The same holds for its potential cost-effectiveness, as it is conceivable that prompt discontinuation of treatment, once the functional goals have been achieved, could lead to savings on the costs of PPT.

Measurement instruments to evaluate the outcome of physical function in THA and TKA patients

Appropriate measurement of outcomes, from both the clinician's and patient's perspectives, is crucial to evaluate and monitor the effects of PPT in THA and TKA. For that purpose, the combination of both performance-based tests as well as patient-reported outcome measures (PROMs) are advocated (8, 30). Utilizing both performance based tests and PROMs offers a comprehensive and accurate evaluation of functional status, enhancing clinical decision-making and aligning with patient-centered care.

Examples of performance-based tests are gait speed, sit-to-stand ability or stair climbing, as well as measurements of other aspects such as joint range of motion (ROM) or muscle strength. Specific performance based test recommended in clinical practice guidelines include the 30 seconds "Chair-Stand Test", the "40m (4x10m) Fast Paced Walk Test walk", and the "Stair Climb Test" test (30).

PROMs are important to capture subjective experiences that may not be observable through clinical examination alone. As an example, the International Consortium for Health Outcomes Measurement (ICHOM) suggests a standardized PROMS set of health outcome measurements relevant for OA patients (31). Specific instruments that are recommended and most often used in the Netherlands are the the 5-item short version of the Hip disability and Osteoarthritis Outcome Score (HOOS-PS) (32) and the 7-item short version of the Knee injury and Osteoarthritis Outcome Score (KOOS-PS) questionnaire (33, 34). The Oxford Hip score (35) and the Oxford Knee Score (36) are used to measure functional limitations in several daily activities and pain intensity. These questionnaires are routinely administered as part of the standard data collection by the Dutch Arthroplasty Register (LROI) (9).

Despite the value of the combination of performance-based tests and PROMs, both types of instruments may have some limitations. Performance-based tests may not completely represent real-life activities and cannot be completed by all patients due to physical impairments, whereas patients with lower health literacy levels may not be able to complete questionnaires. To address these limitations, the Animated Activity Questionnaire (AAQ) was developed (37, 38). The AAQ uses avatar animations to depict activities of daily living at various difficulty levels, allowing patients to select the animation that best matches their recent performance. The AAQ thus provides insights into real-world functioning and was found to correlate well with both PROMs and performance-based tests in OA patients (37-41). It is, however, currently unclear whether the AAQ is valid and responsive in patients with OA after THA or TKA, as

these measurement properties have not yet been assessed in this specific patient group. More insight into the value of the AAQ in PPT will help to select the set of outcome measures that is most appropriate in this patient group. This knowledge gap is in line with the need for adequate assessment tools to evaluate the effectiveness of PT after THA or TKA, which was identified as a research topic on the research agenda of the NOV (42) that was developed in collaboration with the KNGF.

Impact of COVID-19 pandemic on postoperative rehabilitation following THA and TKA
The provision of PPT is not solely related to the patient's health status and preferences and the perspectives of the PT and treating physician, but is also dependent on contextual factors. A contextual factor playing a major role in the delivery of PPT in the past years was the occurrence of the COVID-19 pandemic from 2020-2022. In response to the COVID-19 pandemic in the first two years strict containment measures, including national lockdowns and quarantines, were implemented. Studies reported increased psychological distress and reduced quality of life in the general population, particularly among younger individuals, females, those with poor health and with a lower socioeconomic status (43-45).

The first lockdown in the Netherlands (March 16 – June 1, 2020) led to the closure of many health care services, including primary care physical therapy. Elective orthopaedic care was minimized (46), with priority given to patients with the greatest need and expected benefits. Overall, about 20% fewer primary total joint arthroplasties than expected were performed during the pandemic in the Netherlands (46). Also, proportionally more acute (fractures, tumours, post-traumatic) THA and TKA were performed, whereas the numbers for end-stage hip and knee OA decreased. PT practices in the Netherlands were fully closed between March 23 – May 11, 2020. PTs were advised by the KNGF to provide remote care via telephone, email, or video consultations (47, 48). After reopening, guidelines continued to recommend remote care, the use of personal protective equipment and physical distancing (47, 48).

The pandemic and ensuing lockdown potentially reduced the uptake of postoperative rehabilitation after THA and TKA procedures, and as a consequence may have negatively influenced their outcomes. Understanding the impact of the COVID-19 pandemic is crucial for the evaluation of the effectiveness of interventions. Remote care has emerged as a promising alternative for PT, yet the effects of pandemic-related restrictions, practice closures, and remote care recommendations on PT outcomes after THA and TKA are unclear. Gaining insight into the extent to which the rehabilitation process was affected and into evidence of negative effects of the lockdown on the rehabilitation process are important steps toward a better

understanding of the impact of drastic societal events, such as a pandemic. Assessing this impact is crucial for refining rehabilitation strategies and ensuring continuity of care during future healthcare disruptions.

Rationale for this thesis

THA and TKA are widely performed surgical procedures improving pain, physical function and quality of life of people with end-stage hip and knee OA. PPT is a proven effect treatment to enhance recovery, however, there is substantial practice variation. Knowledge on the association between the duration of current PPT and postoperative recovery is scarce. Professional guidelines are, apart from the optimal duration, not specific regarding the timing and content, and local treatment protocols vary. An integrated care trajectory, with treat-to-target approach, which focuses on individualized milestones, might optimize PPT after THA and TKA. Further research to identify the added value of such a strategy was however lacking.

Regarding the evaluation and monitoring of functional outcomes, performance-based tests and PROMs that are currently recommended in practice guidelines, have a number of limitations, that can be overcome by the use of Innovative assessment instruments such as the AAQ. The AAQ has been evaluated in patients with OA, however, whether it is suitable for monitoring recovery in patients who underwent THA or TKA remained unclear.
During the conduct of the studies described in this thesis, the COVID-19 pandemic occurred, having a profound impact on healthcare systems worldwide, including in the Netherlands. The impact of external crises, such as the COVID-19 pandemic, on post-operative recovery and PT delivery had been insufficiently explored.

By addressing the abovementioned knowledge gaps, this thesis aims to contribute valuable insights to the field of orthopaedic rehabilitation, in particular physical therapy, ultimately improving post-operative recovery and patient-centred care following THA and TKA.

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Chapter 2

Recovery and the use of postoperative physical therapy after total hip or knee replacement

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Abstract

Background:
Total hip or knee arthroplasties (THA/TKA) show favorable long-term effects, yet the recovery process may take weeks to months. Physical therapy (PT) following discharge from hospital is an effective intervention to enhance this recovery process. To investigate the relation between recovery and postoperative PT usage, including the presence of comorbidities, 6 months after THA/TKA.

Methods:
Multicenter, observational study in primary THA/TKA patients who completed preoperative and 6 months postoperative assessments. The assessments included questions on PT use (yes/no and duration; long term use defined as ≥12 weeks), comorbidities (musculoskeletal, non-musculoskeletal, sensory comorbidities and frequency of comorbidities). Recovery was assessed with the HOOS/KOOS on all 5 subdomains. Logistic regression with long term PT as outcome was performed adjusted for confounding including an interaction term (comorbidity*HOOS/KOOS-subdomain).

Results:
In total, 1289 THA and 1333 TKA patients were included, of whom 95% received postoperative PT, 56% and 67% received postoperative PT ≥12 weeks respectively. In both THA and TKA group, less improvement on all HOOS/KOOS domain scores was associated with ≥12 weeks of postoperative PT (range Odds Ratios 0.97-0.99). In the THA group the impact of recovery was smaller in patient with comorbidities as non- musculoskeletal comorbidities modified all associations between recovery and postoperative PT duration (Odds Ratios range 1.01-1.05). Musculoskeletal comorbidities modified the associations between Function-in-Daily-Living-and Sport-and-recreation recovery and postoperative PT. Sensory comorbidities only had an effect on Sport-and-recreation recovery and postoperative PT. Also the frequency of comorbidities modified the relation between Function-in-Daily-Living, pain and symptoms recovery and postoperative PT. In the TKA group comorbidity did not modify the associations.

Conclusion:
Worse recovery was associated with longer duration of postoperative PT suggesting that PT provision is in line with patients' needs. The impact of physical recovery on the use of long-term postoperative PT was smaller in THA patients with comorbidities.

Introduction

Total hip or knee arthroplasties (THA/TKA) are effective procedures in patients with end stage hip or knee osteoarthritis (OA)(1, 2). Overall, THA and TKA show favorable long-term effects, yet the recovery process may take weeks to months. Physical therapy (PT) following discharge from hospital is an effective intervention to enhance this recovery process(3-6). Several guidelines recommend the use of PT to improve recovery after THA/TKA(7-9). In Western Europe, post discharge PT after THA/TKA range from 35% to 99%(10-12). A rise in use of postoperative PT is expected due to the foreseen increase in arthroplasty procedures(2, 13, 14).

Previous studies report variation in treatment modalities, the timing and/or the frequency and duration of post discharge PT indicating no clear consensus on its optimal dosage and timing(10, 15-19). Also, studies identified determinants that affected use of inpatient versus outpatient PT treatment and its program intensity. It was found that patients referred to the less intensive outpatient PT were more often younger, had less comorbidities, a public insurance status and less functional disability, also referral depended on the treating hospital(10, 19-21) as compared to those having more intensive and/or inpatient PT. Understanding the relationships between these factors and the use of postoperative PT could provide better patient expectations, more patient specific advice and targeted postoperative PT care for patients after THA/TKA(22-25).

The patient's physical recovery after THA/TKA, including the presence of comorbidities and its effect on the duration of postoperative PT, has not yet been extensively studied, while it is likely that patients with worse overall health status might have a greater need for PT. To our knowledge only the study of Smith et al., relying on data from the National Joint Registry for England, showed that worse functional outcomes at 12 months after THA/TKA were related to longer duration of PT. However, this relationship was not adjusted for patient characteristics(12).

Therefore, the aim of the present study was to examine the association between recovery and the duration of postoperative PT, taking into account individual patient characteristics and in particular the presence of comorbidities, as these can have a significant influence on the recovery after arthroplasty as well as PT(26, 27). A better understanding of the relationships between these factors and the use of postoperative PT could provide new insights into the process of recovery after THA/TKA and targets for optimization of care.

Methods

Study design

This study was part of the ongoing multi-center, prospective cohort Longitudinal Leiden Orthopaedics Outcomes of Osteo-Arthritis study (LOAS) (Trial ID NTR3348) (28). Ethical approval was obtained from the Medical Ethics Committee of the Leiden University Medical Center (Registration number P12.047). Since 2012 the LOAS includes consecutive patients scheduled for primary THA/TKA as a result of OA in seven participating hospitals: Leiden University Medical Center, Leiden; Alrijne Hospital, Leiden and Leiderdorp; Groene Hart Hospital, Gouda; Reinier de Graaf Hospital, Delft; Lange Land Hospital, Zoetermeer; Albert Schweitzer Hospital, Dordrecht; and Waterland Hospital, Purmerend. All participants signed an informed consent form prior to start of the study in accordance with the Handbook for Good Clinical Research Practice of the World Health Organization and Declaration of Helsinki principles (29).

Study population

Patients eligible for the LOAS were aged 18 years or older, physically and/or mentally able to complete questionnaires in Dutch and underwent primary THA/TKA for OA. The present study included a subset of patients from the LOAS who were included between June 2012 and June 2018, who filled out questions on the use of PT pre- and postoperatively and completed the questionnaires on hip/knee function and quality of life both preoperatively and 6 months after surgery. Patient who did not have postoperative PT were excluded from the analysis because they were not seen by a physical therapist after being discharged from the hospital.

Assessments

Patient Characteristics

Patient characteristics were recorded preoperatively and included age (years), sex, living status (living alone / living with partner, children or other(s)), working status (having a paid job yes/no) and the Body Mass Index (BMI (kg/m2)).

In addition, information on self-reported pain, quality of life and comorbidities were gathered preoperatively. Hip and knee pain severity in rest and during activities in the past week were assessed by the Numeric Rating Scale (NRS)(30), with scores ranging between 0 (no pain) and 10 (worst pain imaginable). Regarding quality of life, the SF-12 was administered (31) from which the Physical and Mental Component Summary scales (PCS and MCS) were computed, with scores ranging between 0 (worst physical/

mental health) and 100 (best physical/mental health). Self-reported comorbidities were gathered with a questionnaire developed by the Dutch Central Bureau of Statistics (CBS)(32, 33), in which the presence of comorbidities in the previous year was determined (yes/no). According to the paper of Peter et. al.(27), comorbidities were classified into three domains: Musculoskeletal comorbidities (elbow, wrist, hand, or back pain; other rheumatic diseases), non-musculoskeletal comorbidities (chronic lung, cardiac, or coronary disease; arteriosclerosis; hypertension; [consequences of] stroke; severe bowel disorder; diabetes mellitus; migraine; psoriasis; chronic eczema; cancer; urine incontinence) and sensory impairments (hearing or vision impairments; dizziness in combination with falling). Also the numbers of comorbidities were categorized into 4 groups: none comorbidities, 1–2 comorbidities, 3–4 comorbidities, and ≥ 5 comorbidities.

Physical therapy use

The use of preoperative PT was measured by one question: "Did you have contact with a PT before surgery for your hip or knee complaints in the past 6 months?" (yes/no). The use of postoperative PT was measured by three questions: "Did you receive physical therapy after surgery?" (yes/no); "What was the estimated duration of physical therapy?" (4 weeks, 6 weeks, 8 weeks or 12 weeks or more); and "What was the average frequency of physical therapy?" (Once a week, twice a week or three times per week or more). According to the Dutch guideline, long duration of PT was specified as 12 weeks of PT treatment or more (9).

Hip and knee related health status recovery and quality of life

The Hip disability and Osteoarthritis Outcome Score (HOOS) and the Knee injury and Osteoarthritis Outcome Score (KOOS) were used to assess hip and knee related symptoms (health status) preoperatively and 6 months after surgery(34, 35). The questionnaires contain 40 and 42 items, respectively, categorized into five domains (function in daily living; pain; symptoms; sport and recreation; quality of life). All scores ranging from 0 (severe impairments) to 100 (no impairments). To determine the impact of recovery on the use of postoperative PT, all domains of the HOOS/KOOS were included. The extent of recovery was expressed as the absolute HOOS/KOOS domain scores at 6 months adjusted for the preoperative values. The distribution based Minimal Clinical Important Differences (MCID) for the HOOS/KOOS domains have been reported to be around 8-9 points(36).

Statistical analysis

All analyses were performed for THA and TKA separately. Descriptive statistics (mean and standard deviation (SD), median with interquartile range or numbers and

percentages) were used to present the patients' preoperative characteristics, level of overall health status, pain and use of PT.

Baseline characteristics were presented according to postoperative PT (divided into none, <12 weeks or ≥ 12 weeks), using One-way ANOVA, Student t tests, Mann-Whitney-U tests or Chi Square tests to test differences between these groups or combinations of these groups, where appropriate patients who did not make use of post-discharge PT were excluded from further analyses. To study the association between recovery and the duration of postoperative PT, the 6-month HOOS/KOOS separate domain absolute scores, as well as their change scores were presented for the total group of postoperative PT users and compared between the groups with short and long duration of postoperative PT by means of Paired t tests (results expressed as mean difference in change with the 95% confidence interval (CI)). In addition, to account for potential confounders, logistic regression analyses were performed, in which duration of postoperative PT (< or ≥ 12 weeks) was the dependent variable and the 6-month absolute scores of the HOOS/KOOS domain scores were each separately considered as independent variables. Comorbidities were included as possible effect modifier and the following potential confounders, which were based on previous literature: age, sex, BMI, baseline HOOS/KOOS scores, living status and mental health(22). For each of the three different comorbidity domain groups (musculoskeletal, non- musculoskeletal and sensory impairments), we performed separate analyses as patients could have several comorbidities and therefore could be included in more than one comorbidity domain. In addition, we performed a separate analyses on the number of comorbidities (continuous variable) within a patient as possible effect modifier. All statistical analyses were performed on complete cases, two-sided with 95% Confidence Intervals (95%CI), using SPSS software (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

Results

Study population

The flow of participants in this study is presented in FIGURE 1. In total, 2279 and 2164 patients received a primary THA/TKA, respectively. Of these patients, 1289 THA and 1333 TKA patients were finally included for the present analysis. The included THA/TKA patients were on average somewhat younger, scored higher on the MCS and had a larger proportion of patients with ≥12 weeks of postoperative PT compared to the excluded patients (SUPPLEMENTARY TABLE 1).

Characteristics of THA and TKA patients

TABLE 1 shows the baseline characteristics of the patients. Both THA/TKA patients were on average 68 years old (THA SD 8.8; and TKA SD 8.4 years), and 60% and 63% of THA/TKA patients were female. Among patients younger than 67 years old, 55% and 53% of THA/TKA patients had a paid job before surgery. Overall, 39% of the THA patients had a musculoskeletal comorbidity, 62% had a non-musculoskeletal comorbidity and 5% had a sensory impairment. Of them 26.7% had a comorbidity in two domains and 2.3% in all 3 domains (SUPPLEMENTARY TABLE 2). 42% of the TKA patients had a musculoskeletal comorbidity, 62% had a non-musculoskeletal comorbidity and 6% had a sensory impairment . Of them 27.3% had a comorbidity in two domains and 2.5% in all 3 comorbidity domains.

Use of preoperative and postoperative PT

TABLE 1 shows that 728 (57%) THA patients and 676 (51%) of the TKA patients received preoperative PT. After surgery 91% of THA patients and 98% of TKA received PT. The large majority used primary care PT and 676 (55.9%) THA patients and 925 (65.5%) TKA patients used it for 12 weeks or more, whereas 49% of THA patients and 66% of TKA patients reported an average frequency of PT of twice a week.

Regarding the comparison of the characteristics of patients who had no postoperative PT or who had <12 weeks PT versus those who had ≥12 weeks postoperative PT, it appeared that in both THA/TKA, patients with ≥12 weeks postoperative PT were more often female, younger and employed. Also, they used preoperative PT more often and received ≥2 sessions of postoperative PT treatments per week than patients who received PT <12 weeks.

Additionally, the THA group with ≥12 weeks postoperative PT scored lower on all HOOS subdomains apart from subdomain sport at baseline compared to the THA group with PT <12 weeks. The TKA group with ≥12 weeks postoperative PT received PT in primary care more often. No differences on KOOS subdomains were found between both groups.

Physical recovery and postoperative PT

TABLE 2 shows the crude absolute HOOS/KOOS domain scores at 6 months as well as their changes compared to the preoperative scores for patients who received <12 weeks postoperative PT and those who received ≥ 12 weeks postoperative PT. We found that the group with ≥ 12 weeks postoperative PT had smaller improvements in HOOS/KOOS domain scores at 6 months. All differences between the groups were clinically relevant.

Associations of recovery, comorbidities and duration of postoperative PT

TABLES 3 and 4 show the adjusted Odds Ratios of the associations between recovery on all subdomains of the HOOS/KOOS and the duration of postoperative PT including the influence of comorbidities within these associations. For both THA/TKA we found that better recovery at 6 months was associated with shorter postoperative PT on all subdomains of the HOOS/KOOS (TABLES 3 and 4, model 1).

In THA patients, the existence of non-musculoskeletal comorbidities modified the associations between recovery and the duration of postoperative PT (TABLE 3). In patients with a non-musculoskeletal comorbidity, the impact of physical recovery on the risk of long term PT was smaller than in the patients without musculoskeletal comorbidity (SUPPLEMENTARY FIGURE 1-A). Hence in patients with a low HOOS subscore the probability of >12 weeks of PT therapy was lower in patients with a non-musculoskeletal as compared to patients without a non-musculoskeletal comorbidity. However, in patients with high HOOS subscores this probability was higher in patients with a non-musculoskeletal comorbidity than in patients without such a comorbidity. Table 5 showed hypothetical examples of combined data within different HOOS / KOOS function scores to clarify our results. Moreover, the presence of a musculoskeletal comorbidity was identified as an effect modifier with regard to Activities of daily living (ADL) and Sport and recreation recovery and postoperative PT. Sensory comorbidities only had an effect on Sport and recreation recovery and postoperative PT. Also the number of comorbidities within a patient was identified as effect modifier in the HOOS subdomains ADL, pain and symptoms meaning the impact on recovery was lower in patients with more comorbidities. In TKA patients (TABLE 4) the existence of comorbidities as well as their frequency did not modify the associations between recovery and the duration of postoperative PT (TABLE 4).

Discussion

We evaluated whether the patient's recovery 6 months after THA/TKA, including the presence of comorbidities, was related to the duration of postoperative PT. Approximately 95% of the study population received postoperative PT in a primary setting, where 49% of THA patients and 66% of TKA patients reported an average frequency of PT of twice a week. In about 56% of the THA and 66% of the TKA patients the average duration of postoperative PT was 12 weeks or more. Worse recovery at 6 months was associated with a longer duration of postoperative PT. The association between physical recovery and the use of long-term postoperative PT was weaker in THA patients with comorbidities than in patients without such a comorbidity. In TKA patients, comorbidities did not modify the association between recovery and postoperative PT duration.

Compared to Peter et al.(10), the frequency and duration of postoperative PT was slightly lower, but it was still substantially high compared to other Western countries(10-12). Our findings regarding the patient's recovery and duration of postoperative PT are in line with the study of Smith et al(12). They found that THA/TKA patients who received more than 10 postoperative PT sessions reported more complaints on average one year after surgery than patients who had less PT sessions. However, in the study of Smith et al., no adjustments were made and comorbidities were not taken into account. Nevertheless, the finding of both previous as well as the current study suggest that patients who were likely to have a greater need of PT due to insufficient recovery, indeed received it over a prolonged period. Hence, although currently clear evidence-based postoperative PT treatment protocols are absent, physical therapists seem to be able to adapt the PT treatment duration to the individual patient needs.

In 85% of our population at least one comorbidity was present, which is similar to previously published prevalence's in OA patients, which ranged from 68%-85%(37-40). In THA patients, the presence of musculoskeletal, non-musculoskeletal or sensory impairments and the frequency of comorbidities modified the association between recovery and postoperative PT in at least one of the HOOS domains. In THA patients with such or more comorbidities the effect of recovery on the use of long-term postoperative PT was smaller than patients without such or with less comorbidities. This may be explained by the impact a comorbidity has on the postoperative PT treatment. Hence, the presence of comorbidities may require a more tailored PT treatment approach, in which the physical complaints resulting from the comorbidity can have a more prominent role and the recovery of the THA surgery may be less leading(41). For example, a patient with heart failure may not be able to perform strenuous exercise, thereby some complaints possibly cannot be improved as much as when these exercises could be performed. Moreover, for these patients improvement of the aerobic capacity may be an additional goal. As such, the PT goals will differ from patients without such a comorbidity. In TKA patients, the presence of comorbidities had no moderating effect on the effect of recovery and long-term PT. A possible explanation could be that recovery after TKA is more complex and takes a longer period of time than after THA(42), as such the role of a comorbidity on the PT treatment may be less pronounced.

Nonetheless, these protocols could be important in the delivery of the most optimal composition, dosage and mode of PT treatment(43). Hence, the rising number of arthroplasty surgeries and their accompanying strain on the health care systems and society as a whole warrant for a very efficient postoperative PT approach. Here there

may be a role for a multidisciplinary consultation between health care providers (general practitioners, orthopedic surgeons, physical therapists), thereby improving communication, and increasing knowledge and agreement on rehabilitation treatment. Additionally, monitoring the recovery of a patient by a healthcare provider appears to be beneficial for better outcomes (44). Future studies should focus on the possibilities to improve or accelerate recovery using PT, thereby decreasing the duration of PT for THA/TKA patients. The PT has an excellent position to monitor the recovery process and identify patients with insufficient improvement due to the fact that the PT sees a patient twice a week on average in the first weeks after surgery, as opposed to a regular consultation by the orthopedic surgeon which is usually scheduled once in this period.

A strength of this study is the large regional, multicenter prospective cohort study design, in which we obtained both preoperative and postoperative assessments. Secondly, we used validated surveys to obtain recovery scores after surgery. However, this could also be a possible limitation, as we asked patients at six months about the duration of PT, which could have induced some recall bias. Examination of medical records could have provided more reliable and additional information, such as the content of the PT treatment. However, this method could not be used in the framework of this study. A second limitation is that we did not have information on the severity of the different comorbidities. Another possible limitation is the inability to account for all potential confounders, as such residual confounding may be an issue have occurred. Lastly, all patients were included in the Netherlands, therefore the results may not be one to one generalizable to other countries with different health insurance systems. Nevertheless, the sociodemographic and clinical characteristics of the participants were quite similar to those of persons who underwent THA/TKA in other observational studies (16, 27, 40, 45, 46).

Conclusion

In conclusion, less recovery was associated with longer duration of postoperative PT use after THA/TKA. The impact of physical recovery on the use of long-term postoperative PT was smaller in THA patients with comorbidities, but not in TKA patients. Patients with longer postoperative PT use showed worse recovery than patients with a shorter duration of PT use, suggesting that PT provision is in line with patients' needs.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained from the Medical Ethics Committee of the Leiden University Medical Center (Registration number P12.047). All participants signed an informed consent form prior to start of the study.

Consent for publication
No individual person's data will be published, therefore consent for publication is not applicable.

Availability of data and materials
Data is owned by a third party. The data underlying this article were provided by the LOAS study group by permission. The data will be shared on reasonable request to the corresponding author, with permission of the LOAS study group.

Competing interests
None of the authors have a conflicts of interest to disclose.

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Authors contribution
LG,DL,TVV and MG have contributed to the conception of this study. LG, DL,MG did the analysis and wrote this manuscript. All authors were involved in revising the manuscript critically for important intellectual content. All authors read and approved the final manuscript. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Tables and figures

Table 1. Characteristics of patients participating in a study on the use of physical therapy

	THA	TKA	THA				TKA			
	n = 1289	**n = 1333**	**No post-operative PT n = 110**	**<12 weeks post-operative PT n = 503**	**≥12 weeks post-operative PT n = 676**	**Difference between PT groups P Value**	**No post-operative PT n = 31**	**<12 weeks post-operative PT n = 377**	**≥12 weeks post-operative PT n = 925**	**Difference between PT groups P Value**
Sex, female; n (%)	771 (59.8)	844 (63.3)	63 (57.3)	279 (55.5)	429 (63.5)	0.018	7 (54.8)	218 (57.8)	609 (65.8)	0.015
Age, years	68.3 (8.8)	67.5 (8.4)	69.9 (8.1)	69.3 (8.5)	67.3 (9.1)	<0.001	67.1 (9.6)	69.9 (7.9)	66.5 (8.4)	<0.001
Body mass index; kg/m^2	27.2 (4.2)	29.3 (4.6)	27.4 (4.9)	27.1 (4.1)	27.4 (4.2)	0.409	28.9 (5.4)	29.6 (4.7)	29.2 (4.5)	0.309
Living status; n (%)										
- Alone	281 (21.8)	309 (23.2)	36 (32.7)	104 (20.7)	141 (20.9)	0.015	12 (38.7)	100 (26.5)	197 (21.3)	0.015
- With others	1008 (78.2	1024 (76.8)	74 (67.3)	399 (79.3)	535 (79.1)		19 (61.3)	277 (73.5)	728 (78.7)	
- Working, yes; n (%)	306 (23.9)	327 (24.5)	23 (20.9)	103 (20.6)	180 (26.8)	0.036	5 (16.1)	57 (15.2)	265 (29.0)	<0.001
- Working <67 years	280 (55.0)	303 (53.0)	21 (56.8)	91 (51.1)	168 (57.3)	0.412	5 (41.7)	49 (42.6)	249 (56.2)	0.024
Comorbidity*, yes, n (%)										
- Musculo-skeletal	501 (38.9)	557 (41.8)	47 (42.7)	195 (38.8)	259 (38.3)	0.978	13 (41.9)	159 (42.2)	385 (41.6)	0.833
- Non-musculoskeletal	795 (61.7)	821 (61.6)	71 (64.5)	291 (57.9)	433 (64.1)	0.381	20 (64.5)	238 (63.1)	536 (60.39)	0.170
- Sensory impairments	65 (5.0)	73 (5.5)	3 (2.7)	21 (4.2)	41 (6.1)	0.176	4 (12.9)	23 (6.1)	46 (5.0)	0.121
Comorbidity, count, n (%)										
- 0	214 (16.6)	184 (13.8)	14 (12.7)	88 (17.5)	112 (16.6)	0.45	5 (16.1)	43 (11.4)	136 (14.7)	0.23
- 1 or 2	738 (57.3)	727 (54.5)	74 (67.3)	294 (58.4)	370 (54.7)		16 (51.6)	207 (54.9)	504 (54.5)	
- 3 or 4	280 (21.7)	334 (25.1)	18 (16.4)	97 (19.3)	165 (24.4)		8 (25.8)	97 (25.7)	229 (24.8)	
- 5 or more	57 (4.4)	88 (6.6)	4 (3.6)	24 (4.8)	29 (4.3)		2 (6.5)	30 (8.0)	56 (6.1)	
Preoperative PT, n (%)	728 (56.5)	676 (50.7)	63 (57.3)	246 (50.9)	419 (64.3)	<0.001	13 (41.9)	167 (47.7)	496 (55.6)	0.037

Postoperative PT										
- Primary care	1038 (89.6)	1171 (92.3)	-	437 (88.8)	601 (90.2)	0.433	-	331 (89.7)	840 (93.3)	0.028
- Secondary care	120 (10.4)	98 (7.7)		55 (11.2)	65 (9.8)			38 (10.3)	60 (6.7)	
Frequency postoperative PT										
- 1 x per week	556 (47.5)	397 (30.6)	-	295 (59.4)	261 (38.8)	<0.001	-	178 (47.5)	219 (23.7)	<0.001
- 2 x per week	572 (48.9)	853 (65.7)		178 (35.8)	394 (58.5)			190 (50.7)	663 (71.8)	
- ≥ 3 x per week	42 (3.6)	48 (3.7)		24 (4.8)	18 (2.7)			7 (1.9)	41 (4.4)	
HOOS or KOOS										
- Symptoms	40.9 (18.5)	49.8 (18.3)	42.6 (19.7)	42.3 (18.4)	39.6 (18.3)	0.030	50.7 (20.2)	50.9 (18.3)	49.3 (18.3)	0.345
- Pain	39.1 (18.5)	39.4 (17.4)	41.6 (22.7)	40.7 (18.5)	37.6 (17.7)	0.008	37.1 (16.5)	40.3 (16.5)	39.1 (17.8)	0.404
- ADL	41.6 (19.2)	45.9 (18.1)	43.1 (21.5)	43.4 (19.0)	39.9 (18.8)	0.007	44.8 (21.6)	46.8 (17.7)	45.6 (18.2)	0.544
- Sport	19.6 (18.9)	10.7 (14.2)	20.4 (18.7)	20.5 (19.1)	18.7 (18.8)	0.236	10.5 (16.5)	11.5 (14.4)	10.4 (14.1)	0.452
- Quality of life	29.5 (16.4)	26.5 (15.3)	29.6 (16.8)	31.3 (17.3)	28.2 (15.5)	0.007	25.3 (17.0)	27.6 (15.5)	26.1 (15.1)	0.266
NRS pain score;										
- During rest	4.6 (2.5)	4.7 (2.6)	4.0 (2.5)	4.7 (2.4)	4.8 (2.6)	0.014	5.8 (2.9)	4.3 (2.5)	4.8 (2.6)	0.035
- During activity	6.8 (2.2)	6.7 (2.5)	6.5 (2.3)	6.7 (2.3)	6.9 (2.1)	0.287	7.4 (2.5)	6.4 (2.7)	6.7 (2.4)	0.230
SF-12										
- MCS	53.7 (10.2)	54.9 (9.6)	53.4 (11.7)	54.1 (9.8)	53.4 (10.3)	0.434	53.6 (10.7)	55.1 (9.6)	54.8 (9.6)	0.705
- PCS	32.9 (6.2	32.9 (6.1)	32.5 (6.5)	33.2 (6.3)	32.8 (6.0)	0.333	33.3 (6.1)	32.9 (6.1)	32.8 (6.1)	0.895
Duration of PT; n (%)										
- No PT	110 (9.1)	31 (2.2)								
- 4 weeks	126 (10.4)	75 (5.3)								
- 6 weeks	160 (13.2)	142 (10.1)								
- 8 weeks	217 (17.9)	160 (11.3)								
- >12 week	676 (55.9)	925 (65.5)								

Legend to TABLE 1: Data is presented as mean and standard deviation between parentheses or reported otherwise.

HOOS= Hip disability and Osteoarthritis Outcome Score; KOOS= Knee injury and Osteoarthritis Outcome Score; NRS= Numeric Rating Scale; SF-12 = Short Form-12; THA=total hip arthroplasty; TKA= total knee arthroplasty; PT= Physical therapy.

* The 3 comorbidity groups are not mutually exclusive.

Table 2. Physical recovery and postoperative physical therapy after total hip or knee arthroplasty surgery

	THA					TKA				
	postoperative PT < 12 weeks n = 503		postoperative PT ≥12 weeks n = 676			postoperative PT < 12 weeks n = 377		postoperative PT ≥12 weeks n =925		
HOOS/ KOOS domain score	**6 months mean (SD)**	**Change score 6 months (95% CI)**	**6 months mean (SD)**	**Change score 6 months (95% CI of mean difference)**	**Mean difference in change score between groups (95% CI of mean difference)**	**6 months Mean (SD)**	**Change score 6 months (95% CI)**	**6 months Mean (SD)**	**Change score 6 months (95% CI of mean difference)**	**Mean difference in change score between groups (95% CI of mean difference)**
Symptoms	82.7 (16.9)	40.8 (42.9 – 38.8)	73.9 (21.2)	34.5 (36.3 – 32.6)	8.8 (6.6 – 11.0)	77.5 (15.0)	25.9 (28.1 – 23.6)	69.1 (17.6)	19.7 (21.2 – 18.1)	9.5 (7.4 – 11.6)
Pain	90.6 (12.8)	50.4 (52.2 – 48.5)	83.5 (19.3)	45.9 (47.7 – 44.1)	7.1 (5.3 – 9.0)	86.6 (16.2)	46.0 (48.3 – 43.7)	77.1 (20.2)	38.2 (39.8 – 36.6)	8.4 (6.5 – 10.3)
Activities of daily living	87.3 (14.2)	44.5 (46.3 – 42.6)	79.3 (19.4)	39.7 (41.5 – 43.7)	8.0 (6.0 – 9.9)	84.4 (16.8)	37.1 (39.3 – 34.9)	77.4 (19.1)	31.9 (33.4 – 30.5)	7.0 (4.9 – 9.1)
Sport	69.0 (25.1)	48.4 (51.0 – 45.8)	59.0 (28.2)	40.5 (42.7 – 38.2)	10.0 (6.9 – 13.1)	47.7 (28.3)	36.5 (39.5 – 33.5)	35.4 (26.3)	25.2 (27.0 – 23.5)	12.3 (8.9 – 15.8)
Quality of life	79.9 (19.5)	48.8 (51.0 –46.6)	68.9 (22.5)	40.7 (42.7 – 38.8)	11.0 (8.5 – 13.4)	68.3 (20.9)	40.3 (42.7 – 37.9)	58.9 (21.2)	32.9 (34.4 – 31.3)	9.4 (6.9 – 12.0)

Legend to TABLE 2. HOOS= Hip disability and Osteoarthritis Outcome Score (range 0-100); KOOS= Knee disability and Osteoarthritis Outcome Score (range 0-100); PT = physical therapy; THA = total hip arthroplasty; TKA = total knee arthroplasty

Table 3. Association of duration of postoperative physical therapy and recovery in physical function in total hip arthroplasty patients 6 months after surgery

	Model 1 Multivariable OR [95% CI]	**Model 1 + Musculoskeletal comorbidities** OR [95% CI]	**Model 1 +Non-musculoskeletal comorbidities** OR [95% CI]	**Model 1 + Sensory Impairments** OR [95% CI]	**Model 1 + frequency comorbidities** OR [95% CI]
HOOS ADL	0.97 [0.96 – 0.98]	0.96 [0.95 – 0.98]	0.95 [0.93 – 0.97]	0.97 [0.96 – 0.98]	0.96 [0.95 – 0.98]
Comorbidity	NA	0.15 [0.03 – 0.87]	0.71 [0.01 – 0.59]	0.23 [0.03 – 2.20]	0.70 [0.99 – 1.01]
ADL* comorbidity	NA	1.02 [1.00 – 1.04]	1.03 [1.01 – 1.06]	1.02 [0.99 – 1.05]	1.01 [1.00 – 1.01]
HOOS Pain	0.97 [0.97 – 0.98]	0.97 [0.96 – 0.99]	0.94 [0.91 – 0.96]	0.97 [0.96 – 0.98]	0.96 [0.95 – 0.97]
Comorbidity	NA	0.62 [0.10 – 3.75]	0.01 [0.001 – 0.17]	0.23 [0.02 – 2.71]	0.58 [0.38 – 0.88]
Pain* comorbidity	NA	1.01 [0.99 – 1.03]	1.05 [1.02 – 1.08]	1.02 [0.99 – 1.05]	1.01 [1.00 – 1.01]
HOOS Symptoms	0.98 [0.97 - 0.98]	0.97 [0.96 – 0.99]	0.96 [0.94 – 0.97]	0.98 [0.97 – 0.98]	0.97 [0.96 – 0.98]
Comorbidity	NA	0.39 [0.10 – 1.45]	0.19 [0.04 – 0.82]	0.52 [0.08 – 3.34]	0.72 [0.53 – 0.98]
Symptoms* comorbidity	NA	1.01 [0.96 – 1.03]	1.03 [1.0 – 1.04]	1.01 [0.99 – 1.04]	1.01 [1.00 – 1.01]
HOOS Sport and Recreation	0.99 [0.98 – 0.99]	0.98 [0.97 – 0.99]	0.98 [0.97 – 0.99]	0.99 [0.98 – 0.99]	0.98 [0.98 – 0.99]
Comorbidity	NA	0.39 [0.17 – 0.85]	0.74 [0.32 – 1.67]	0.52 [0.16 – 1.67]	0.90 [0.74 – 1.09]
Sport and Recreation* comorbidity	NA	1.02 [1.00 – 1.03]	1.01 [1.00 – 1.02]	1.02 [1.00 – 1.04]	1.00 [0.99 – 1.01]
HOOS QoL	0.98 [0.97 – 0.98]	0.97 [0.96 – 0.99]	0.97 [0.95 – 0.98	0.98 [0.97 – 0.98]	0.96 [0.96 – 0.98]
Comorbidity	NA	0.64 [0.20 – 1.99]	0.99 [0.99 – 1.00]	0.51 [0.09 – 3.06]	0.73 [0.56 – 0.96]
QoL* comorbidity	NA	1.01 [0.99 – 1.02]	1.02 [1.00 – 1.03]	1.01 [0.99 – 1.04]	1.01 [1.00 – 1.01]

Legend to TABLE 3. ADL= Activities of daily living; HOOS= Hip disability and Osteoarthritis Outcome Score; THA = total hip arthroplasty
Model 1: long duration of PT = bo+b1x (HOOS score) adjusted for HOOS score baseline, BMI, age, sex, living status, and Short Form-12 Mental Component Summary scale and HOOS score baseline. In the other models comorbidities (musculoskeletal, non-musculoskeletal or sensory impairment and the frequency of comorbidities) and their interaction with recovery were also taken into account.

Table 4. Association of recovery and duration of postoperative physical therapy in total knee arthroplasty patients 6 months after surgery

	Model 1 Multivariable OR [95% CI]	Model 1 + Musculoskeletal comorbidities OR [95% CI]	Model 1 +Non-musculoskeletal comorbidities OR [95% CI]	Model 1 + Sensory Impairments OR [95% CI]	Model 1 + frequency comorbidities OR [95% CI]
KOOS ADL	0.97 [0.97 – 0.98]	0.99 [0.98 – 1.00]	0.98 [0.96 – 1.00]	0.97 [0.96 – 0.98]	0.97 [0.96 – 0.99]
Comorbidity	NA	5.78 [1.21 – 27.67]	1.64 [0.24 – 11.04]	1.41 [0.12 – 17.14]	0.94 [0.64 – 1.41]
ADL* comorbidity	NA	0.98 [0.96 – 1.00]	0.99 [0.97 – 1.01]	0.99 [0.96 – 1.03]	1.00 [1.00 – 1.01]
KOOS Pain	0.97 [0.96 – 0.98]	0.99 [0.97 – 1.00]	0.98 [0.97 – 1.00]	0.97 [0.96 – 0.98]	0.98 [0.96 – 0.99]
Comorbidity	NA	6.17 [1.23 – 30.92]	3.95 [0.66 – 23.60]	0.83 [0.06 – 2.32]	1.13 [0.72 – 1.76]
Pain* comorbidity	NA	0.98 [0.96 – 1.00]	0.98 [0.96 – 1.00]	1.00 [0.97 – 1.03]	1.00 [0.99 – 1.00]
KOOS Symptoms	0.97 [0.96 – 0.98]	0.98 [0.97 – 1.00]	0.97 [0.95 – 0.99]	0.97 [0.96 – 0.98]	0.97 [0.96 – 0.99]
Comorbidity	NA	3.55 [0.76 – 16.60]	0.93 [0.18 – 4.91]	5.56 [0.24 – 131.75]	1.04 [0.70 – 1.55]
Symptoms* comorbidity	NA	0.99 [0.97 – 1.01]	1.00 [0.98 – 1.02]	0.97 [0.93 – 1.02]	1.00 [0.99 – 1.00]
KOOS Sport and Recreation	0.98 [0.98 – 0.99]	0.99 [0.98 – 0.99]	0.98 [0.97 – 0.99]	0.98 [0.98 – 0.99]	0.98 [0.97 – 0.99]
Comorbidity	NA	0.98 [0.53 – 1.82]	0.92 [0.47 – 1.78]	1.24 [0.45 – 3.42]	0.93 [0.79 – 1.08]
Sport and Recreation* comorbidity	NA	1.00 [0.99 – 1.01]	1.00 [0.99 – 1.01]	0.98 [0.96 – 1.01]	1.00 [1.00 – 1.00]
KOOS QoL	0.98 [0.97 – 0.98]	0.99 [0.98 – 1.00]	0.98 [0.97 – 0.99]	0.98 [0.97 – 0.99]	0.98 [0.97 – 0.99]
Comorbidity	NA	2.27 [0.82 – 6.29]	0.90 [0.29 – 2.80]	1.05 [0.23 – 4.76]	1.00 [0.78 – 1.30]
QoL* comorbidity	NA	0.99 [0.97 – 1.00]	1.00 [0.98 – 1.02]	1.00 [0.97 – 1.02]	1.00 [1.00 – 1.00]

Legend to TABLE 4. ADL= Activities of daily living; KOOS= Knee disability and Osteoarthritis Outcome Score; TKA = total knee arthroplasty
Model 1: long duration of PT=bo+b1x (KOOS score) adjusted for KOOS score baseline, BMI, age, sex, living status, Short Form-12 Mental Component Summary scale and KOOS score baseline. In the other models comorbidities (musculoskeletal, non-musculoskeletal or sensory impairment and the frequency of comorbidities) and their interaction with recovery were also taken into account.

Table 5. Hypothetical examples of combined data within different Hip disability and Osteoarthritis Outcome Score / Knee disability and Osteoarthritis Outcome Score function scores

Arthroplasty	HOOS / KOOS ADL score 6 months after surgery	Comorbidity	Risk on longer duration of PT after THA/TKA surgery
Scenario: A female patient of 67 year, a BMI of 29, living with a spouse, HOOS ADL baseline score of 40 and a MCS of 54			
THA			
1	75	Without musculoskeletal comorbidity	66%
2		With musculoskeletal Comorbidity	72%
3		Without non- musculoskeletal Comorbidity	70%
4		With non- musculoskeletal Comorbidity	57%
5		Without sensory impairment	68%
6		With sensory impairment	71%
7	89	Without musculoskeletal comorbidity	57%
8		With musculoskeletal Comorbidity	62%
9		Without non- musculoskeletal Comorbidity	60%
10		With non- musculoskeletal Comorbidity	50%
11		Without sensory impairment	58%
12		With sensory impairment	71%
13	95	Without musculoskeletal comorbidity	52%
14		With musculoskeletal Comorbidity	57%
15		Without non- musculoskeletal Comorbidity	55%
16		With non- Musculoskeletal Comorbidity	48%
17		Without sensory impairment	53%
18		With sensory impairment	71%

TKA			
Scenario: A female patient of 67 year, a BMI of 29, living with a spouse, KOOS ADL baseline score of 45 and a MCS of 55			
1	69	Without musculoskeletal comorbidity	82%
2		With musculoskeletal Comorbidity	72%
3		Without non- musculoskeletal Comorbidity	80%
4		With non- musculoskeletal Comorbidity	77%
5		Without sensory impairment	80%
6		With sensory impairment	78%
7	85	Without musculoskeletal comorbidity	73%
8		With musculoskeletal Comorbidity	68%
9		Without non- musculoskeletal Comorbidity	71%
10		With non- musculoskeletal Comorbidity	70%
11		Without sensory impairment	72%
12		With sensory impairment	70%
13	94	Without musculoskeletal comorbidity	67%
14		With musculoskeletal Comorbidity	66%
15		Without non- musculoskeletal Comorbidity	65%
16		With non- musculoskeletal Comorbidity	66%
17		Without sensory impairment	67%
18		With sensory impairment	66%

Legend to TABLE 5. ADL= Activities of daily living; HOOS= Hip disability and Osteoarthritis Outcome Score; KOOS= Knee disability and Osteoarthritis Outcome Score; THA = total hip arthroplasty TKA = total knee arthroplasty ; MCS= Mental Component Summary scale of the Short Form-12

Scenarios are based on the 25th, 50th and 75th percentile of the HOOS/KOOS score 6 months after surgery.

Figures

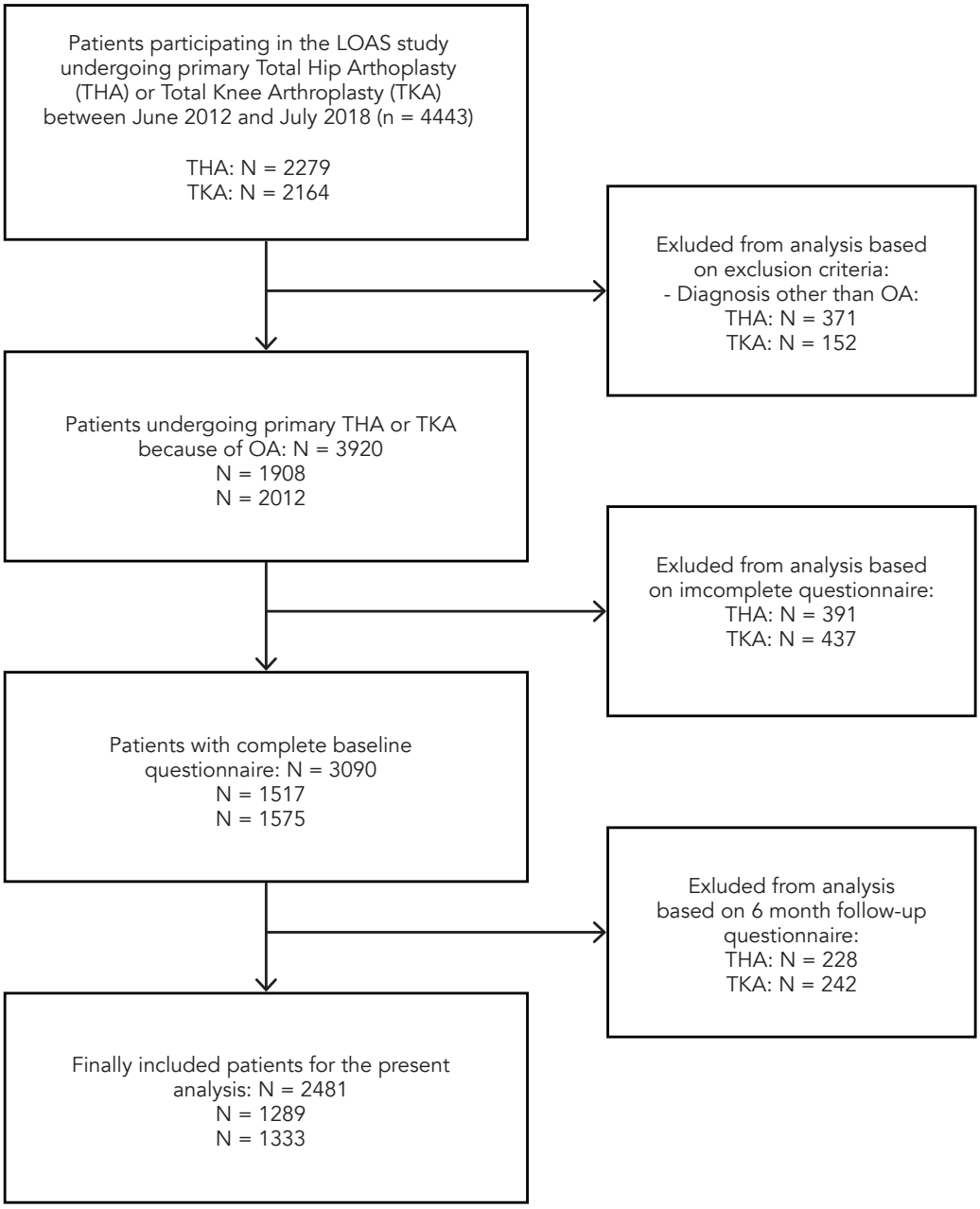


Figure 1. Flowchart of patients in a study on the use of physical therapy before and after THA/TKA

Chapter 3

Rationale and design of the PaTIO study: PhysiotherApeutic Treat-to-target Intervention after Orthopaedic surgery

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Abstract

Background:
Physiotherapy is a proven effective treatment strategy after total knee and hip arthroplasty (TKA/THA), however there is considerable practice variation regarding its timing, content and duration. This study aims to compare the (cost-) effectiveness of a standardized, treat-to-target postoperative physiotherapy strategy with usual postoperative care.

Methods:
Using a cluster randomized study design, consecutive patients scheduled for a primary TKA/THA in 18 hospitals in the Netherlands will be assigned to the treat-to-target physio therapy strategy or usual postoperative care. With the treat-to-target strategy a standardized, individually tailored, exercise program is aimed at the attainment of specific functional milestones. Assessments are done at baseline, 6 weeks and 3, 6, 9 and 12 months follow up. The primary outcome will be the Knee injury / Hip disability and Osteoarthritis Outcome Score - Physical Function Short Form (KOOS-PS / HOOS-PS) at 3 months follow up. Secondary outcomes are the numeric rating scale for pain, the Oxford Knee and Hip Scores, performance-based test and the EuroQol 5D-5L for quality of life. Healthcare use, productivity and satisfaction with postoperative care are measured by means of questionnaires. In total, 624 patients will be needed of which 312 TKA and 312 THA patients.

Discussion:
The study will provide evidence concerning the (cost-) effectiveness of the treat-to-target postoperative physiotherapy treatment compared to usual postoperative care. The results of this study will address an important evidence gap and will have a significant impact in daily practice of the physio therapist.

Trial registration
Registered in the Dutch Trial Registry on April 15, 2018. Registration number: NTR7129. https://www.trialregister.nl/trial/6933.

Background

In patients undergoing total knee or hip arthroplasty (TKA/THA) for osteoarthritis (OA) postoperative physiotherapy (PPT) is a recommended treatment (1-4). Several studies have demonstrated its effectiveness in improving function, range of motion and quality of life (5-8). Moreover, PPT also seems to play an important role in achieving functional independence such as return to work (9, 10).

Despite the current evidence, there is no consensus on the optimal composition of the treatment, timing (when to start and stop), and dosage (frequency). This has led to considerable practice variation, as demonstrated by a number of studies (11-13). For instance, a Dutch multicenter study on 522 TKA and THA patients found variation in the use of active and passive treatment modalities, and large individual differences in duration of treatment (14). Potential sources of variation are constituted by different postoperative treatment protocols used by orthopedic surgeons and hospital physio therapists (PTs) (15), as well as variation among primary care PTs delivering the intervention. About 1.66 and 1.26 per 1000 people receive TKA or THA respectively in western countries each year (16). From the health care and societal perspective, it is highly relevant that the most optimal PPT treatment strategy is used. Therefore, more knowledge on optimized PPT strategies is necessary (16, 17).

It is conceivable that PPT may be optimized by using a standardized treatment, that is tailored to the patient's individual situation. Previous research has shown that targeting treatment using specific milestones, also called treat-to-target strategy, was found to assist physicians in disease management, by simplifying and facilitating disease management decisions (18). It is proven effective in improving clinical outcomes in various chronic conditions such as, cardiovascular disease and rheumatoid arthritis (12, 19, 20). However, milestones are currently not routinely used in PPT after TKA or THA to direct treatment. Another way via which care can be optimized is by use of a transmural care pathway, which includes a short stay (1-2 days) and acute (secondary care) and post-acute care (primary care). In TKA and THA these transmural pathways are known to result in less postoperative complications, shorter length of hospital stay and lower costs during hospital stay when compared to standard care (3-4 nights inpatient)(21-23). Hence, a transmural pathway for PPT after TKA and THA linking all organizational aspects related to the continuum of TKA/THA care might also improve PPT. As such, we propose an individualized PPT intervention that is relatively standardized, yet the precise content, frequency and duration of treatment are determined by the acquisition of individualized, functional milestones.

This research topic was prioritized on the research agenda of the Dutch Orthopaedic Association (NOV). Within this project, the NOV and the Royal Dutch Society for Physio therapy (KNGF) collaborate.

Trial objectives

The aim of the present study is to evaluate the (cost-) effectiveness of a standardized, treat-to-target PPT strategy in TKA and THA patients compared to usual PPT. We hypothesize that with the standardized treat-to-target strategy better functional outcome can be achieved compared to usual care with lower costs (superiority study). The results of this study will be used to develop and implement a nationwide treatment strategy for PT after TKA/THA , and will be integrated in national guidelines of PTs and orthopedic surgeons.

Primary objective

1. To assess whether the functional outcome of a standardized, personalized treat-to-target PT strategy after TKA and THA is superior to usual care PPT after 3 months follow-up.
2. To assess whether a standardized, personalized treat-to-target PPT strategy is more cost-effective compared to usual care PPT after 12 months follow-up.

Secondary objective

1. To assess whether the functional outcome of a standardized, personalized treat-to-target PPT strategy after TKA and THA is superior to usual care PPT during the follow-up of 12 months.
2. To assess the difference in function, performance-based tests, pain and quality of life, as well as anchor questions, and satisfaction question; between both groups over time (6 weeks, 3,6,9 and 12 months) during the first year.

Methods

Study design and setting

We will use a multicenter, cluster randomized design. The 18 active including centers are; Alrijne hospital (Leiderdorp), Bergman Clinics (Rijswijk), Canisius Wilhelmina hospital (Nijmegen), Diakonessenhuis (Utrecht), Elisabeth-Tweesteden hospital (Tilburg), Erasmus MC University Medical Center (Rotterdam), HAGA hospital (Den Haag), hospital Gelderse Vallei (Ede), Leiden University MC (Leiden), Máxima MC (Eindhoven), MC Leeuwarden, Northwest Clinics (Alkmaar) OLVG (Amsterdam), Spaarne hospital (Hoofddorp), Tergooi hospital (Hilversum), University MC Groningen, University MC

Maastricht and Zuyderland MC (Sittard). Lange Land hospital (Zoetermeer) and Reinier de Graaf Gasthuis (Delft) are participating in the study however they are not including patients. Reinier de Graaf is involved in developing the PPT protocol and a part of the patients of HAGA hospital will have surgery in Lange Land hospital.
In the intervention group, PT is delivered by selected primary care practices by specially trained PTs. The training is a physical training and will be given by the same project members. In the control group the choice to use PT and the primary care practice is left to the discretion of the orthopaedic surgeon and the patient. In the Netherlands, after TKA or THA, a referral from the orthopaedic surgeon is needed for the healthcare insurance. This referral is standardly given by discharge from the hospital.

The planned duration of the study is three years.

The study protocol was reviewed and approved by the Erasmus MC Medical Ethics Committee (registration code NL61763.078.17) and was registered in the Dutch Trial Registry (registration number NTR7129). In all participating hospitals, the local responsible authorities approved the conduct of the study.

Study population

Inclusion and exclusion criteria

- Inclusion: Patients eligible for this trial are; a. patients with clinical and radiological knee or hip OA who are scheduled for a primary TKA or THA, b. willing to comply with the study protocol and c. providing written informed consent.
- Exclusion: Patients with a TKA or THA for a diagnosis other than OA; b. uncontrolled cardiovascular disease or hypertension; c. history of neuromuscular disorder that affects lower extremity function, d. terminal illness; e. planned replacement of another joint during study follow-up; f. not able to attend follow-up measurements; g. not able to attend the PPT in primary setting; h. serious psychiatric disorders; i. insufficient command of the Dutch language, spoken and/or written.

Recruitment

Patients who are scheduled for a primary TKA or THA in one of the participating hospitals and meet the eligibility criteria will be informed about the study by means of oral and written information. After written consent, baseline measurements are carried out. Recruitment is done by an orthopedic surgeon or researcher on his/her behalf.

Randomization
To avoid contamination between treat-to-target intervention and usual care, randomization will take place on hospital level.

A randomization list was created by an independent statistician using Sealed Envelope (London, UK). Random permuted blocks sizes of 4, 6 and 8 were used, and randomization was stratified by type of hospital (academic or general). Upon request of the trial management, the independent statistician randomized a site using the randomization list and communicated the site allocated treatment strategy by e-mail. The trial management remained blind to the randomization throughout the study.

Blinding
The study is an open-label trial.

Intervention
Development Treat-to-target intervention

The treat-to-target PPT is presented in the form of a transmural care pathway and was developed in four different phases knowingly, 1) an inventory phase, 2) development of the first draft, 3) development second draft, 4) finalizing treat-to-target PPT (Figure 1)). In the first phase, a literature study on the efficacy of PPT was done, in which guidelines regarding THA and TKA were taken into account. Also, an assessment of the existing perioperative treatment protocols in the Netherlands was conducted. Based on a selection of best practice (integrality and evidence based), one protocol was selected as the fundament for our treat-to-target intervention. In the second phase this protocol was adapted and supplemented using literature and guidelines. Hereafter the first concept of the protocol was discussed in an expert meeting of one primary and one secondary PT, a patient and orthopedic surgeons. In the third phase, the concept protocol was adjusted and details regarding the implementation in daily practice were added by 2 PTs who have extensive experience in the field of developing treatment protocols. The second concept of the protocol was again presented to the PTs, the patient and orthopedic surgeons who attended the first expert meeting for feedback. In the fourth and last phase, the protocol was adjusted based on the feedback of the expert panel resulting in final our treat-to-target intervention. This intervention consists of a preoperative assessment by the primary PT, secondary PPT and a comprehensive and personal transferal from the hospital PT including a Modified Iowa Levels of Assistance Scale (MILAS) score as a starting point of the secondary PPT.

Intervention arm: Treat-to-target intervention

First the necessity of PPT will be screened by a standardized assessment of the patient's health status, personal-, external factors and achievement of functional milestones. This assessment will be performed by the primary care PT in the first appointment after surgery (within 3 days after discharge from the hospital). Those needing PPT in primary care receive a standardized, personalized, time contingent program, focused on evidence-based components such as muscle strengthening and functional exercises. Exercises, selected by the PT, are available via an app or printed by the PT via Physitrack , an online available exercise program. The progress of functioning of the patient will be regularly evaluated regarding achievement of functional milestones. After reaching the milestones, PPT is ended and patients will receive a tailored advice with home-based exercises in combination with referral to exercise activities in the community.

Control arm: Usual Care

The use of PT and the choice of the physical therapist, is left to the discretion of the treating physician and the patient.

Assessments

Patients will be asked to fill in questionnaires at baseline, and at 6 weeks, 3- (primary end-point), 6-, 9 and 12-months follow-up. Performance-based tests will be performed at baseline, 6- and 12 months (see Table 1 for an overview). In each participating hospitals an assessor will be trained by the coordinating researcher to perform these Performance-based tests.

Patient characteristics

At baseline the following patient characteristics will be obtained: age, sex, side affected, height, weight, education level, ethnical background, living situation (living alone, living with partner, living with partner and child(ren) and living with children), duration of complaints, previous surgery and existing comorbidities.

Primary outcomes

Physical functioning

Physical functioning, assessed by the 5-item short version of the validated Dutch translation of the Hip disability and Osteoarthritis Outcome Score (HOOS) (24, 25) or the 7-item short version of the Dutch translation of the knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire (26, 27). Function scores will be determined on a scale from 0 (severe impairments in function) to 100 (no impairments in function).

Direct and indirect costs

Medical consumption (visits to health care providers and usage of prescribed or over the counter medication), absence from work or decreased productivity at work, and patient costs to be able to do cost-effectiveness analysis will be assessed with a questionnaire at 3,6,9 and 12 months postoperative. Our questionnaire is based on the questionnaire for Costs associated with Psychiatric Illness (TiC-P) from the institute of medical technology assessment (28). We have left out the irrelevant questions about psychiatric consultations. We added questions about PT consultation (frequency) and specified medication in use of pain medication.

Secondary outcomes

Pain and functioning

performance-based test

performance-based test as recommended by Osteoarthritis Research Society International (OARSI) (29) namely , 30 sec "chair-stand test", "40m walk test" and "stair negotiation" test, will be evaluated by the assessor. Assessors in all participating hospitals are trained in using a Dutch translated OARSI protocol. These tests will be performed at baseline, 3 months and 12 months.

Self-reported pain and function

Numeric Rating Scale

Hip and knee pain severity in rest and during activities in the past week will be assessed by the Numeric Rating Scale (NRS) (30). Scores range between 0 (no pain) and 10 (worst pain imaginable).

Oxford Hip score / Oxford Knee Score

Pain intensity and functional limitations in daily activities will be assessed by the Oxford Hip score (OHS) (31) and the Oxford Knee Score (OKS) (32). Both consist of 12 questions; each question will be scored from 0 to 4 with 4 being the best outcome. Overall scores running from 0 to 48 with 48 being the best functional outcome.

The Animated Activity Questionnaire (AAQ)

Basic daily activity limitations will be assessed with the Animated Activity Questionnaire (AAQ) (33) in which patients see video animations of 17 different basic daily life activities. These activities closely mimic real-life situations. For each activity, three to five different levels of difficulty in performing the activity are shown as video animations at the same time. The patient is asked to choose the video that best matches his or her own performance. Function scores will be determined on a scale from 0 (severe impairments in function) to 100 (no impairments in function). This video

animated questionnaire will be assessed during the physical assessment appointment at baseline, 3 months and 12 months.

Quality of life

EuroQol-5D-5L

Health-related quality of life will be assessed by the EuroQol-5D-5L (EQ-5D-5L)(34). This questionnaire consists of five domains (mobility, self-care, daily activities, pain/discomfort, and anxiety/depression) in which the patient can self-rate their severity of problems on a 5-point scale ranging from no problems to extreme problems or unable to perform the task.

Postoperative physical therapy (PPT)

Based on experiences in previous studies among physical therapists and patients (14), we will retrospectively evaluate, in the intervention group, the care of the PPT and the compliance of the patients by asking the physical therapists and patients to fill out predefined report forms (14). The set of questions comprised the survey regarding PPT. In a random sample of 5% we will evaluate the status of the patient of the participating physical therapist what the given PPT care was (content, duration, frequency), and whether this agrees with the case report forms as described above. In the control group we will also retrospectively evaluate the content, duration and frequency of the PPT with the same report forms.

Process evaluation

Anchor and satisfaction questions

Two anchor questions ("How is your daily functioning changed since your surgery?"/ "How are your pain complaints changed since your surgery?", a patient satisfaction question on their surgery ("How satisfied are you (in general) about the results of your surgery?"), and a question regarding the given PPT ("How satisfied are you (in general) about the results of your PT treatment?") will be evaluated at all postoperative time points.

(Serious) Adverse events & dropout rates

Any (S)AE will be communicated by the local researcher to the central researcher as soon as they become aware of it. The central researchers will report a SAE by the Centrale Commissie Mensgebonden Onderzoek (CCMO) via Toetsingonline within 7 (death or life threatening situations) or 15 (remaining SAE's) days. All drop-outs and protocol violations will be recorded.

An overview of the assessments can be found in table 1.

Sample size and power calculation

Our primary research hypothesis is that the improvement in physical function in our "treat-to-target" intervention will be superior to the improvement in the usual care group at 3 months, measured by the HOOS-PS/KOOS-PS score.

The power calculation is based on the proof of superiority, and calculated for patients undergoing TKA and THA separately. The reported standard deviation (SD) of the KOOS-PS and HOOS-PS 3 months after physiotherapy in TKA and THA patients was 15.6 and 11.8, respectively (35-41). For the intra cluster correlation coefficient we used an interclass correlation coefficient (ICC) of 0.06, which is generally reported in literature for hospital processes. To detect superiority of the treat-to-target PPT intervention to usual PPT we assessed the required sample size based on the following assumptions, a minimally clinical important difference (MCID) of 10 points, and a SD of 15.6. Since a MCID of the KOOS-PS and HOOS-PS after postoperative physiotherapy in TKA/THA patients is not yet available, a MCID was chosen based on expert opinion, namely 10 points on the KOOS-PS and HOOS-PS (42, 43).

Primary outcome

We propose a cluster RCT (randomization on hospital level) with an intracluster correlation coefficient of 0.06 and in total 18 participating hospitals. Sample sizes of 90 in group one and 90 in group two, which were obtained by sampling 9 clusters with an average of 10 subjects each in group one (180 patients) and 9 clusters with an average of 10 subjects each in group two (180 patients), achieve 90% power to detect a difference between the group means of at least 10. The coefficient of variation of cluster sizes is 0,500. A two-sided t-test was used with a significance level of 0,05. This test used degrees of freedom based on the number of subjects. To account for a 25% of drop out 240 TKA and 240 THA patients will be needed.

Secondary outcomes

We also assessed the needed numbers to detect superiority of the treat-to-target PPT intervention to usual PPT for the outcome improvement of pain severity as assessed by the NRS. Based on a MCID of 1 point on the NRS, and a SD of 2 the needed numbers were assessed. Sample sizes of 117 in group one and 117 in group two, which were obtained by sampling 9 clusters with an average of 13 subjects each in group one (234 patients) and 9 clusters with an average of 13 subjects each in group two (234 patients), achieve 91% power to detect a difference between the group means of at least 1. The SD of subjects is 1.7. The intracluster correlation coefficient is 0.06. The coefficient of variation of cluster sizes is 0.500. A two-sided t-test was used with a significance level of 0.05. This test used degrees of freedom based on the number of subjects. To account for a 25% of dropout,624 patients will be needed of which 312 TKA and 312 THA patients.

Feasibility of recruitment

Given the planned inclusion period of 12 months and the 18 centers participating and with an expected 100 inclusions a year (~2 per week), accounting for patients who are not willing to participate, we expect to have sufficient numbers for our hypothesis. The length of the inclusion period is based on the inclusion rate of the assumed slowest including hospitals (UMCs).

Data management

All data are handled confidentially and anonymized in compliance with the Dutch Personal Data Protection Act ("Wet Bescherming Persoonsgegevens"). Questionnaires are collected digitally, and the patient study data are stored in a coded way using secured data management software system Castor EDC (44). In case an email address is not available, a paper case report form is sent to the patient. When patients fill in their questionnaires on paper, documentation is stored in the investigator site file. Each patient is assigned a random study number that is used for all documentation, study reports and publications. The key to this study number is handled by an independent researcher. All data will be stored during the study period in Castor EDC, after the study is finished the data will be stored for 15 years. Documentation, such as questionnaires filled in on paper and signed informed consent forms, stored in the investigator site file will be stored at each site.

Statistical analysis

The results will be analyzed separately for TKA and THA. We will analyze patients as treated.

Primary outcome measure

The difference between both groups in change of KOOS-PS/HOOS-PS between baseline and 3 months follow-up score will be used as primary outcome. Patients will be analyzed as treated.

The primary analyses will be performed by using mixed models (change in KOOS-PS/HOOS-PS during 3 months as dependent and intervention as independent variable). Change between baseline and 3 months follow-up score will be used as primary outcome. Hospital variable will be used to indicate the correlation structure in the model. Adjustments will take place for baseline values of KOOS-PS/HOOS-PS. Of variables of which a priori is known that they are associated with the change in KOOS/HOOS-PS, based on previous studies or based on a strong clinical rationale will be considered as covariates in the primary analysis. These covariates are age, gender, BMI, and surgical approach in THA (anterior, lateral and postero-lateral). The assumptions of constant

variance and linear relationships will be assessed. Should any of these assumptions seriously fail then transformation of the dependent or independent variable(s) (where applicable) will be used. The choice of which transformation (e.g. square root, logarithm) will be used will be based on the specific distribution of the residuals.

Secondary outcomes

By using repeated measures mixed models analyses the course of the secondary outcome(s) over time of both interventions will be compared. The following time points will be used, baseline and follow-up measurements at 6 weeks, 3, 6, 9, 12 months.

Change in secondary outcomes will be used as dependent variable. As secondary outcomes will be used: KOOS-PS/HOOS-PS; OKS/OHS, NRS, AAQ, EuroQol-5D-5L, performance-based test and the anchor and satisfaction questions.

Economic evaluation

The economic evaluation will consist of a cost-utility analysis from a societal perspective (costs per QALY), based on patient reports and with an undiscounted one-year time horizon. Average costs and outcomes will be statistically compared using net-benefit analysis, with multiple imputation to account for missing data. Quality-adjusted life years (QALYs) will be estimated using the Dutch tariff for the quarterly EQ-5D-5L measurements. Societal costs will include healthcare costs, patient and family costs, and productivity costs. The timing, contents, frequency and duration of PPT will be measured using the study registrations. Other healthcare use and productivity will be reported by patients using quarterly questionnaires (including general practitioner visits, outpatient visits, hospital days, medication, home and informal care, patient costs, absence from work, and productivity while at (unpaid) work). Healthcare will be valued using reference prices obtained from the Dutch guidelines for economic evaluations in healthcare, including time and travel costs. Sensitivity analysis will be performed on the cost perspective (healthcare instead of societal perspective), the valuation of productivity (human capital instead of friction cost approach) and the utility measure used to calculate QALYs (Visual analogue scale for health (with power transformation) instead of Dutch EQ-5D-5L tariff).

In addition to the CUA, a budget impact analysis (BIA) will be performed. In a cost-calculator spreadsheet model, budget impact will be evaluated from the perspectives of the Dutch 'Budgettair Kader Zorg' (BKZ), health insurers, and the different care providers. The analysis will take into account the current mix of treatments, with prices appropriate for the perspective, a 4-year time-horizon and different scenarios for the rate of uptake.

Discussion

The PATIO trial is, to our knowledge, the first study that analyses the (cost-)effectiveness of a standardized, personalized postoperative physiotherapy protocol compared to usual postoperative care in patients with OA receiving TKA/THA.

Given the large variation in the provision of PPT, which seems to be not or weakly associated with patient characteristics, a more standardized, personalized approach seems warranted. The planned randomized controlled trial, with an economic evaluation will answer the question whether patients who receive a treat-to-target intervention recover with better functional outcomes against lower costs compared to the usual care PPT. From the health care and societal perspective it is extremely relevant that the most optimal PPT treatment strategy is used, as it concerns about 1.66 (THA) and 1.26 (TKA) per 1.000 people per year in western countries (16).

Besides measuring the (cost-) effectiveness of a treat-to-target PPT we also asses a broader range of health aspects (e.g. physical function, pain, comorbidities, perceived health and mental factors, information on insurance and satisfaction level of the results of their surgery and the PT) because several factors can influence the individual recovery after TKA/THA.

Strengths of the study include the nationwide multicenter design, supported by multiple involved professions. PTs are trained to work with the treat-to-target protocol. PTs who are trained on the protocol will unconsciously adapt their usual care treatment. To avoid contamination between the treat-to-target PPT and the usual care PPT a cluster RCT design was chosen. When a PT is trained by the treat-to-target protocol he/she will only treat patients in the intervention group. Since the power and precision of a cluster randomized trial is lower than an individually randomized trial, our study needs more participants to obtain the same statistical power. Another possible limitation of the study is the variation in surgical techniques which may have a different effect in the first months of the revalidation period of the patient.

The results of this study will address an important evidence gap and will have significant impact on the daily practice of the physiotherapist.

Trial status

The study inclusion has started in August 2018 and is still ongoing.

Declaration

Ethics approval and consent to participate

The study has been reviewed and approved by the Medical Ethics Committee (registration code NL61763.078.17) of the Erasmus MC. This approval covered all study sites. All participants signed an informed consent form prior to start of the study.

Consent for publication

No individual person's data will be published, therefore consent for publication is not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

MG,WP, WvdH, HV, TVV and MR have contributed to the conception of the study. LG wrote this manuscript. All authors were involved in the study design and revising the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

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Tables & figures

Table 1. Overview of measurement PATIO study.

	Allocation	Enrolment	Post-allocation	Close-out
TIMEPOINT	Randomization	Baseline, at inclusion	6 weeks ,3, 6, 9 -months follow-up	12-months follow-up
ENROLMENT				
Eligibility screen		X		
Informed consent		X		
Allocation	X			
INTERVENTIONS				
Intervention group: Treat to target			X	X
Control group: Usual care			X	X
ASSESSMENTS:				
Demographic; age, gender, side affected, BMI, education level, comorbidity		X		
HOOS-PS / KOOS - PS		X	X	X
OHS / OKS		X	X	X
NRS		X	X	X
AAQ		X	X (only at 3 months)	X
EQ5-D5L		X	X	X
Satisfaction question			X	X
Cost-effectiveness			X	X
Performance-based tests		X	X (only at 3 months)	X
(Serious) Adverse events			X	X

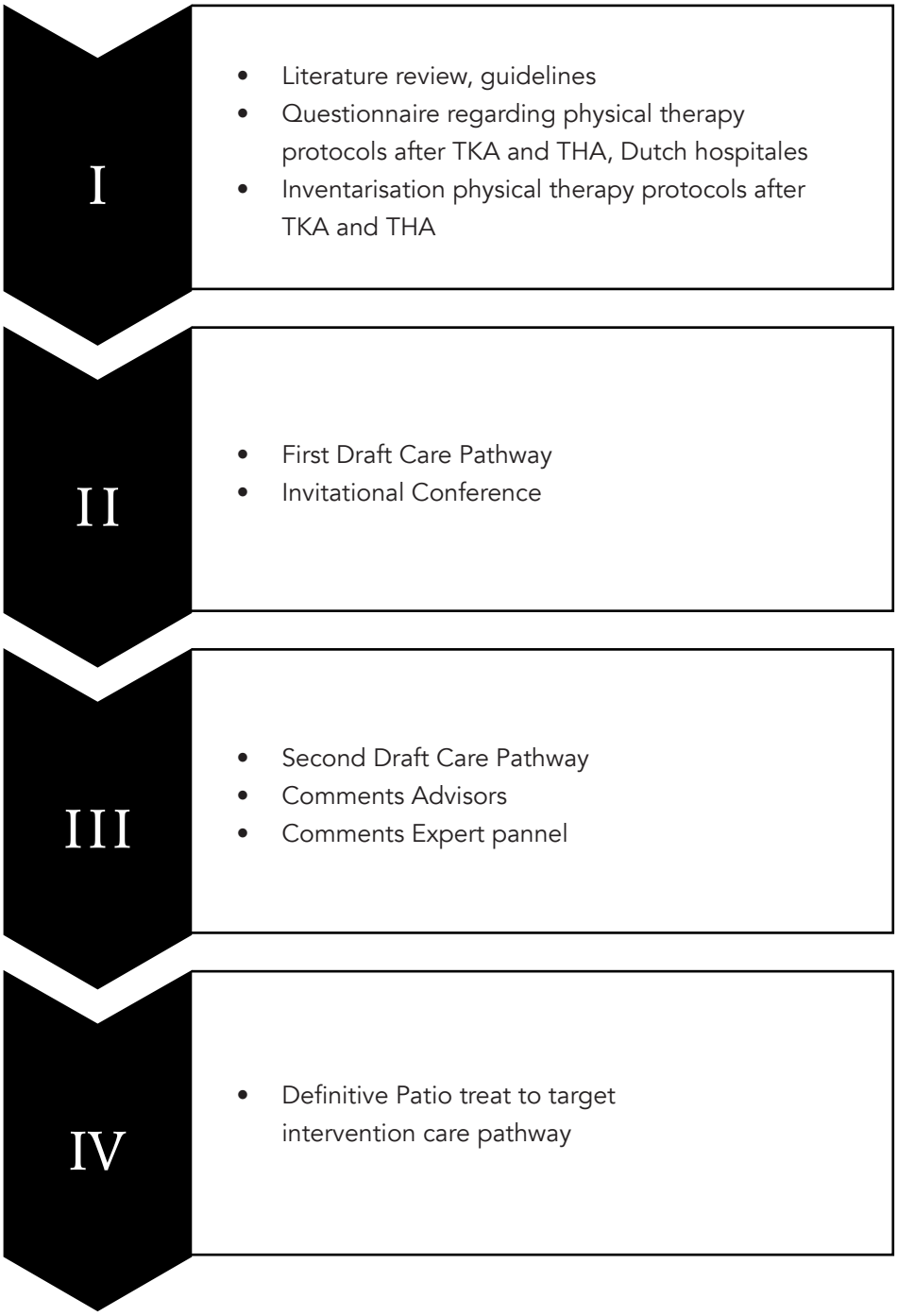


Figure 1. Development PATIO treat to target intervention care pathway

Chapter 4

PhysiotherApeutic Treat-to-Target Intervention after Total Hip and Knee Arthroplasty Does Not Improve Outcomes Compared to Usual Physical Therapy: The PATIO Study

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Abstract

Introduction
This nationwide superiority cluster randomized controlled trial evaluated the effectiveness of a personalized, treat-to-target postoperative physical therapy (PPT) strategy compared to usual care after total hip arthroplasty (THA) and total knee arthroplasty (TKA).

Methods
There were 18 hospitals randomized to treat-to-target or usual PPT, with 624 patients undergoing primary THA or TKA being eligible for participation. Assessments were conducted preoperatively and at six, 12, 24, and 52 weeks after surgery. The primary outcome was change in physical functioning three months after surgery, assessed with the Hip/Knee injury Disability and Osteoarthritis Outcome Score - Physical Function Short Form (HOOS-PS/KOOS-PS). Comparisons between groups were done using marginal models, including hospital as a fixed effect, with adjustment for sociodemographic and clinical characteristics. There were 312 THAs (53% women, age 67 years (range, 40 to 88)) and 312 TKAs (55% women, age 67 years (range, 41 to 88)) included. The THA patients received, on average, around 20 PPT sessions, and TKA patients around 30 sessions.

Results
All groups showed significant and clinically relevant improvements in function. There were no statistically significant between-group differences in change scores found for either HOOS-PS (19.9 (95% confidence interval (CI) 17.8 to 22.1) in the intervention group versus 18.2 (95% CI 16.0 to 20.5) in the control group) or KOOS-PS (31.3 (95% CI 29.3 to 33.4) versus 31.1 (95% CI 29.0 to 33.2), respectively) at 3-month follow-up.

Conclusion
The use of a personalized treat-to-target PPT strategy had no additional benefits over usual PPT regarding physical functioning after THA or TKA. The COVID-19 pandemic is a potential study limitation; findings should therefore be interpreted with caution.

Introduction

In Western countries, each year about 1.66 and 1.26 per 1,000 people receive total hip or knee arthroplasty (THA or TKA), respectively (1, 2). Postoperative physical therapy (PPT) is recommended in both orthopaedic and physical therapy (PT) guidelines (3-7). A PPT is used by the large majority of patients (8, 9) and delivered by primary care physical therapists (PTs).

In daily clinical practice, the provision of PPT delivery varies substantially in timing, content, intensity, and frequency (10-16). This variation may stem partly from professional guidelines lacking detailed recommendations (8, 17) and from studies providing only brief intervention descriptions (17). Overall, most interventions include aerobic, muscle-strengthening, and range-of-motion exercises, similar to observational studies (8). An important aspect of treatment that is currently lacking is the employment of individual goal setting, in particular regarding the achievement of functional milestones.

Patient-specific functional milestones may enhance outcomes after THA or TKA (18), however, their use was limited until recently. A treat-to-target strategy focusing on specific milestones was considered to be a promising avenue to more standardization regarding its focus on patient-specific goals and criteria to stop treatment if goals had been attained(18, 19). In other populations, such as mobility-impaired elderly, this strategy has proven cost-effective (10, 20, 21). At the time of the study, the Dutch clinical practice guideline for physical therapy in patients who had hip or knee osteoarthritis was in effect (5), which included only general recommendations regarding pre- and postoperative exercise therapy. There was no detailed guidance on the specific content of exercises, dosage (e.g., intensity or duration), or criteria for starting or ending treatment was provided. These general recommendations are also reflected in the guideline by van Doormaal et al. (22). Similarly, the orthopaedic surgeons' national guideline (6, 7) offered only broad statements regarding PPT. While standardized rehabilitation protocols promote consistency and facilitate the delivery of evidence-based care, incorporating elements of individualization remains essential to address patient-specific needs and variability in clinical presentation. Achieving an optimal balance between standardization and tailored interventions is critical to maximizing treatment effectiveness and improving rehabilitation outcomes (23, 24). Another key improvement area is the appropriate PPT timing, as studies suggest that clear referral guidelines and timely initiation reduce complications, shorten hospital stays, and improve outcomes and satisfaction (18, 25-27). We developed a study

concerning a timely provided tailored PPT intervention, including the setting and monitoring of personal milestones guiding the content, frequency, and duration of treatment modalities (28). The primary aim of the study was to assess whether the change in functional outcomes of a personalized treat-to-target PPT strategy after THA and TKA was superior to usual care PPT after three months of follow-up. The secondary aim concerned the effects on functional outcomes, pain, and quality of life.

Methods

Study design and setting

The PhysiotherApeutic Treat-to-target Intervention after Orthopaedic Surgery (PATIO) study was an open-label, multicenter, cluster-randomized controlled trial designed as a superiority study. The study protocol was published previously (28). In brief, patients were recruited between August 1, 2018, and July 1, 2021, in 18 hospitals in the Netherlands. The Erasmus MC University Medical Center ethical review board approved the research protocol (registration code NL61763.078.17). The study was registered in the Dutch Trial Registry (https://onderzoekmetmensen.nl/en/trial/55756) with the number NL-OMON55756. In all participating hospitals, local responsible authorities approved the conduct of the study. This study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist for cluster randomized controlled trials (29). The study population is described in our study protocol (28).

Randomization and masking

Randomization took place with clustering at the hospital level by an independent researcher. The study was an open-label trial. Patients who were in the control group were asked not to disclose their participation in the study to their treating physical therapist (PT). Those physical therapists (PTs) were only informed about the study afterwards. During the data analysis, the intervention and control allocations were masked.

Intervention and control conditions

Intervention arm: Treat-to-target intervention

The postoperative physical therapy (PPT) was delivered by specially trained PTs working in selected primary care practices in the vicinity of the intervention hospitals. The intervention is structured into clearly defined phases, each with specific start and end points. Within each phase, milestones are discussed and achieved. These milestones determine whether to proceed to the next phase, adjust the therapy, or discontinue it. The treatment protocol is described in detail in Appendix 1.

Control arm: Usual Care

The advice on and use of PPT and the choice of the PT were left to the discretion of the treating orthopaedic surgeon and the patient. When PPT was provided, the PTs followed their own program or protocol specific to their practice, which varied in content and was unknown at the start of the therapy. Additionally, some orthopaedic practices were part of local or regional networks of PTs with whom they collaborated. However, for each participating hospital and PT, we did not systematically record whether they were involved in such an orthopaedic network.

In the Netherlands, the reimbursement of PPT following total hip arthroplasty (THA) or total knee arthroplasty (TKA) is structured within a specific insurance model. Patients are initially required to cover the cost of the first 20 sessions themselves. These sessions may be paid out-of-pocket or reimbursed through additional (supplementary) health insurance, depending on the patient's coverage. Starting from the 21st session onward—and up to 12 months postoperatively—PT is reimbursed through the mandatory basic health insurance package.

Assessments

Assessments consisted of questionnaires and performance-based tests, where questionnaires were administered at baseline (preoperatively) and six weeks, three (primary endpoint), six, nine, and 12 months after surgery. These time points were in line with those from the mandatory set of Patient-Reported Outcome Measures (PROMS) of the Dutch Orthopaedic Interventions Registry (LROI), with the exception of six weeks and nine months (2). The specific time window in our study was baseline up to 182 days before surgery; six weeks ranging from 28 to 56 days after surgery; three months ranging from 63 to 110 days after surgery; six months ranging from 154 to 210 days after surgery; nine months ranging from 235 to 303 days after surgery; and 12 months ranging from 323 to 407 days after surgery. When patients did not fill in the questionnaires within the defined time windows, we registered this as a time violation and excluded the patient for that specific time point. Performance-based tests were done at baseline and at three and 12 months and executed by a trained assessor.

Patient and surgical characteristics

At baseline, the following information was collected: sex, age, height (cm), weight (kg), living alone (yes/no), education level, physical activity, surgical date, THA or TKA, date of surgery, operated side (left/right), surgical approach in THA patients, and presence of comorbidities.

Characteristics and use of postoperative physical therapy

Characteristics of the PTs were measured after completion of the PT treatment with an assessment including years of experience of the PT and the PT with specialization. Specialization included manual therapy, pediatrics, oncologic/lymphedema, geriatrics, occupational/workplace, sports, pelvic, psychosomatic, or other. The use of PT was assessed using this same assessment, collecting data on the location of PT (home, online, by phone, PT practice, nursing home, hospital outpatient clinic, rehabilitation center, or elsewhere), frequency per week (less than once a week, once a week, twice a week, or three times a week or more), duration of PT (two to four weeks, five to eight weeks, nine to 12 weeks, longer than 12 weeks, or other (e.g., a single session or less than four weeks)), and total number of PT treatment sessions.

Primary outcome

The primary outcome was change in physical functioning three months after surgery as measured by the 5-item short version of the validated Dutch translation of the Hip disability and Osteoarthritis Outcome Score Physical Function Short Form (HOOS-PS) (30) or the 7-item short version of the Dutch translation of the Knee injury and Osteoarthritis Outcome Score-PS (KOOS-PS) questionnaire (31, 32). For both HOOS-PS and KOOS-PS, the scores range from 0 (severe impairments) to 100 (no impairments).

Secondary outcomes

Pain and functioning

Self-reported hip and knee pain at rest and during activities in the past week was assessed by the Numeric Rating Scale for severity (NRS) (0 = no pain; 10 = worst pain imaginable) (33). Self-reported pain and functional limitations in daily activities were assessed by the Oxford Hip and Knee scores (OHS and OKS) (34, 35) (0 = worse functional outcomes; 48 = best functional outcome). The performance-based tests were those recommended by Osteoarthritis Research Society International (OARSI) (36) and included the 30-second "chair-stand test," the "40 m walk test," and the "stair negotiation" test. Basic daily activity limitations were assessed with the Animated Activity Questionnaire (AAQ) (0 = severe impairments in function; 100 = no impairments in function) (37).

Serious adverse events

Serious adverse events (SAEs) or adverse events (AEs) were prospectively recorded on a standardized form by the local researchers. The SAEs clearly related to the surgical intervention (i.e., THA or TKA procedure) and not to the given PPT were not reported as SAE. An elective hospital admission was not considered an SAE.

Process Evaluation

Adherence

The use of PPT was evaluated among PTs and patients by a predefined report form on content, duration, and frequency of PPT after completion of the treatment. Intervention PTs received extra questions about the milestones. The compliance of intervention PTs was evaluated in a sample of 19 patients with fidelity assessments at the end of the study. In the electronic files of these patients, the presence of three key elements of treatment was ascertained: setting and evaluation of short- and long–term milestones, use of muscle-strengthening exercises, and training of functional activities (Supplement Table 3). The PTs were considered compliant if they met all three key elements.

Patient satisfaction

The process evaluation among patients comprised two anchor questions and two satisfaction questions, which are described in more detail in our study protocol (28). We used the three-month point to describe our results.

Sample size calculation

To demonstrate the superiority of the treat-to-target PPT intervention as compared to usual PPT, a minimal clinically important difference of 10 points on HOOS-PS/KOOS-PS and a standard deviation (SD) of 15.6 was used (38, 39). In total, 312 THA and 312 TKA patients would be needed, accounting for a dropout of 25%.

Data Analyses

All analyses were stratified for THA or TKA and performed according to the intention-to-treat principle. The latter is in contrast with the procedure as described in the published study protocol (28). The superiority of the intervention with respect to improving HOOS-PS and KOOS-PS scores at three months was tested using marginal models (Generalized Estimating Equations (GEE) approach), including hospital as a fixed effect and a compound symmetry covariance matrix. The GEE is used for analyzing correlated data, such as repeated measures, similar to repeated-measures Analysis of Variance (ANOVA) or mixed models. Unlike mixed models, which estimate subject-specific effects, GEE provides population-averaged estimates and is robust to misspecification of the correlation structure—making it suitable when the focus is on overall group effects. On the basis of a strong clinical rationale, we adjusted for baseline values of HOOS-PS / KOOS-PS, age, sex, and body mass index (BMI), as well as surgical approach (in THA patients, direct anterior, lateral, and posterior-lateral). The same approach was used with the secondary outcomes. We also performed marginal models (GEE approach). These models included the hospital as a fixed effect

and a compound symmetry covariance matrix. These models were adjusted for age, sex, BMI, and surgical approach in THA patients. For all models, the assumptions of constant variance and linear relationships were assessed. Analyses were performed in IBM Statistical Package for Social Sciences (SPSS) Statistics version 28 (Chicago, Illinois, United States) and R version 4.2.1 (Auckland, Auckland Region, New Zealand).

Study population

Figure 1 presents the flowchart of THA and TKA patients in the present study. A total of 312 THA patients and 312 TKA patients were included in the study. Of the THA patients, one patient in the intervention group and two in the control group did not receive THA. There were seven patients in the intervention group who did not receive the treat-to-target PPT. After three months, 93% of patients in both groups completed the HOOS-PS; after 12 months, this was 85% in the intervention group and 91% in the control group. Of the 312 TKA patients, three patients in the intervention group did not receive TKA, and 10 did not receive the treat-to-target PPT. After three months, 95% of patients in the intervention group and 88% in the control group completed the KOOS-PS; after 12 months, this was 86% in the intervention group and 82% in the control group.

Characteristics of THA and TKA patients

Among THA patients, women comprised 45% of the intervention group and 60% of the control group. The mean age was 66 years (range, 40 to 83) in the intervention group and 68 years (range, 43 to 88) in the control group. Other baseline characteristics were comparable across groups for both THA and TKA (Table 1).

Characteristics and use of postoperative physical therapy

Table 2 shows the use of PPT in THA and TKA patients. A total of 121 physiotherapists from 63 practices were trained in the intervention protocol. Data for the control group were limited due to a low response rate (47%). On average, 76% of THA patients in both groups reported receiving PPT, 10% did not receive PPT, and 14% had missing data. Among TKA patients, 83% in the intervention group and 79% in the control group reported receiving PPT, with 17% missing data. The mean number of PT sessions was 20 (SD [standard deviation] 17) for THA intervention patients and 19 (SD 17) for control patients. For TKA patients, the mean was 29 (SD 20) in the intervention group and 32 (SD 27) in the control group. Frequency and duration of PPT were similar across groups: most patients attended two sessions per week, with treatment lasting over nine weeks for most THA patients and over 13 weeks for most TKA patients. There were no significant differences observed between groups in exercise type, instructions, or activities of daily living (ADL) practice (Supplementary Table S1).

Compliance with the intervention protocol was 13 of 19 physiotherapists based on a sample of 19 patients (Supplementary S3). According to the defined key elements described in Supplementary S3, most of the non-compliant PTs did not evaluate the phase 1 milestones during the first treatment session.

Results

Primary outcome

Figure 2 shows the adjusted change in the Hip/Knee injury Disability and Osteoarthritis Outcome Score - Physical Function Short Form (HOOS-PS/KOOS-PS) three months after surgery. Both total hip arthroplasty (THA) and total knee arthroplasty (TKA) groups showed clinically relevant improvements in HOOS-PS/KOOS-PS at three months of follow-up. We found no statistically significant differences between the intervention and the control group for both THA (-2.40 (95% CI [confidence interval]: -6.21 to 1.41)) and TKA patients (-0.85 (95% CI: -4.46 to 2.75)) at three months follow-up.

Secondary outcomes

Tables 3 and 4 show the estimated means from our Generalized Estimating Equations (GEE) models at each measurement point. In addition, the adjusted differences at each specific time point are shown. Hence, these differences accounted for baseline imbalances between the intervention and control groups and may, therefore, differ from the observed differences in estimated group means at each time point. For the HOOS-PS scores, no significant differences were shown for the secondary endpoints. Most other secondary outcomes also showed no significant differences in the THA population. However, at both three and six months, the Animated Activity Questionnaire (AAQ) showed a significant improvement in the intervention group compared to the controls (Table 3), whereas the Rating Scale for Severity (NRS) during activity showed a more pronounced improvement in the control group compared to the intervention group at three, six, and 12 months. Also, in the TKA population, most secondary outcomes showed no significant difference between the groups (Table 4). However, at 12 months the TKA intervention group showed a significantly greater improvement in KOOS-PS with 3.63 points (95% CI: -6.62 to 0.63); also, they improved more with regard to the 40-meter fast-paced walk test, with change score differences of 3.10 seconds (95% CI: -5.56 to -0.64) at three months and 3.25 seconds (95% CI: -5.95 to -0.55) at 12 months.

Anchor and satisfaction scores

Regarding the anchor questions, THA patients in the intervention group reported a mean score of 5.75 (95% CI: 5.54 to 5.99) for change in functioning and 6.07 (95% CI: 5.88 to 6.26) for change in pain (Table 3). THA patients in the control group reported a mean score of 5.73 (95% CI: 5.50 to 5.95) for change in functioning and 6.16 (95% CI: 5.95 to 6.37) for change in pain. In TKA intervention patients, these scores were 5.23 (95% CI: 5.00 to 5.45) and 5.45 (95% CI: 5.24 to 5.67), respectively (Table 4). For the TKA control group, these scores were 5.08 (95% CI: 4.85 to 5.31) and 5.46 (95% CI: 5.24 to 5.68), respectively. The THA patients reported satisfaction with the result of treatment after three months: a 7.85 in the intervention group and an 8.36 in the control group. For TKA patients, these scores were 8.25 and 8.14, respectively (Table 2).

Adverse and serious adverse events

The adverse events (AEs) were not actively solicited; only those reported by participating centers or patients were documented. There were no study-related serious adverse events (SAEs) that occurred in either group (Supplementary Table S2).

Discussion

This study assessed the effectiveness of a personalized, treat-to-target postoperative physical therapy (PPT) strategy compared to usual care following total hip arthroplasty (THA) or total knee arthroplasty (TKA). Both THA and TKA patients showed improvements in functional outcomes, quality of life, and pain post-surgery. However, our personalized, treat-to-target PPT intervention did not demonstrate greater benefits in improving these outcomes compared to usual care.

There were two systematic reviews on physical therapy (PT) after THA and TKA in osteoarthritis (OA) patients that reported improvements in physical function, mobility, pain, and quality of life (40, 41). However, direct comparison with our study is challenging, as none of the reviewed interventions employed a treat-to-target including milestones compared to usual care. Furthermore, the Dutch standard of care may differ from other (European) healthcare systems due to its distinct organization and funding structure. The lack of contrast between groups may be partly explained by the fact that, postoperatively, all patients—regardless of allocation—had access to an unlimited number of reimbursed sessions the first year after surgery. This context-specific feature of the healthcare system may limit the generalizability of findings to countries with different insurance structures. However, the first 20 sessions require out-of-pocket payment or additional insurance coverage, which may inadvertently

contribute to disparities in access and outcomes, particularly among patients who have limited financial resources or inadequate supplementary coverage (42, 43).

Contrary to our expectations, THA and TKA patients in the intervention and control groups received a similar number of PT sessions, with no differences in PPT frequency or duration. Several factors may explain the lack of this contrast. Physical therapy (PT) practices have improved, with greater adherence to the Royal Dutch Society for Physiotherapy (KNGF) guidelines and more personalized treatment protocols (9). This is reflected in the observed increase in the use of active exercise therapy and the similarity in PPT content between group observations (12, 15). Hence, the KNGF guidelines generally recommend personalized care approaches and the use of patient-centered tools, such as the Patient-Specific Complaints instrument (PSK), for goal setting and evaluation (5). Additionally, variation in PPT care appears to have decreased compared to previous studies (12, 15).

However, the low response rate of the physical therapists (PTs) in the control group may have introduced selection bias, warranting cautious interpretation of these results. Further improvements in OA care, including better collaboration between orthopaedic surgeons and PTs and a shift toward patient-centered care, likely contributed (40, 41). For instance, slower recovery after arthroplasty has been associated with prolonged PT duration, suggesting that individualized treatment plans are now commonly used (15). The establishment of PT networks with standardized protocols and the introduction of 1.5-line care have further streamlined transitions between primary and secondary care, improving access to specialized services. Another interesting observation is the higher proportion of specialized PTs in the control groups who may bring greater motivation and expertise (44-46). While no specific THA or TKA specialization exists in the Netherlands, specialized PTs may still enhance outcomes. Intervention compliance may have played a role. A random sample showed 79% compliance among intervention PTs, but the small sample size may have led to an over- or underestimation. Another possible explanation for the absence of observed differences is a ceiling effect (47). Commonly used outcome measures in THA and TKA show ceiling effects in 15 to 20% or more of patients, potentially limiting the detection of further functional improvements (48, 49). However, the studies reporting these effects used different primary outcome measures and had longer follow-up periods than ours, which was limited to the first postoperative year. There is one study that indicates the Knee injury and Osteoarthritis Outcome Score - 12 items (KOOS-12) has no ceiling effect one year postoperatively (50). Finally, our study, conducted between August 2018 and June 2021, was affected by the COVID-19 pandemic. During the pandemic, PT practices were closed for extended periods, leading patients to either

forego PPT or participate in remote sessions. Personal contact, a critical aspect of PT, likely enhances rehabilitation outcomes (51). This might have had a larger impact after TKA, as TKA recovery is often more complex than recovery after THA. As such, it may require closer monitoring due to pain, mobility challenges, and the need for muscle strengthening and gait training. These factors make hands-on, in-person therapy particularly important, especially in the early stages (52).

The study used a cluster design with hospital-level randomization, requiring each hospital to enroll a similar number of patients. Enrollment rates varied, with some hospitals completing recruitment before the pandemic, while others continued during it. Consequently, more intervention group patients received PPT during COVID-19, while control group patients were more likely to receive PPT pre-pandemic. We expected that all these challenges would impact the outcomes; however, we found no significant differences in clinical outcomes for patients rehabilitating during the pandemic (51, 53). The COVID-19 pandemic had some impact on study procedures, particularly regarding physical assessments, which could not be conducted in several hospitals. This led to missing data for certain physical outcome measures. Although previous studies suggest that patient engagement was not substantially influenced by the pandemic (51), a potential impact cannot be entirely excluded.
Strengths of the study include its nationwide multicenter design, aligning with the Dutch Orthopaedic Association (NOV) and KNGF knowledge agenda, enhancing collaboration and potential guideline implementation. Also, standard Patient-Reported Outcome Measures (PROMs) for THA and TKA improved data collection response rates.

Potential limitations include timing discrepancies between control and intervention groups due to the COVID-19 pandemic. Contrary to the study protocol, we used an intention-to-treat approach instead of an as-treated approach, which more conservatively reflects real-world conditions. Another potential limitation is the risk of performance bias due to possible disclosure of group allocation. Although control group patients were asked not to inform their PTs, study participation may be unintentionally disclosed. This may have led to differences in care, potentially influencing the study outcomes. Our study sample had a higher proportion of women, a lower average age, and higher baseline scores compared to the Dutch Arthroplasty Register (54), suggesting a more physically fit cohort. Standardizing measurements across sites was challenging, but outcome assessors were trained at each hospital. Also, although this study concerns a cluster randomized controlled trial in the analysis, they were adjusted for pre-specified confounders; residual confounding cannot be ruled out.

Based on our findings, we conclude that the use of milestones within a personalized PT intervention does not provide additional benefits over usual care for patients after THA or TKA. While we do not dispute the potential benefits of using milestones and personalized treatment strategies, it is possible that healthcare practices have evolved to incorporate these approaches more frequently. Future research should establish this. Moreover, future trials could investigate the (cost-) effectiveness of personalized rehabilitation, with particular focus on whether individualized treat-to-target strategies yield differential efficacy across distinct patient subgroups such as the frail elderly.

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Competing interests
The authors declare that they have no competing interests.

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Tables and Figures

Table 1. Baseline characteristics of the total hip and total knee arthroplasty population in a randomized control trial

	THA		**TKA**	
	Intervention group n = 156	Control group n = 156	Intervention group n = 156	Control group n = 156
Sex, women, n (%)	71 (45.51)	94 (60.26)	88 (56.4)	81 (51.9)
Missing	*2 (1.3)*	*0*	*1 (0.6)*	*2 (1.3)*
Age, years (range)	65 (40,83)	68 (43,88)	66 (52,82)	68 (41,88)
Missing	*2*	*0*	*1*	*2*
BMI, kg/m² (range)	26,98 (18.29, 43.49)	27,23 (17.93, 43.95)	29.47 (18.08, 51.27)	29.30 (19.83, 42.86)
Missing	*2*	*0*	*1*	*2*
Living condition, n (%)				
- alone	33 (21.2)	34 (21.8)	25 (16.0)	27 (17.3)
- with partner and/or children	117 (75.0)	120 (76.9)	128 (82.1)	125 (80.1)
Missing	*6 (3.8)*	*2 (1.3)*	*3 (1.9)*	*4 (2.6)*
Education, n (%)				
- low	60 (38.5)	60 (38.5)	74 (47.4)	74 (47.4)
- middle	39 (25.0)	37 (23.7)	51 (32.7)	35 (22.4)
- high	50 (32.1)	52 (33.3)	27 (17.3)	41 (26.3)
- other	1 (0.6)	5 (3.2)	1 (0.6)	2 (1.3)
Missing	*6 (3.8)*	*2 (1.3)*	*3 (2.0)*	*4 (2.6)*
Meeting the WHO guidelines on physical activity, n (%)	54 (34.6)	58 (37.2)	58 (38)	61 (40)
Missing	*6 (3.8)*	*2 (1.3)*	*3*	*4*
Comorbidity, >= one, n (%)	67 (43.0)	68 (43.6)	58 (37.2)	61 (39.1)
Missing	*6 (3.8)*	*2 (1.3)*	*3 (1.9)*	*4 (2.6)*
Surgical approach, n (%)				
- anterior lateral	27 (17.3)	13 (8.3)	-	-
- posterior lateral	47 (30.1)	101 (64.8)		
- direct anterior	80 (51.3)	40 (25.6)		
Missing	*2 (1.3)*	*2 (1.3)*		
HOOS-PS/KOOS-PS score (0 – 100) ‡	40.70 (15.9)	37.05 (16.3)	44.46 (16.5)	43.11 (14.7)
Missing	*5*	*2*	*2*	*3*

OHS/OKS score (0 – 48) † *Missing*	24.99 (8.4) *5*	26.96 (8.1) *3*	26.57 (8.1) *2*	27.11 (8.0) *3*
NRS pain (0 – 10) ‡ **- in rest** *Missing* **- during activity** *Missing*	 5.00 (2.4) *6* 3.70 (3.0) *6*	 4.97 (2.4) *2* 4.10 (3.1) *2*	 4.70 (2.3) *2* 6.71 (1.9) *2*	 4.72 (2.4) *3* 6.66 (2.1) *3*
AAQ score (0 – 100) † *Missing*	75.79 (16.9) *16*	80.33 (16.1) *6*	76.54 (17.2) *12*	78.56 (16.9) *3*
30 seconds chair-stand test, counts *Missing*	9.74 (3.3) *5*	9.98 (3.6) *3*	9.64 (3.0) *11*	9.63 (3.8) *3*
40 meter fast paced walk test, seconds *Missing*	36.40 (12.8) *5*	38.69 (12.8) *4*	36.04 (9.6) *13*	38.94 (12.1) *4*
Stair climb test, seconds *Missing*	18.42 (10.7) *7*	20.70 (13.9) *7*	20.22 (14.1) *7*	24.22 (14.5) *10*

Continuous variables reported with means and standard deviations, discrete variables reported with numbers and percentages excluding missing data. AAQ: Animated Activity Questionnaire; BMI: Body Mass Index; HOOS-PS: Hip disability and Osteoarthritis Outcome Score – Physical function Short form; KOOS-PS: Knee disability and Osteoarthritis Outcome Score – Physical function Short form; OHS: Oxford Hips Score; OKS: Oxford Knees Score; NRS: Numeric Rating Scale; THA: total hip arthroplasty; TKA: total knee arthroplasty. † Higher is better. ‡ Lower is better. Level of education is defined as low (Pre-vocational secondary education), middle (Senior general secondary education, Pre-university education, Secondary vocational education) and high (Higher Vocational and Academic education)

Table 2. characteristics and use of postoperative physical therapy treatment in total hip arthroplasty and total knee arthroplasty patients, reported by physical therapists.

	Intervention THA n = 156	**Control THA n = 156**	**P-values**	**Intervention TKA n = 156**	**Control TKA n = 156**	**P-values**
Years of experience of PT	2.51 (1.4)	3.47 (1.5)	0.01	2.24 (1.4)	3.19 (1.6)	0.01
Missing	28	68		38	84	
PT with specialization, n (%)	40 (25.6)	53 (34.0)	0.01	41 (26.3)	42 (26.9)	0.01
Missing	28 (17.9)	68 (43.6)		38 (24.4)	84 (53.8)	
Location of PT (multiple answers possible) , n (%) ‡						
- at home	56 (35.9)	79 (50.6)	0.02	63 (40.4)	84 (53.8)	0.01
- at practice	97 (62.2)	88 (56.4)	0.16	101 (64.7)	104 (66.7)	0.23
- consultations by telephone	10 (6.4)	4 (2.6)	0.06	8 (5.13)	3 (1.9)	0.70
- consultations by video call	9 (5.8)	2 (1.3)	0.22	3 (1.9)	5 (3.2)	0.65
- *other*	16 (10.3)	9 (5.8)	0.19	22 (14.1)	8 (5.1)	0.01
Missing	13	10		13	15	
Frequency of PPT per week, n (%)						
- < 1 session	30 (19.2)	18 (11.5)	0.92	11 (7.0)	2 (1.3)	0.01
- 1 session	41 (26.3)	31 (19.9)		31 (19.9)	22 (14.1)	
- 2 sessions	55 (35.3)	36 (23.1)		75 (48.1)	45 (28.9)	
- >= 3 sessions	1 (0.6)	1 (0.6)		1 (0.6)	3 (1.9)	
Missing	29 (18.6)	70 (44.9)		38 (24.4)	84 (53.8)	

Duration (weeks) of PPT, n (%)						
- 2 - 4 weeks	12 (7.7)	10 (6.4)	0.19	6 (3.8)	4 (2.6)	0.92
- 5 - 8 weeks	20 (12.8)	16 (10.3)		7 (4.5)	4 (2.6)	
- 9 - 12 weeks	28 (18.0)	27 (17.3)		31 (19.9)	15 (9.6)	
- >= 13 weeks	53 (34.0)	29 (18.6)		72 (46.1)	47 (30.1)	
- other	13 (8.3)	3 (1.9)		2 (1.3)	2 (1.3)	
Missing	*30 (19.2)*	*71 (45.5)*		*38 (24.4)*	*84 (53.8)*	
Total number of treatment sessions	20.21 (19.2)	19.18 (17.2)	0.94	29.5 (19.8)	32.42 (27.5)	0.82
Missing	*30*	*72*		*38*	*85*	
Satisfaction with the result of treatment after 3 months (0 – 10) †‡	7.85 (2.3)	8.36 (1.6)	0.13	8.25 (1.7)	8.14 (1.5)	0.39
Missing	*31*	*32*		*14*	*27*	

Continuous variables reported with means and standard deviations, discrete variables reported with amount and percentages including missing data. PT: Physical Therapy; THA: Total Hip Arthroplasty; TKA: Total Knee Arthroplasty. † Higher is better. ‡ Reported by patients.

Table 3. Outcomes at six weeks, and at three, six, and 12 months in total hip arthroplasty patients over time

	Baseline	3 months	6 months	12 months
HOOS-PS (0-100) ‡				
Intervention	40.45 (38.33 to 42.58)	19.93 (17.80 to 22.06)	15.36 (13.19 to 17.54)	13.38 (11.18 to 15.57)
Control	36.66 (34.40 to 38.91)	18.25 (15.97 to 20.52)	13.33 (11.06 to 15.61)	10.82 (8.54 to 13.10)
Adjusted Difference	3.78 (0.77 to 6.82)*	-2.12 (-5.24 to 1.00)	-1.76 (-4.93 to 1.40)	-1.24 (-4.42 to 1.94)
P-values	0.01	0.18	0.27	0.44
OHS (0-48) †				
Intervention	24.90 (23.78 to 26.02)	39.20 (38.08 to 40.32)	41.94 (40.79 to 43.08)	42.48 (41.33 to 43.64)
Control	27.30 (26.11 to 28.49)	40.93 (39.73 to 42.13)	43.03 (41.83 to 44.23)	44.63 (43.43 to 45.84)
Adjusted Difference	-2.40 (-4.00 to -0.81)*	0.67 (-0.95 to 2.30)	1.31 (-0.34 to 2.96)	0.26 (-1.40 to 1.91)
P-values	<0.01	0.42	0.12	0.76
NRS rest (0-10) ‡				
Intervention	5.04 (4.74 to 5.33)	1.26 (0.96 to 1.56)	0.94 (0.64 to 1.24)	1.13 (0.83 to 1.44)
Control	4.85 (4.54 to 5.16)	0.93 (0.62 to 1.24)	0.69 (0.38 to 1.00)	0.48 (0.17 to 0.78)
Adjusted Difference	0.19 (-0.23 to 0.61)	0.14 (-0.35 to 0.64)	0.13 (-0.37 to 0.63)	0.46 (-0.04 to 0,.6)
P-values	0.38	0.57	0.81	0.07
NRS during activity (0-10) ‡				
Intervention	3,63 (3,27 to 399)	2.12 (1.76 to 2.48)	1.58 (1.21 to 1.95)	1.58 (1.21 to 1.96)
Control	3,97 (3,5.9 to 4.35)	1.67 (1.28 to 2.05)	1.34 (0.95 to 1.72)	0.86 (0.48 to 1,.5)
Adjusted Difference	- 0.34 (-0.86 to 0.17)	0,.9 (0.21 to 1.37)*	0.56 (-0.00 to 1.18)	1.06 (0.47 to 1.65)*

P-values	0.19	<0.01	0.05	<0.01
AAQ score (0 –100)				
Intervention	76.10 (73.88 to 78.33)	88.68 (86.28 to 91.08)	-	91.32 (88.75 to 93.88)
Control	81.91 (79.51 to 84.30)	90.68 (88.09 to 93.27)	-	93.63 (90.97 to 96.28)
Adjusted Difference	-5.80 (-8.93 to -2.68)*	3.80 (0.73 to 6.88)*	-	3.48 (0.25 to 6.73)*
P-values	<0.01	0.02		0.04
30 seconds chair-stand test, counts				
Intervention	9.72 (9.11 to 10.33)	11.89 (11.22 to 12.56)	-	13.54 (12.85 to 14.23)
Control	10.50 (9.83 to 11.17)	12.36 (11.63 to 13.08)	-	13.57 (12.84 to 14.30)
Adjusted Difference	-0.78 (-1.64 to 0.09)	0.31 (-0.55 to 1.17)	-	0.75 (-0.13 to 1.63)
P-values	0.08	0.48		0.09
40 meter fast paced walk test, seconds				
Intervention	37.29 (35.66 to 38.91)	31.77 (29.99 to 33.55)	-	29.61 (27.77 to 31.45)
Control	37.61 (35.82 to 39.40)	33.80 (31.87 to 35.74)	-	30.93 (28.98 to 32.88)
Adjusted Difference	-0.33 (-2.65 to 2.00)	-1.71 (-3.91 to 0.50)	-	-0.99 (-3.27 to 1.28)
P-values	0.78	0.13		0.39
Stair climb test, seconds				
Intervention	19.39 (17.74 to 21.04)	15.02 (13.29 to 16.74)	-	14.55 (12.77 to 16.33)
Control	19.35 (17.53 to 21.18)	16.31 (14.40 to 18.21)	-	14.86 (12.94 to 16.78)
Adjusted Difference	0.03 (-2.34 to 2.41)	-1.32 (-2.97 to 0.33)	-	-0.34 (-2.05 to 1.37)
P-values	0.98	0.12		0.69

Anchor question (0-10) function				
Intervention	-	5.75 (5.54 to 5.99)	-	-
Control	-	5.73 (5.50 to 5.95)	-	-
P-values		0.89		
Anchor question (0-10) pain				
Intervention	-	6.07 (5.88 to 6.26)	-	-
Control	-	6.16 (5.95 to 6.37)	-	-
P-values		0.51		

Data is presented as adjusted means with 95% confidence intervals between parentheses. Adjustments are made for sex, age, BMI, and surgical approach.
* p<0.05 HOOS-PS: Hip disability and Osteoarthritis Outcome Score – Physical function Short form; OHS: Oxford Hip Score; NRS: Numeric Rating Scale. † Higher is better. ‡ Lower is better. Scores of 9 months are not presented because of the many timeframes. The adjusted differences account for baseline imbalances between the intervention and control groups and may therefore differ from the observed differences in estimated group means at each time point.

Table 4. Outcomes at six weeks, and three, six, and 12 months in total knee arthroplasty patients over time

	Baseline	3 months	6 months	12 months
KOOS-PS (0-100) ‡				
Intervention	44.15 (42.08 to 46.21)	31.34 (29.26 to 33.43)	26.20 (24.10 to 28.30)	23.51 (21.37 to 25.66)
Control	42.92 (40.86 to 44.99)	31.09 (28.96 to 33.22)	27.41 (25.24 to 29.59)	25.92 (23.74 to 28.09)
Adjusted Difference	1.22 (-1.69 to 4.14)	-0.96 (-3.88 to 2.00)	-2.44 (-5.40 to 0.53)	-3.63 (-6.62 to -0.63)*
P-values	0.41	0.52	0.11	0.02
OKS (0-48) †				
Intervention	26.78 (25.60 to 27.96)	36.27 (35.08 to 37.46)	39.85 (38.65 to 41.05)	41.55 (40.33 to 42.78)
Control	27.24 (26.05 to 28.42)	36.16 (34.94 to 37.38)	39.16 (37.92 to 40.40)	40.59 (39,.5 to 41.83)
Adjusted Difference	-0.46 (-2.13 to 1.21)	0.57 (-1.03 to 2.18)	1.15 (-0.48 to 2.77)	1.42 (-0.22 to 3.07)
P-values	0.59	0.48	0.17	0.09
NRS Rest (0-10) ‡				
Intervention	4.68 (4.34 to 5.01)	2.37 (2.04 to 2.71)	1.50 (1.16 to 1.85)	1.48 (1.13 to 1.83)
Control	4.68 (4.34 to 5.01)	2.42 (2.08 to 2.77)	1.67 (1.31 to 2.02)	1.59 (1.24 to 1.95)
Adjusted Difference	-0.00 (-0.47 to 0.47)	-0.05 (-0.58 to 0.48)	-0.16 (-0.70 to 0.37)	-0.11 (-0.65 to 0.44)
P-values	1.00	0.86	0.55	0.70
NRS active (0-10) ‡				
Intervention	6.66 (6.31 to 7.02)	3.52 (3.16 to 3.88)	2.41 (2.04 to 2.77)	1.90 (1.53 to 2.28)
Control	6.63 (6.28 to 6.99)	3.44 (3.07 to 3.81)	2.55 (2.17 to 2.93)	2.14 (1.76 to 2.52)

Difference	0.03 (-0.47 to 0.53)	0.05 (-0.50 to 0.60)	-0.18 (-0.73 to 0.38)	-0.27 (-0.83 to 0.29)
P-values	0.90	0.86	0.54	0.35
AAQ score (0 –100)				
Intervention	76.84 (74.51 to 79.17)	83.42 (80.78 to 86.06)	-	91.89 (88.96 to 94.83)
Control	78.76 (76.50 to 81.02)	84.26 (81.73 86.79)	-	90.24 (87.47 to 93.01)
Adjusted Difference	-1.91 (-5.16 to 1.32)	1.08 (-2.78 to 4.93)	-	3.57 (-0.64 to 7.79)
P-values	0.25	0.58		0.10
30 seconds chair-stand test, counts				
Intervention	9.67 (9.12 to 10.22)	10.96 (10.36 to 11.57)	-	12.39 (11.73 to 13.06)
Control	9.70 (9.17 to 10.24)	10.88 (10.29 to 11.47)	-	12.03 (11.40 to 12.66)
Adjusted Difference	-0.03 (-0.80 to 0.74)	0.12 (-0.69 to 0.92)	-	0.40 (-0.49 to 1.28)
P-values	0.93	0.77		0.38
40 meter fast paced walk test, seconds				
Intervention	36.06 (34.69 to 37.73)	33.65 (31.83 to 35.47)	-	29.37 (27.36 to 31.38)
Control	38.55 (36.93 to 40.16)	39.24 (37.46 to 41.02)	-	35.10 (33.32 to 37.00)
Adjusted Difference	-2.49 (-4.81 to -0.16)*	-3.10 (-5.56 to -0.64)*	-	-3.25 (-5.95 to -0.55)*
P-values	0.04	0.01		0.02
Stair climb test, seconds				
Intervention	20.23 (18.40 to 22.06)	19.63 (17.67 to 21.60)	-	15.47 (13.36 to 17.59)
Control	24.02 (22.23 to 25.82)	23.69 (21.78 to 25.61)	-	18.53 (16.51 to 20.54)

Adjusted Difference	-3.79 (-6.35 to -1.23)*	-0.30 (-2.56 to 2.02)	-	0.74 (-1.77 to 3.25)
P-values	<0.01	0.82		0.56
Anchor question (0-10) function				
Intervention	-	5.23 (5.00 to 5.45)	-	-
Control	-	5.08 (4.85 to 5.31)	-	-
P-values		0.38		
Anchor question (0-10) pain				
Intervention	-	5.45 (5.24 to 5.67)	-	-
Control	-	5.46 (5.24 to 5.68)	-	-
P-values		0.98		

Data is presented as adjusted means with 95% confidence intervals between parentheses. Adjustments are made for sex, age and BMI.* $p<0.05$. KOOS-PS: Knee disability and Osteoarthritis Outcome Score – Physical function Short form; OKS: Oxford Knees Score; NRS: Numeric Rating Scale. † Higher is better. ‡ Lower is better. Scores of 9 months are not presented because of the many timeframes. The adjusted differences account for baseline imbalances between the intervention and control groups and may therefore differ from the observed differences in estimated group means at each time point.

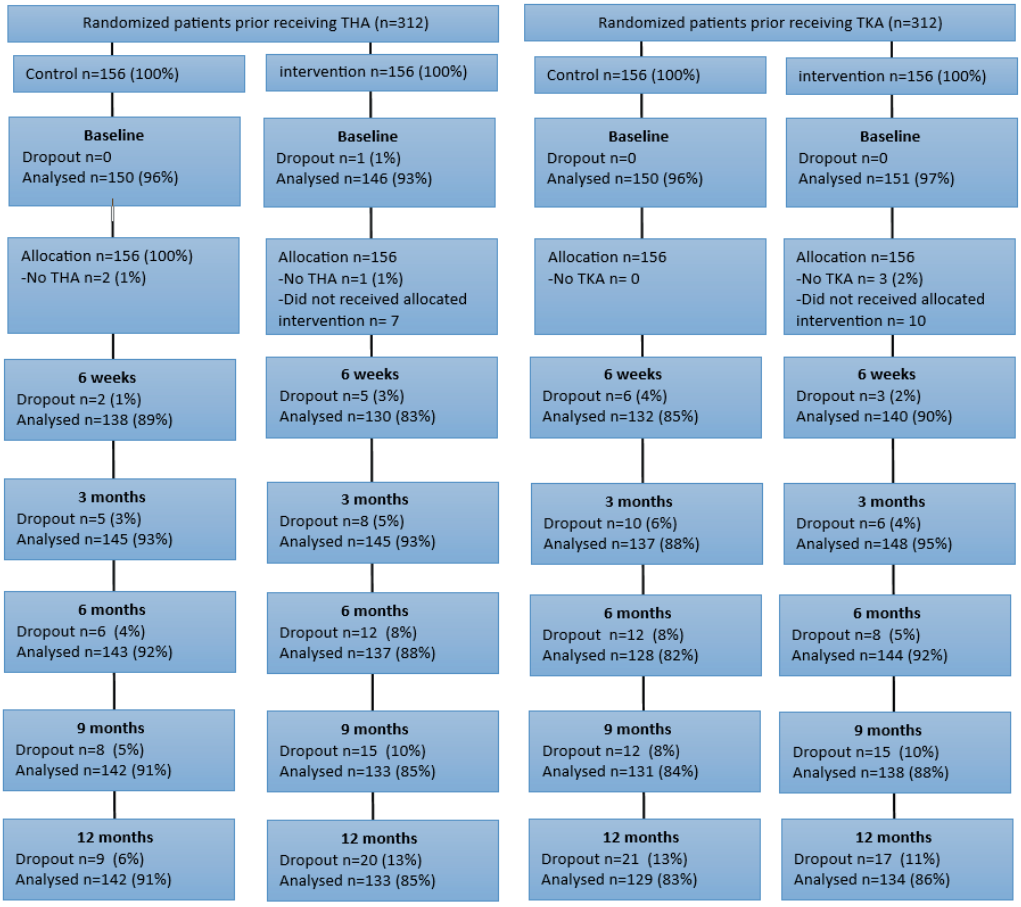


Figure 1: flowchart of participant progression showing allocation, follow-up, and analysis. The figure indicates the number of patients lost to follow-up at each time point, as well as the number of patients included in the analysis at that specific measurement. Together, these numbers do not add up to 100%. The remaining category includes patients who either did not complete a questionnaire at that specific time point or submitted their questionnaire outside the designated time window.

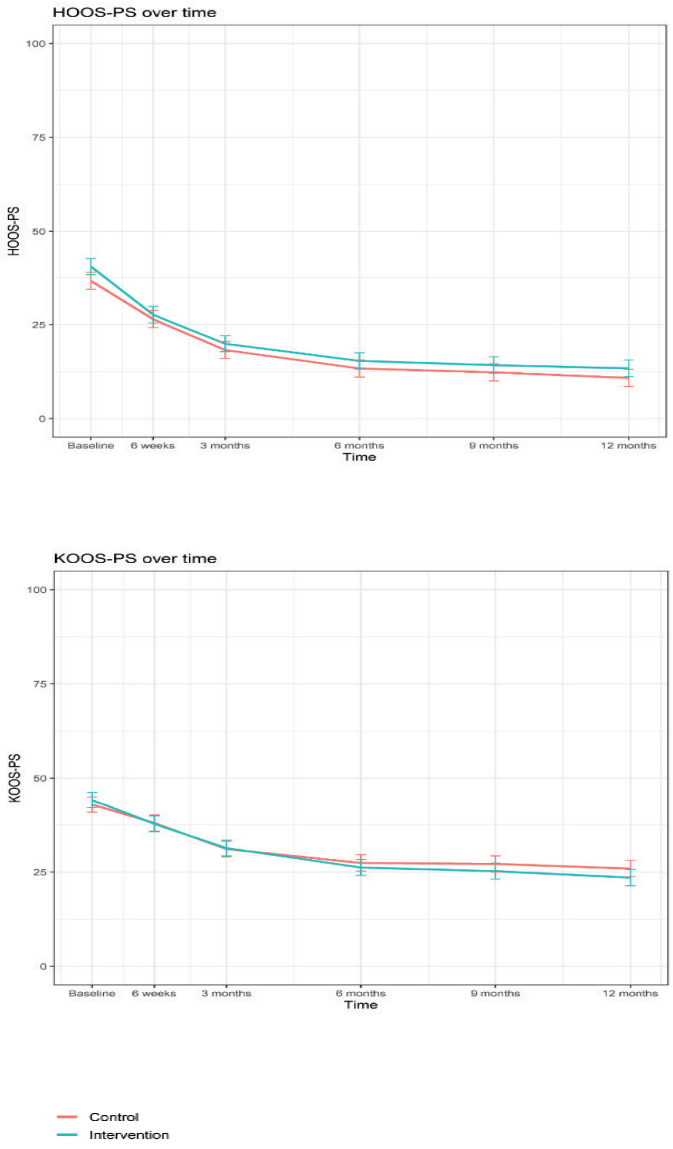


Figure 2: secondary outcomes of adjusted HOOS-PS and KOOS-PS over time. For HOOS-PS adjustments are made for sex, BMI, age, and surgical approach. For KOOS-PS adjustments are made for sex, BMI, and age.

Supplementary table S1.

Content of the postoperative physical therapy asked to physical therapists.

	THA		TKA	
Content	Intervention group (n = 156)	Control group (n = 156)	Intervention group (n = 156)	Control group (n = 156)
Number of responses	138 (88)	92 (59)	131 (84)	80 (51)
Content of therapy, n (%)				
– Passive mobilization	53 (38)	38 (41)	97 (74)	51 (64)
– Active mobilization	104 (75)	73 (79)	118 (90)	67 (84)
– Massage	12 (9)	12 (13)	32 (24)	20 (25)
– Muscle strengthening	109 (79)	75 (82)	112 (85)	71 (89)
– Gait training	108 (78)	80 (87)	106 (81)	65 (81)
– Balance	105 (76)	80 (87)	103 (79)	62 (78)
– Improving aerobic capacity	63 (46)	40 (43)	63 (48)	34 (42)
– Using walking aids	88 (64)	62 (67)	99 (76)	49 (61)
– Homework on paper/digitally	76 (55)	54 (59)	61 (47)	50 (62)
– Homework orally	68 (49)	51 (55)	77 (59)	43 (54)
– Heat therapy	1 (1)	0 (0)	0 (0)	0 (0)
– Ice packs	2 (1)	3 (3)	16 (12)	13 (16)
– Phone apps	1 (1)	1 (1)	10 (8)	0 (0)
– Scar massage	27 (20)	23 (25)	61 (47)	25 (31)
– Fluid in the leg	36 (26)	28 (30)	75 (57)	46 (58)
– Other	17 (12)	4 (4)	10 (8)	2 (2)
Practice with patient, n (%)				
– Walking stairs	97 (70)	66 (72)	95 (73)	60 (75)
– Walking at home	96 (70)	70 (76)	89 (68)	62 (78)
– Walking outside	75 (54)	55 (60)	68 (52)	46 (58)
– Cycling outside	18 (13)	13 (14)	25 (19)	14 (18)
– Cycling on a home trainer	88 (64)	63 (68)	106 (81)	64 (80)
– Standing up and sitting down	96 (70)	71 (77)	97 (74)	64 (80)
– Sports	54 (39)	37 (40)	61 (47)	33 (41)
– Other	12 (9)	2 (2)	3 (2)	2 (2)

All variables are reported with numbers and percentages excluding missing data.
THA: Total Hip Arthroplasty; TKA: Total Knee Arthroplasty.

Supplementary table S2. Serious adverse event during follow-up period in total study population.

	THA		TKA	
	Intervention group	**Control group**	**Intervention group**	**Control group**
Hospitalization (THA or TKA related), n	**5**	**2**	**3**	**10**
Infection prostheses	**5**	**2**	**1**	**3**
- Knee mobilization surgery	**-**	**-**	**2**	**7**
Hospitalization (Not THA or TKA related), n	**5**	**4**	**4**	**3**
Mortality, n	**0**	**1**	**0**	**1**

All THA and TKA SAEs that were reported during follow up are shown irrespective of fulfilment of our SAE definition. Hence none of these seemed to be related to the intervention. THA: Total Hip Arthroplasty; TKA: Total Knee Arthroplasty.

Supplementary S3 Evaluation of treatment compliance of the physical therapists. In a sample of 19 physical therapists the compliance with the personalized treat-to-target PT strategy was evaluated. We assessed 1 THA and 1 TKA patient in each intervention hospital, totaling 20 patients. One of these patients did not receive PT, so we were unable to score the points on the assessment. Compliance was assessed during a video call or physical visit with the physical therapists, in which a trained research assistant assessed the inclusion of key elements by questionnaire based on the patient records of a single patient. The following key elements were assessed and are depicted in the table below:

1. The milestones were evaluated in phase 1 during the first treatment session.
2. Short-term (Phase 2) and long-term milestones (Phase 3) were discussed and documented.
3. The Milestone form was reviewed and filled out during Phase 2.
4. Muscle-strengthening exercises were performed in Phase 2.
5. Functional activities (Phase 2) were part of the treatment.
6. Executed achievable milestones for Phase 2 and satisfied with the execution (Phase 3).
7. Muscle-strengthening exercises were performed in Phase 3.
8. Functional activities (Phase 3) were part of the treatment.

	Presence of Key elements of the treatment							
	1	2	3	4	5	6	7	8
Patient 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 4	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 8	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Patient 9	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 10	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 11	No	Yes	Yes	No	Yes	Yes	Yes	Yes
Patient 12	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 13	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 14	No	Yes	No	Yes	Yes	Yes	Yes	Yes
Patient 15	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 16	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 17	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient 18	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Patient 19	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Chapter 5

Cost utility analysis of a PhysiotherApeutic Treat-to-target Intervention after total hip and knee arthroplasty: a cluster randomized controlled trial, The PaTIO study

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Abstract

Objective: To assess whether a treat-to-target postoperative physical therapy (PPT) strategy is cost-effective compared to usual PPT care in total hip arthroplasty (THA) or total knee arthroplasty (TKA) patients.

Methods: A cost-utility analysis alongside a cluster randomized controlled trial in which 18 hospitals compared treat-to-target versus usual PPT in 624 patients undergoing primary THA or TKA. Assessments of costs included healthcare and productivity as recorded by patients and healthcare providers. Assessments were conducted at baseline, 3, 6, 9 and 12 months after surgery. Quality-adjusted life years (QALYs) were estimated using the EuroQol-5D-5L (EQ-5D) and EuroQol Visual Analogue Scale (EQ-VAS). Analyses followed the intention-to-treat principle using cost-effectiveness acceptability curves from healthcare and societal perspectives.

Results: The 1-year societal costs favored usual care, but were not significantly different from the intervention group, by €1,219 for THA patients (95% CI €-413 to €2852) and €926 for TKA patients (95% CI €-562 to €2,415). QALYs were non-significantly higher in usual care for THA patients by 0.01 (EQ-5D-5L: 95% CI -0.20 to 0.04; EQ-VAS: 95% CI -0.01 to 0.03), with no differences between intervention and control TKA patients (EQ-5D-5L: 95% CI -0.03 to 0.03; EQ-VAS: 95% CI -0.02 to 0.02). For a willingness-to-pay threshold of €50,000 per QALY, there is a less than 50% probability that the intervention is cost- effective compared to usual care.

Conclusion: No differences were found in this economic evaluation between the PPT strategy and usual PPT. The treat-to-target strategy has no beneficial effect compared to standard PPT.

Keywords: Cost-Utility; Economic evaluation; costs; Health-related quality of Life; QALY; Total Hip; Total Knee; Exercise therapy; Physical Therapy

Significance and Innovations

- No differences were found in this economic evaluation between the PPT strategy and usual PPT
- There is a less than 50% probability that the intervention is cost-effective compared to usual care in both THA and TKA patients

Introduction

Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) surgeries have become standard procedures for addressing end stage joint degeneration. In Western countries, approximately 1.66 and 1.26 out of every 1,000 people undergo a THA or TKA each year, respectively(1, 2). Physical therapy plays an important role in the postoperative care of patients undergoing these procedures, aiming to enhance mobility, strength, and overall function (3-7). However, substantial variation have been observed in the delivery of postoperative physiotherapy (PPT) treatment (8-14).

The variability in the delivery of PPT following THA and TKA surgeries is multi-faceted. First, there is considerable variation in both the frequency and duration of PPT. While some individuals may receive a less extensive course of rehabilitation, others undergo more extensive and prolonged interventions. Second, this variability may stem from differences in healthcare provider preferences, institutional protocols, or patient-specific factors. Despite existing national guidelines (3-5) providing a framework for postoperative rehabilitation, a significant proportion of patients opt for more extensive and prolonged physiotherapy (13). Consequently, the costs are higher because physical therapy is funded on a per-session basis.

The utilization of a treat-to-target approach in which milestones are used to target treatment can simplify and facilitate disease management decisions (15, 16) and improve recovery outcome, emphasizing the importance of aligning therapy duration with individual patient needs (13). This approach has demonstrated effectiveness in enhancing clinical outcomes across various chronic conditions, such as rheumatoid arthritis (8, 17, 18). In previous research, we evaluated PPT care following THA and TKA, investigating whether a treat-to-target treatment protocol, including personal milestones is more effective for recovery compared to usual care (19). Despite the expectations, we did not find any differences in recovery after THA or TKA surgery in patients using a treat-to-target protocol and patients receiving usual care. However, evaluating the cost-effectiveness of this intervention is still important because from healthcare system and societal perspective, it is highly relevant that the most cost-effective PPT treatment strategy is used.

Here we will present the economic evaluation of the PhysiotherApeutic Treat-to-target Intervention after Orthopaedic surgery (PaTIO) study, estimating cost effectiveness of a personalized, treat-to-target PPT strategy compared with usual care in patients after primary THA or TKA surgery.

Methods

This cost-effectiveness analysis (CEA) is a part of a cluster randomised controlled trial (RCT) that has been described in more detail elsewhere (19, 20). Briefly, the PhysiotherApeutic Treat-to-target Intervention after Orthopaedic surgery (PaTIO) study is an open labelled, multicenter, cluster randomized controlled trial. Patients were recruited between August 2018 and June 2021 from 18 hospitals (4 university- and 14 non-university hospitals) in the Netherlands. Within the study, randomization took place at hospital level as they acted as the clusters. The study was registered in the Dutch Trial Registry (registration number NTR7129 / NL-OMON55756) prior to the inclusion of the first participant. In all participating hospitals, the local responsible authorities approved the conduct of the study. This trial is reported according to the CONSORT 2010 checklist for cluster randomized controlled trials (21).

Study population

Inclusion criteria were: patients with clinical and radiological hip or knee osteoarthritis (OA) who were scheduled for a primary THA or TKA; willing to comply with the study protocol and providing written informed consent. Exclusion criteria were: patients with a THA or TKA for a diagnosis other than OA; uncontrolled cardiovascular disease or hypertension; history of neuromuscular disorder that affects lower extremity function; terminal illness; planned replacement of another joint during study follow-up; not able to attend follow-up measurements; not able to attend the PPT in primary setting; serious psychiatric disorders; insufficient command of the Dutch language, spoken and/or written.

Intervention

In the intervention group, the necessity of primary care PPT was assessed by a specifically trained physical therapist using a standardized assessment of the patient's health status, personal-, external factors and achievement of functional milestones. If PPT was needed, patients received a personalized program in which their functional progress was regularly evaluated in relation to the achievement of their functional milestones. Physical therapy was ended after achieving the personal milestones. In our control group, patients received usual care, in which the use of physical therapy and the choice of the physical therapist was left to the discretion of the treating physician and the patient.

Assessments

At baseline the following patient and surgical characteristics were obtained by means of a questionnaire: sex, age, height, weight, surgical date, THA or TKA, which side operated, and surgical approach in THA patients. Physical functioning was measured by the 5-item short version of the validated Dutch translation of the Hip disability and Osteoarthritis Outcome Score (HOOS-PS) (22) or the 7-item short version of the Dutch translation of the Knee injury and Osteoarthritis Outcome Score (KOOS-PS) questionnaire (23, 24). For both the HOOS-PS and the KOOS-PS the scores range from 0 (severe impairments) to 100 (no impairments). Self-reported pain and functional limitations in daily activities were assessed by the Oxford Hip and Knee scores (OHS and OKS)(25, 26) (0 = worse functional outcomes; 48 = best functional outcome). The HOOS-PS, KOOS-PS and OHS and OKS were administered at multiple time points within the RCT, but only baseline values are used in this economic evaluation to characterize patients' QA severity.

Healthcare and productivity costs

Costs were estimated from a societal perspective, encompassing visits to healthcare providers and the utilization of prescribed or over-the-counter medications, along with absence from work. These were reported by patients through a structured questionnaire administered at 3, 6, 9, and 12 months after surgery. The questionnaire employed for this assessment is adapted from the instrument utilized in the evaluation of Costs associated with Psychiatric Illness (TiC-P) by the Institute of Medical Technology Assessment (27) including both medical consumption and productivity costs. In this adaptation, we have left out the presumed irrelevant questions about psychiatric consultations. We added specific questions about physical therapy consultation (frequency) and pain medication. Societal costs included healthcare costs, patient and family costs, and productivity costs. These questionnaires also included general practitioner visits, outpatient visits, hospital days for hospitalization other than hospitalization for primary THA or TKA surgery, medication, home and informal care, patient costs, absence from work, and productivity while at (unpaid) work. The timing, contents, frequency, and duration of PPT were measured using the study questionnaires provided to the physical therapist. In analysing the number of consultations with the general practitioner and physiotherapist, we also distinguished whether these appointments were related to their THA or TKA, or for another issue. This allowed to differentiate the costs associated with postoperative THA/TKA care from other healthcare expenses. Healthcare and productivity were valued in accordance with the Guideline for economic evaluations in healthcare (28), using reference prices obtained from the Dutch guidelines for economic evaluations in healthcare. Costs are reported in Euros, at price level 2023.

Quality of life and QALYs

Health-related quality of life was assessed using the five-level EuroQol questionnaire (EQ-5D-5L)(29).This questionnaire was assessed at baseline, 6 weeks, 3, 6, 9 and 12 months after surgery. The EQ-5D-5L questionnaire has 5 dimensions on which patients can self-rate their severity of problems on a 5-point scale ranging from no problems to extreme problems or unable to perform the task. Using the Dutch National Value set an utility index score was calculated (-0.329 = poorest health; 1.0 = perfect health) (30). The EuroQol Visual Analogue Scale (VAS) asks patients to rate their current health status on a scale ranging from 0 to 100, indicating worst and best health, respectively. The obtained VAS values were transformed into an utility score using the power function EQ-VAS = 1–(1–(VAS/100))$^{1.61}$ (31). One-year quality-adjusted life years (QALYs) were estimated by the area-under-the curve of the EQ-5D and EQ-VAS utility scores. One-year QALYs are a commonly used measure to inform healthcare resource allocation decisions (32) and were calculated by the area under the curve of each of the utility measures over the follow-up period.

Analysis

The economic evaluation consisted of a cost-utility analysis from a societal perspective (costs per QALY), based on patient reports and with an undiscounted one-year time horizon. All analyses were performed separately for THA and TKA patients and according to the intention-to-treat principle to reflect daily practice. Multiple imputation with 100 imputed data sets was used to account for missing data and to preserve power and possibly reduce bias (33). Randomization was used as an independent variable in the imputation model. Cost-effectiveness acceptability curves were constructed to show the probability that the longstanding exercise therapy was cost-effective compared to usual care, depending on the societal willingness-to-pay (WTP) for an additional QALY. These curves were calculated as the one-sided p-value for the differences in NetBenefit = WTP X QALY - Costs between the patients in the intervention and the usual care group (34). In the Netherlands, accepted WTP levels range from 20,000 to 50,000 or 80,000 Euros per QALY, depending on the severity of the condition (35). For the current patient population, we considered the intermediate 50,000 Euros per QALY as most appropriate. Sensitivity analyses were performed on the cost perspective (healthcare instead of societal perspective), the valuation of productivity (human capital instead of friction cost approach) and the utility measure used to calculate QALYs (EQ-VAS instead of EQ-5D).

Results

Study population

The baseline (preoperative) characteristics of the patients are depicted in Table 1. In total, 312 THA patients and 312 TKA patients were included in the study. Over the course of the one-year follow-up, 7 (4%) THA patients in the intervention group and 19 (12%) patients in the control group were lost to follow up. In TKA patients, 21 patients (13%) and 14 patients (9%) were also lost to follow up respectively. Regarding the EQ-5D-5L questionnaire in THA patients, missing data were 2.9% at baseline, 11.8% at 6 weeks, and 5.4%, 9.6%, 11.8%, and 10.9% at 3, 6, 9, and 12 months, respectively. In TKA patients, missing data was 6.1% at baseline, 10.9% at 6 weeks and 8.0%, 12.2%, 13.1%, and 15.5% at 3, 6, 9, and 12 months, respectively. Regarding the cost questionnaires, the missing data was 10.9% at 3 months follow- up, 12.8% at 6 months follow- up, 13.4% at 9 months follow- up and 14.1% at 12 months in THA patients. In TKA patients, missing data was 12.5%, 15.4%, 15.1% and 18.9% at 3, 6, 9, and 12 months, respectively. All missing data was imputed.

Healthcare and societal costs

Tables 2 and 3 show the costs over 12 months in the intervention and control groups for THA and TKA, respectively.

Regarding the use of physical therapy, the mean number of hip-related visits to the physical therapist after THA was 19 in both the intervention and control groups (mean difference 2 Euros (95% CI: -195 to 199). For TKA patients, the mean number of knee-related visits to the physical therapist after surgery was 29 in both the intervention and control groups. Hence costs for knee-related physical therapy treatment were similar in both groups (mean difference 7 Euros (95% CI: -279 to 293).

In the THA group, the average total healthcare costs per patient were significantly higher in the intervention group than in the control group (3334 versus 2294 Euros, mean difference 1041 Euros (95% CI: 30 to 2051). This difference is mainly due to more and longer hospitalizations for any reason in the intervention group. With regard to the proportion of hospitalized patients in the follow up period after THA or TKA surgery, we found that in the THA intervention group 20.7% (29 out of 156) of the patients reported hospitalization compared to 13.8% (20 out of 156) in the control group (p=0.13). Moreover, one patient in the intervention group was hospitalized twice due to a THA infection and stayed in the hospital for 82 days. Overall, the average hospital stay for hospitalization in the intervention group is about twice as long as in the control group (2.9

versus 1.3 days, p=0.04). With regard to the occupational physician, more visits took place in the control group of the THA patients, resulting in a statistically significant but small mean difference of –41 Euros between the groups (95% CI: -179 to 96). In patients with a TKA, no differences in the separate healthcare categories or in the total healthcare costs were found between the intervention and control groups (2397 versus 2424 Euros, mean difference -27 Euros (95% CI: -565 to 511).

Concerning the productivity and total societal costs, for both THA and TKA patients, no significant differences were found (Table 2 and 3). The total societal cost in THA patients are 5477 Euros in the intervention group and 4258 in the control group, with a mean difference of 1219 Euros (95% CI -413 to 2852). In TKA patients these total societal costs are 5456 Euros versus 4530 Euros, respectively with a mean difference of 926 Euros (95% CI-562 to 2415).

QALYs

Regarding both THA and TKA patients' valuation of their quality of life (QoL) over time, no differences between the intervention and the control groups are found in the QALYs assessed by the EQ-5D and the EQ-VAS (supplemental table 1).

Cost-effectiveness acceptability curves

Due to the small differences in QALYs, the incremental cost-effectiveness ratios (ICERs) are high: €108,000 and €375,000 per QALY, respectively. In some sensitivity analyses, the ICER is negative and the ICERs confidence intervals are unbounded. Therefore, cost-effectiveness acceptability curves (CEACs) provide a clearer interpretation of the results. The CEAC from societal perspective is shown by the black curve in figures 1 and 2 for both THA and TKA patients. The figures show that, for both THA and TKA patients, there is a less than 50% probability that the intervention is cost- effective compared to usual care. Especially for low willingness to pay per QALY, the intervention is unlikely to be cost-effective, since the costs were more favorable in the control group. For higher willingness to pay, the probabilities are more fifty-fifty, as the differences in QALYs were small.

Sensitivity analysis

Sensitivity analysis with 3 different perspectives (Healthcare perspective, Human capital approach, VAS-based QALY's) were performed in both THA and TKA patients (figure 3). The sensitivity analyses do not show a different outcome, indicating a 19% to 58% probability that the PaTIO intervention is cost-effective in both THA and TKA patients. All probabilities are mainly below 50% except for the sensitivity analysis with healthcare perspective in TKA patients, in which the probabilities were above 50%. This pattern remains the same in relation to the base analysis.

Discussion

This study presented an economic evaluation of a personalized, treat-to-target PPT strategy compared with usual care for patients undergoing THA or TKA surgery. Overall, in both the intervention and control group, THA and TKA patients improved in QoL after surgery. The personalized, treat-to-target PPT intervention was not likely to be cost-effective compared to usual care.

Findings of previous systematic reviews on (cost-) effectiveness in physical therapy after THA or TKA conclude that physical therapy is clinically effective and, in some cases, also cost-effective in THA patients (36, 37). However, these reviews only included two studies on cost-effectiveness of physical therapy interventions in which accelerated physical therapy was compared with standard physiotherapy and in-patient physical therapy with out-patient physical therapy. They found that a short PPT program after THA was associated with cost savings and an additional 0.13 QALY (36). This seems logical because patients followed an accelerated process and received less care in a shorter time period. Our study did not employ an accelerated program; instead, it focused specifically on the individual needs of each patient, using personalized milestones. This is a different intervention and difficult to compare with a study that focused on an accelerated program. In TKA patients, no studies on physical therapy after TKA were found to be cost-effective (37). Due to the limited number of studies in this review and the difference in nature of the interventions, direct comparison with our trial is not possible. It is important to note that the cost-effectiveness of the interventions was influenced by factors such as the healthcare system in different countries, duration of interventions, patient compliance, and price per session of physical therapy. No studies from the Netherlands were included in both reviews, complicating the comparison of our study's findings with those presented. In the Netherlands, we have a different healthcare reimbursement system compared to other European countries. In the Netherlands, physiotherapy is reimbursed in a standardized manner. Each treatment session is paid for individually at a fixed rate, regardless of the condition being treated, and all sessions have the same duration. Whether a Patient is (partially) reimbursement for this depends on the specific health insurance package they have.

In our trial, we expected the intervention group to have fewer physical therapy sessions than the usual care group. However, both THA and TKA patients had a similar number of treatment sessions, weekly frequency, and overall duration in both groups (19). The lack of contrast in PPT treatment strategies between the groups in

our trial may explain the observation that the treat-to-target PPT intervention was not cost-effective compared to usual care. Changes in physical therapy practices in usual PPT, such as more adherence to the national physical therapy guidelines and more personalized protocols, might also explain the similarity (10, 13). The increase in active exercise therapy and standardized physical therapy treatments in our study supports these changes in physical therapy practices.

The analysis revealed nuanced findings regarding the costs associated with the intervention. While there were no significant differences in productivity and total societal costs between intervention and control groups, disparities emerged in healthcare costs, particularly for THA patients. The intervention group incurred significantly higher total healthcare costs, primarily driven by increased hospitalizations, compared to the control group. These higher costs are attributed to a single patient who had an exceptionally long hospital stay during the follow-up period. No significant differences were observed in patients' quality of life over time, as assessed by Quality-adjusted life years (QALYs) calculated from the EQ-5D and Visual Analog Scale (EQ-VAS). Previously research reported that readmission rates for THA are approximately 5-10% within 30 days post-surgery (38). The reasons for these readmissions include infections, dislocations, and other complications such as thromboembolic events and wound issues. These numbers are comparable with our study in which 10% of the THA patients were readmitted within 3 months after surgery. This 10% includes also other reasons than THA surgery related issues. This supports that, apart from the elevated costs associated with a single THA patient, no other significant differences exist between our groups.

The COVID-19 pandemic may have played a role in the lack of differences between our groups. Our study was conducted between August 2018 and June 2021 and therefore influenced by the COVID-19 pandemic. Throughout the pandemic less surgeries were performed and physical therapy facilities experienced prolonged closures, prompting patients to either forego physical therapy entirely or engage in remote sessions facilitated via video communication platforms. The aspect of personal interaction in physical therapy holds the potential to optimize patient rehabilitation outcomes more effectively (39). Additionally, our study employed a cluster randomized design, wherein randomization was executed at the hospital level, with each hospital aiming to enroll a comparable number of patients. However, the rate of patient inclusion varied among hospitals, resulting in some completing enrollment prior to the onset of the pandemic, while others did not. Notably, a greater proportion of patients in the intervention group received physical therapy during the COVID-19 period compared to the control group, where more patients had received physical

therapy prior to the pandemic outbreak. Despite these discrepancies, our prior findings indicate no substantial disparities in outcomes among patients undergoing rehabilitation amidst the COVID-19 period (39, 40).

A strength of our study is its nationwide multicenter design, ensuring a representative study population. Moreover, our study aligns with the national research agenda of the Orthopedic (NOV) and Physical Therapy (KNGF) associations resulting in good collaboration and potential integration of the intervention into both organizations' guidelines. Secondly, we aimed to increase the response rate of data collection resulting in a low number of missing questionnaires and did not need to impute much data. A limitation of a large nationwide multicenter study is the standardization of measurements and the difficulty to monitor the intervention. To address this, we provided comprehensive training to all assessors in each hospital. The results of this study are context-dependent, as we have a specific healthcare system in the Netherlands with a complex structure for financial reimbursement of physical therapy. What is cost-effective in one country or healthcare system may not necessarily be cost-effective in another country or system. This makes it difficult to compare the results with studies from other countries.

Conclusion

Our economic evaluation shows no differences between the PPT strategy and usual PPT. There is a less than 50% probability that the intervention is cost-effective compared to usual care in both THA and TKA patients. Especially for low willingness to pay per QALY the intervention is unlikely to be cost-effective, since the costs were more favorable in the control group. The treat-to-target strategy has no beneficial effect compared to standard PPT.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1. Baseline (preoperative) characteristics of patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA)

	THA		**TKA**	
	Intervention (n=156)	Control (n=156)	Intervention (n=156)	**Control (n=156)**
Sex, female, n (%)	72 (46)	94 (60)	88 (56)	**82 (53)**
Age, years	65 (9.2)	68 (8.4)	66 (7.4)	**68 (8.9)**
BMI, kg/m²	27 (4.5)	27 (4.5)	29 (5.0)	**29 (4.9)**
HOOS-PS / KOOS-PS score (0 – 100) ‡	41 (16.0)	37 (16)	44.5 (16.5)	**43 (15.0)**
OHS/OKS score (0 – 48) †	25 (8.4)	27 (8.1)	27 (8.0)	**27 (8.0)**
Paid employment, yes, n (%)	**55 (35)**	**38 (24)**	**49 (31)**	**37 (24)**

HOOS-PS= Hip disability and Osteoarthritis Outcome Score- Physical function Short form; KOOS-PS= Knee injury and Osteoarthritis Outcome Score-Physical function Short form; OHS=Oxford Hips Score; OKS= Oxford Knee Score; THA=total hip arthroplasty; TKA= total knee arthroplasty.
† Higher is better. ‡ Lower is better. Data is presented as mean with standard deviation between parentheses unless otherwise stated.

Table 2. Costs over 12 months following surgery in THA patients

	Intervention (n=156)		**Control (n=156)**		**Difference in costs between groups**	
	Mean numbers	Mean costs (€)	Mean numbers	Mean costs (€)	Mean costs (95% CI, €)	**P-value**
Visits physical therapist						
- for hip	19.4	781	19.3	779	2 (-195 to 199)	**0.9**
- other indications	21.7	877	22.0	887	-10 (-220 to 199)	**0.9**
Visits general practitioner						
- for hip	0.6	23	0.7	26	-3 (-18 to 11)	**0.6**
- other indications	3.1	125	3.4	135	-10 (-45 to 23)	**0.5**
Visits occupational physician	0.8	82	1.3	123	-41 (-179 to 96)	**0.001**
Outpatient care visits	4.5	504	3.4	374	130 (-34 to 294)	**0.1**
Hospitalization (days)	2.9	1713	1.3	753	960 (66 to 1855)	**0.04**
Pain medication	-	34	-	21	13 (-3 to 30)	**0.1**
Total healthcare costs	-	**3334**	-	**2293**	**1041 (30 to 2051)**	**0.04**
Absenteeism (hours)	50.5	2143	46.3	1965	178 (-1051 to 1405)	**0.8**
Total societal costs	-	**5477**	-	**4258**	**1219 (-413 to 2852)**	**0.1**

95% CI ; 95% confidence interval; THA=Total Hip Arthroplasty

Table 3. Costs over 12 months following surgery in TKA patients

	Intervention (n=156)		**Control (n=156)**		**Difference in costs between groups**	
	Mean numbers	Mean costs (€)	Mean numbers	Mean costs (€)	Mean costs (95% CI, €)	**P-value**
Visits physical therapist						
- for knee	30.2	1217	30.0	1210	7 (-279 to 293)	**1.0**
- other indications	28.8	1161	29.0	1169	-8 (-287 to 271)	**1.0**
Visits general practitioner						
- for knee	4.5	181	4.0	161	-21 (-38 to 79)	**0.5**
- other indications	1.0	40	1.3	51	-11 (-34 to 13)	**0.4**
Visits occupational physician	0.6	63	0.6	59	4 (-31 to 39)	**0.8**
Outpatient care visits	4.2	463	4.5	500	-37 (-182 to 109)	**0.6**
Hospitalization (days)	0.8	442	0.8	467	-26 (-389 to 338)	**0.9**
Pain medication	-	31	-	27	4 (-5 to 12)	**0.4**
Total healthcare costs	**-**	**2397**	**-**	**2424**	**-27 (-565 to 511)**	**0.9**
Absenteeism (hours)	72.1	3059	49.6	2106	953 (-380 to 2286)	**0.2**
Total societal costs	**-**	**5456**	**-**	**4530**	**926 (-562 to 2415)**	**0.2**

95% CI ; 95% confidence interval; TKA= Total Knee Arthroplasty

Chapter 6

Validity and responsiveness of the Animated Activity Questionnaire for assessing activity limitations in patients after total hip or total knee replacement

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Abstract

Objective*:* The Animated Activity Questionnaire (AAQ) was developed to better understand how patients with hip or knee osteoarthritis (OA) perform Activities of Daily Living (ADL). However, it is unclear whether the AAQ is suitable for monitoring recovery in patients who underwent total hip or knee arthroplasty (THA or TKA). This study aimed to assess the construct validity and responsiveness of the AAQ in THA/TKA patients.

Methods*:* A selection of 584 participants in a nationwide, cluster randomized controlled trial completed the AAQ at baseline and a subgroup completed the AAQ also 3 and/or 12 months postoperatively. To assess construct validity, correlations between the baseline AAQ, three performance-based tests and two questionnaires as comparators were computed. Construct validity was assessed by means of testing hypotheses about expected correlations between the AAQ and the comparators. Responsiveness was assessed by means of testing hypotheses about expected correlations between change in AAQ and change in the scores of the comparators. We considered the AAQ as valid and responsive for THA and TKA separately if at least 75% of the results were in accordance with the hypotheses.

Results: 100% of our construct validity hypotheses were met. 70% of the hypotheses in the responsiveness analyses were met in THA and 75% in TKA patients at 3- and 12 months follow-up.

Conclusion: Based on our results, the AAQ can assess physical function accurately in THA and TKA patients. For TKA patients we found sufficient responsiveness, however, for THA patients responsiveness of the AAQ was limited.

Significance and Innovations

- The AAQ met 100% of predefined hypotheses for construct validity in both THA and TKA patients, demonstrating it is a valid tool for assessing physical function in these populations.
- The AAQ could be particularly valuable in remote or virtual care settings (e.g., phone or video consultations), offering clinicians a way to assess physical function without in-person performance-based tests.
- The AAQ offers the ability to obtain an understanding of how a patient performs specific activities, an aspect that cannot be captured by using PROMS.

Introduction

Over 2.2 million patients undergo total hip arthroplasty (THA) or total knee arthroplasty (TKA) each year in western countries and this number is still rising (1). Health outcome measurements from both the clinician's and patient's point of view are important for both patients and orthopaedic surgeons to evaluate the effect of these procedures on limitations in physical function (2). Performance-based tests and functional joint range of motion (ROM) can be deployed, or patient reported outcome measures (PROMs) can be administered to capture the patient's point of view. Performance-based tests are recommended by the Osteoarthritis Research Society International (OARSI) (3, 4). The international consortium for health outcome measurements (ICHOM) (2) suggests a set of PROMs to assess different health outcomes in osteoarthritis (OA) patients. A combination of both methods are preferred to assess different aspects of physical function.

Both performance-based tests and PROMs for the assessment of physical function after THA and TKA have limitations. PROMs will not always be (completely) filled in by the patient (5-7). Performance-based tests are usually performed in a clinical setting, are time-consuming and not always executable. In addition, they only focus a small aspect of physical function, e.g., the time needed to complete a test or the number of repetitions or distance covered within a particular timeframe. Both methods, however do not measure how patients actually perform activities of daily living (ADL) in their normal life. To gain more insight into how patients with hip or knee OA actually perform ADL tasks the Animated Activity Questionnaire (AAQ) was developed (8). It measures a construct that is closely related to physical function measured by PROMs, but also shows good correlation with performance-based tests in OA patients (8-11). By means of animations of an avatar the AAQ displays several ADL tasks in 3-5 different levels of difficulty. Patients select the animation that best matches their performance of the activity in the past week (https://animated activityquestionnaire.com)

To apply such a new measurement tool to measure the effectiveness of THA and TKA, its psychometric properties should be assessed. Previous studies have shown sufficient validity and reliability of the AAQ in patients with OA (8-12). Another study of Peter et al. found sufficient responsiveness at 6 months follow-up in patients with OA, but not at 3 months follow-up, which is an important time point in rehabilitation after THA and TKA (13). The included patients received however, different treatment modalities in different settings. Some patients underwent surgical treatment and

others conservative treatment in primary or secondary care. These variations might have influenced the responsiveness of the AAQ, for instance due to different levels of pain and function at the stage of (post-surgical) rehabilitation. As such the authors concluded that it could not be determined whether the AAQ is more or less responsive in certain subgroups or settings. Also, the study of Peter et al. included 94 hip and knee OA patients, which is slightly under the preferred 100 patients in responsiveness studies (14, 15). Only 48 patients of these 94 patients underwent THA or TKA (13). The results of these 48 patients were not given separately from the total group.

At this point it is not yet clear if the AAQ is valid and responsive in THA and TKA patients because the validity and responsiveness of the AAQ were not assessed in this specific group of patients. Therefore, the aim of the current study was to evaluate the construct validity of the AAQ in patients with OA who are planned to undergo THA or TKA and to determine responsiveness of the AAQ in patients who underwent THA or TKA, 3 and 12 months after surgery.

Methods

Study design and ethics

Participants of this study were selected from the PhysiotherApeutic Treat-to-target Intervention after Orthopaedic surgery study (PATIO) (Trial ID NTR7129), which is a nationwide, cluster randomized controlled trial designed to evaluate the (cost-) effectiveness of a standardized, treat-to-target postoperative physical therapy (PT) strategy in TKA and THA patients compared to usual postoperative PT (16). Patients were included between August 2017 until September 2020 from 18 participating hospitals; Alrijne hospital (Leiderdorp), Bergman Clinics (Rijswijk), Canisius Wilhelmina hospital (Nijmegen), Diakonessenhuis (Utrecht), Elisabeth-Tweesteden hospital (Tilburg), Erasmus MC University Medical Center (Rotterdam), HAGA hospital (Den Haag), hospital Gelderse Vallei (Ede), Leiden University MC (Leiden), Máxima MC (Eindhoven), Frisius MC Leeuwarden, Northwest Clinics (Alkmaar), OLVG (Amsterdam), Spaarne hospital (Hoofddorp), Tergooi hospital (Hilversum), University MC Groningen, University MC Maastricht and Zuyderland MC (Sittard). Ethical approval was obtained from the Medical Ethics Committee of Erasmus Medical Center (registration number NL61763.078.17). All participants signed an informed consent form prior to start of the study in accordance with the Handbook for Good Clinical Research Practice of the World Health Organization and Declaration of Helsinki principles (17).

Study population

The inclusion criteria for the PATIO study were: patients with clinical and radiological knee or hip OA who were scheduled for a primary TKA or THA, and willing to comply with the study protocol and providing written informed consent. The exclusion criteria were: patients with a TKA or THA for a diagnosis other than OA; uncontrolled cardiovascular disease or hypertension; a history of neuromuscular disorder that affects lower extremity function; a terminal illness; a planned replacement of another joint during study follow-up; not able to attend follow-up measurements; not able to attend postoperative physical therapy in primary care setting; serious psychiatric disorders, and insufficient command of the Dutch language, spoken and/or written (16).

The present study on the AAQ included patients who met the inclusion criteria for the PATIO study, underwent THA or TKA and completed at least one of the assessments at baseline and the follow-up periods of 3 and/or 12 months. Patients in this study were included if they received surgery between 01-09-2018 and 05-12-2020.

Assessments

Assessments comprised paper or electronic questionnaires and performance-based tests that were administered preoperatively, and 3 and 12 months after THA or TKA. The AAQ was administered electronically during the appointment of the performance-based test.

Demographics

The following sociodemographic information were collected at baseline by questionnaire: age, sex, length and weight to compute the body mass index (BMI), treated joint (hip or knee) and existing comorbidities. Self-reported comorbidities (diabetics, brain trauma, cardiac arrest, heart condition, cancer, hypertension, arteriosclerosis, chronic obstructive pulmonary disease, dizziness, bowel disorders, arthrosis, arm and/or hand condition) were gathered with a questionnaire developed by the Dutch Central Bureau of Statistics (CBS) (18), in which the presence of comorbidities in the previous year was determined (yes/no)

Animated activity questionnaire

The AAQ is an online, self-reported, animated questionnaire containing 17 items of single ADL tasks to measure how a patient performs daily activities. Each item simultaneously shows 3–5 animations of an avatar performing an ADL task. The 3–5 videos showing different levels of difficulty and a response option "unable to perform". Patients select the animation that best matches their performance of the task in the past week. These levels of difficulty were scored from 1 to 4, or 5, or 6 and converted into normalized scores ranging from 0 to 100. Higher scores indicated a higher level of functioning. Development

and initial validation of the AAQ is described in detail in earlier publications (8, 12). The AAQ is currently available in eleven languages at https://animatedactivityquestionnaire.com.

Performance-based tests

The following performance-based tests were done, based on the set recommended by the OARSI (3): the 30 seconds "Chair-Stand Test", "40 meter (m) (4x10m) Fast Paced Walk Test", and "Stair Climb Test" (3, 19). These tests were performed in each hospital by assessors who were trained in using a Dutch translated OARSI protocol. Walking aids were only allowed when participants were unable to perform a test without them.

During the 30 seconds Chair Stands Test (CST), the patient performed the maximum number of chair stand repetitions possible without support of the hands in a 30 second period (3, 20). The 40 m Fast Paced Walk Test (FPWT) is a test of walking speed over short distances and changing direction during walking. Time of the whole 40m (132ft) was recorded (3).

Lastly, the Stair Climb Test (SCT) is a test of ascending and descending stair activity including lower body strength and balance. The time (in seconds) it takes to ascend and descend a 9-12 steps stair was recorded (3). The stairs in the hospitals differed in the number of stairs. Therefore, we defined the scores of a 10-step stairs as valid scores, as a 10-step stair was most frequently used.

Self-reported Physical function

The Hip disability or Knee injury and Osteoarthritis Outcome Score

To assess self-reported hip- and knee- related physical functional status the 5-item short version of the validated Dutch translation of the Hip disability and Osteoarthritis Outcome Score (HOOS-PS) (21) and the 7-item short version of the Knee injury and Osteoarthritis Outcome Score (KOOS-PS) questionnaire (22, 23) were used. Physical function status was determined on a scale from 0 (severe impairments in function) to 100 (no impairments in function).

Oxford Hip score / Oxford Knee Score

Functional limitations in several daily activities and pain intensity were assessed by the Oxford Hip score (OHS) (24) and the Oxford Knee Score (OKS) (25). Both consist of 12 questions; each question were scored from 0 to 4 with 4 being the best outcome. Sum scores ranges from 0 to 48, with 48 being the best functional outcome.

Global rating scale of change

At all postoperative follow-up points, a Global Rating Scale of change (GRS) was administered, consisting of a single question asking how much daily functioning was changed since surgery (26). This question comprises seven answer options; much worse, worse, slightly worse, no change, slightly improved, improved, much improved.

Statistical analysis

Descriptive statistics (mean and SD or frequency and percentage) were used to determine the general characteristics for the total study population, the patients' level of physical function, level of functional limitations and the GRS. All analyses were stratified for THA and TKA. One way Analysis of Variance (ANOVA) was used to determine differences in baseline characteristics between patients with and without 3 and 12 months follow-up measurements.

Change scores for all measures except GRS were calculated by subtracting the baseline scores from the follow-up scores (0-3 and 0-12 months). In the subgroup with valid scores on the Stair Climb Test (10-step stairs), scores of the three different performance-based tests (CST, FPWT,SCT) were transformed into Fisher's Z scores to be able to average the scores of the performance-based tests.
After summarizing and averaging the three scores, the correlation was measured between the AAQ score and the average performance-based measure score.

The construct validity of the AAQ is tested by hypothesis testing. The hypotheses are tested by means of calculating correlation coefficients (Spearman's Rho) between an assessment with another measurement instruments that measure constructs that are closely related to the construct of the AAQ. Correlations at baseline were calculated between the AAQ, the performance-based tests, the HOOS/KOOS-PS and the OHS/OKS. We expected moderate correlation coefficients (0.3-0.6) between the AAQ, the performance-based tests and the questionnaires because an animated questionnaire assesses physical function on a different level than performance-based tests and the self-reported questionnaires. The hypotheses for assessing construct validity (27) were based on previous research of Peter et al. (10, 11), and formulated a priori by the PATIO study group. We considered the AAQ as valid for THA and TKA separately if at least 75% of the results were in accordance with the hypotheses (28).

Assuming that responsiveness is an aspect of validity and since we know that there is no gold standard available to compare with, we assessed responsiveness by hypothesis testing. The hypotheses are tested by means of calculating correlation coefficients (Spearman's Rho) between the change of an assessment with changes in

other measurement instruments that measure constructs that are closely related to the construct of the AAQ and an anchor question. The expected correlation of the change in AAQ with the GRS as anchor question was based on an earlier responsiveness study (13) and is the same in THA and TKA. Furthermore, we expected the correlations at 3 months to be higher with the HOOS/KOOS-PS and the OHS/OKS than with performance-based measures based on the earlier responsiveness study (13). We assessed responsiveness by a priori formulated hypotheses (27) which were based on previous research (13). We considered the AAQ responsive to reflect changes in physical function after THA and TKA if at least 75% of the hypothesis were met. The hypotheses are described in Table 2.

Power calculation

For responsiveness studies, at least 100 patients are preferred to make reliable estimates (14, 15). In this study we have sufficient patients, including data, to meet this criteria at all-time points. All analyses were performed using SPSS software, version 25.0. Armonk, New York: IBM Corporation.

Results

Study population

The flow of participants and the distribution of the three different groups in this study are presented in Figure 1. In total, 302 and 282 patients received a primary THA or TKA, respectively. These patients were all included in the analysis of the construct validity of the AAQ (total group), as they all had at least one result on the baseline performance-based tests and/or questionnaires including the AAQ. Of these patients, 288 THA and 264 TKA patients were included for the responsiveness analysis of the AAQ at 3 months after surgery (subgroup with 3 months follow-up measurements) because of complete performance-based tests results and complete questionnaires at baseline and 3 months follow-up. At 12 months follow-up, 239 THA and 221 TKA patients had complete performance-based tests results and questionnaires and were included in the responsiveness analysis of the AAQ at 12 months after surgery (subgroup with 12 months follow-up measurements).

Characteristics of THA and TKA patients

Table 1 shows the baseline characteristics of the 3 different groups. In all groups, between 50%-55% of the patients were female and the average age was about 66 years. The mean AAQ score at baseline in THA patients was between 77.8-79.4 and in TKA patients between 78.2-79.9.

When comparing patients with and without 12 month follow-up data, we found in THA patients differences in the SCT, AAQ, HOOS-PS, OHS and NRS in rest scores. Differences between TKA patients with 12 months follow-up and without 12 months follow-up were found in Sex, SCT, AAQ, KOOS-PS and OKS scores (supplementary table 1).

Physical function after surgery

More than 80% of the THA patients reported at least an improvement on the GRS 3 months after surgery. At 12 months follow-up this percentage was more than 92%. About 74% of the TKA patients reported at least an improvement on the global rating score 3 months after surgery. This percentage of improved TKA patients was over 87% at 12 months follow-up. Also all mean scores of the other physical function assessments improved after surgery (supplementary table 2). The improvements on the HOOS-PS were clinically relevant at 12 months follow-up. The improvement on the KOOS-PS was clinically relevant at 3 and 12 months follow-up (29). All change scores on the OHS and OKS were clinically relevant (30).

Validity of the AAQ

Table 2 shows all a priori hypotheses and the results in relation to our hypotheses on construct validity (hypotheses 1-5) of the AAQ. For all hypotheses in both THA and TKA patients, moderate correlations were found (correlations ranged between 0.51-0.62) . All a priory-defined hypotheses (100%) were met.

Responsiveness of the AAQ

All hypotheses and their corresponding correlation coefficients are reported in Table 2. With regard to the responsiveness of the AAQ , 14 of the 20 hypotheses (70%) in THA patients were met. In TKA patients, 15 of the 20 hypotheses (75%) were met. Tables 3 and 4 show the correlation coefficients between all measurements in THA and TKA patients at different measurements points.

Discussion

In the current study we evaluated the construct validity and responsiveness of the AAQ at 3 and 12 months after THA or TKA. The AAQ met all hypotheses, indicating sufficient construct validity of the AAQ in THA and TKA patients. For the responsiveness of the AAQ, 70% of the hypotheses were met in THA patients, which was below the set threshold of 75%, indicating limited responsiveness at 3 and 12 months after surgery. In TKA patients, 75% of the hypotheses were met indicating sufficient responsiveness at 3 and 12 months after surgery.

We found good construct validity of the AAQ in our study. This is in line with previous research in patients with hip and knee OA (9, 11). The developers of the AAQ stated that the AAQ is a PROM that measures a new construct, closely related to perception of performance and actual life performance. Thus, the AAQ can assess physical function accurately in THA and TKA patients.

In TKA patients, the AAQ showed good responsiveness, while its responsiveness in THA patients was limited compared to the other instruments used. In THA patients, 70% of the hypotheses were confirmed, indicating insufficient responsiveness in this group. However, only one less hypothesis (out of the 20 hypotheses) was confirmed compared to the TKA group. Overall, the results for THA and TKA patients were almost identical, with the only difference observed in the correlation between the change in the total score of the AAQ (0-3 months) and the FPWT, which was at least 0.10 higher than its correlation with the HOOS-PS in TKA patients but not in THA patients. We set the hypothesis confirmation threshold at 75%, based on prior research (13, 28), though this threshold is arbitrary and could lead to different interpretations if a different threshold was applied.

Overall we found lower correlations than expected between change scores on the AAQ and the comparator questionnaires and performance-based tests. This finding is in contrast with the results on the construct validity. However, Peter et al. also found insufficient responsiveness at 3 months follow-up, but sufficient at 6 months (13).

There are several potential explanations for the limited responsiveness of the AAQ. First, the strength of a correlation coefficient is dependent of the homogeneity of the study population as expressed by the SD. We formulated our a priori defined hypothesis based on the research of Peter et al. (13). In our study we found smaller SDs of the change score of the AAQ compared to the study of Peter et al. (13). The SD has an important impact on the correlations between measurements. For example, the SD of the change scores in the performance-based test and the HOOS-PS were smaller in our study compared to the study of Peter et al. Second, compared to the study population of the study of Peter et al. (13), our study population seems to be more homogenous, and scored better on the AAQ, the performance-based tests and reported less pain on the NRS at baseline. As a consequence we have seen lower change scores over time and found lower correlations than expected. Based on this it seems that the AAQ is more responsive in a more heterogeneous study population with lower health outcomes and more change in scores over time.

Third, a reason why our study population is homogenous and scored high on all preoperative measurements can be due to patients believes of their capacity to execute behaviors necessary to produce specific performance attainments, in other words self-efficacy. If patients has a higher self-efficacy, they will give themselves higher scores which makes it more difficult to show improvements after surgery and subsequently lower changes scores and lower correlations. Postoperative self-efficacy seems to play a role in the recovery process in both THA and TKA patients, because patients with better self-efficacy showed longer distance ambulation, exercise repetition and frequency, walking speed and less disability (31). This study showed that patients with better preoperative self-efficacy did not have better functional outcomes after surgery, which might be due to less changes over time. Because our study population scored high on baseline measurements, it is a possibility that their self-efficacy did not change or did not change enough after surgery and showed less changes in the results of the AAQ.

Lastly, the choice of comparator instruments may explain the AAQ's limited responsiveness. Our predefined hypotheses were not met for both questionnaires and performance tests. The lower correlations could be due to using the HOOS-PS and KOOS-PS, which focus only on physical function but may not measure it comprehensively due to limited items. Studies have shown that the full versions of HOOS and KOOS are more reliable and responsive than the short forms (29, 32). The OHS and OKS, however, showed expected correlations in a similar population (33), suggesting the HOOS-PS and KOOS-PS are not responsive, instead of the AAQ.

A strength of our study is its nationwide multicentre design and its high number of included patients. Therefore we could perform stratified analyses on the responsiveness of the AAQ in THA and TKA patients. Consequently, we could make a more reliable statement of the responsiveness of the AAQ at 3 and 12 months follow-up in this specific subgroup. Because we used the standard follow-up measurements and the use of PROMS as used within the national registration system (LROI) (34) we have a high response rate. These measurements are standardized within the usual care. Lastly, the 12 months measurements were a valuable addition to this study because no information on 12 months measurements were available yet.

A limitation of our study is the different execution of the Stair climb test in several hospitals. Most of the patients performed this test on a 10-step stair. Therefore, the scores of patient who performed the test on a 10-step stair were considered as valid. Because of this selection we have a smaller number of patients with valid test results to compare. This group was not a representative sample of the study

population because they had better values on all baseline characteristics. This may have influenced the correlations because of the better test scores and smaller SDs. A second limitation is that our results are difficult to compare with previous research (13) because of the different use and timing of measurements and performance-based tests in this study. Lastly, our a priori formulated hypotheses are arbitrary. Other regression coefficients could have led to other conclusions. However, we are not aware of any there are no other options for this kind of analysis.

Considering the results of this study we can state that the AAQ has the potential to give a good representation of physical function in THA and TKA patients. However, the AAQ seems to measure physical function on a different level compared to questionnaires and performance-based tests. These days, for example especially during the COVID-19 period, orthopaedic surgeons make more use of phone- or video calls. It is possible that the AAQ can be helpful when the patient cannot visit the orthopaedic practice and has his appointment through phone or via a video call. Normally an orthopaedic surgeon can see the quality of the movements during the consult, for example stand up from a chair or walking. This is not possible when a patient cannot visit the orthopaedic practice and has his appointment through phone or via a video call. These phone- or video calls will probably be used more in practice in the near future.

The AAQ showed sufficient construct validity in both THA and TKA patients for assessing physical function at 3 and 12 months post-surgery. For TKA patients we found sufficient responsiveness of the AAQ. However, for THA patients the AAQ showed limited responsiveness, which suggests caution when interpreting changes in physical function over time in this specific population.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Tables and figures

Table 1. Baseline characteristics of study patients.

	Total group (group 1)		Patients with 3 months follow-up data available (group 2)		Patients with 12 months follow-up data available (group 3)	
	THA N=302	TKA N=282	THA N=288	TKA N=264	THA N=239	TKA N=221
Sex, female, n (%)	156 (51.7)	154 (54.6)	148 (51.4)	144 (54.5)	124 (51.9)	113 (51.1)
Missing, n (%)	8 (2.6)	6 (2.1)	4 (1.4)	3 (1.1)	4 (1.7)	4 (1.8)
Age, n, mean (SD)(years)	66.6 (9.0)	66.9 (8.4)	66.6 (8.9)	66.9 (8.3)	66.3 (8.8)	66.9 (8.1)
Missing, n (%)	8 (2.6)	6 (2.1)	4 (1.4)	3 (1.1)	4 (1.7)	4 (1.8)
BMI, n, mean (SD)	27.01 (4.4)	29.4 (5.0)	27.0 (4.5)	29.3 (5.0)	27.0 (4.4)	29.3 (5.1)
Missing, n (%)	8 (2.6)	6 (2.1)	4 (1.4)	3 (1.1)	4 (1.7)	4 (1.8)
Comorbidity, one or more, N (%)	217 (71.9)	210 (74.5)	208 (72.2)	199 (75.4)	172 (72.0)	167 (75.6)
Missing, n (%)	0	0	0	0	0	0
AAQ score (0-100), mean (SD)	77.8 (16.8)	78.2 (16.0)	78.2 (16.5)	78.6 (15.2)	79.4 (15.5)	79.9 (14.6)
Missing, n (%)	17 (5.6)	7 (2.5)	17 (5.9)	6 (2.3)	10 (4.2)	2 (0.9)
30s chair-stand test, mean in count (SD)	9.8 (3.4)	9.6 (3.4)	9.9 (3.4)	9.7 (3.3)	10 (3.5)	9.8 (3.4)
Missing, n (%)	7 (2.3)	8 (2.8)	7 (2.4)	7 (2.7)	4 (1.7)	3 (1.4)
40m fast paced walk test, mean in seconds (SD)	38.0 (13.4)	37.7 10.9)	37.6 (12.9)	37.6 (10.9)	37.8 (12.9)	37.4 (10.2)
Missing, n (%)	7 (2.3)	8 (2.8)	7 (2.4)	6 (2.3)	3 (1.3)	2 (0.9)
Stair climb test, mean in seconds (SD)	17.2 (13.3)	19.7 10.8)	16.5(11.6)	19.3 (10.4)	16.7 (12.4)	19.3 (11.0)
Missing, n (%)	176 (58.3)	181 (64.2)	167 (58.0)	168 (63.6)	134 (56.1)	137 (62.0)

HOOS-PS/ KOOS-PS interval score(0-100), mean (SD)	39.0(16.1)	43.9 (15.5)	38.6 (16.1)	43.7 (15.2)	37.5 (15.5)	42.6 (13.9)
Missing, n (%)	9 (3.0)	6 (2.1)	5 (1.7)	3 (1.1)	5 (2.1)	4 (1.8)
OHS / OKS score (0-48), mean (SD)						
Missing, n (%)	25.8 (8.4)	26.9 (7.8)	26.1 (8.4)	27.0 (7.6)	26.4 (8.3)	27.4 (7.5)
	9 (3.0)	6 (2.1)	5 (1.7)	3 (1.1)	5 (2.1)	4 (1.8)
NRS score pain (0-10), mean (SD)						
In rest	5.0 (2.4)	4.7 (2.3)	4.9 (2.4)	4.7 (2.3)	4.8 (2.4)	4.6 (2.3)
During activity	3.9 (3.0)	6.7 (1.9)	3.9 (3.0)	6.7 (1.9)	3.8 (3.0)	6.8 (1.9)
Missing, n (%)	10 (3.3)	6 (2.1)	6 (2.1)	3 (1.1)	5 (2.1)	4 (1.8)

Legend to Table 1:

AAQ=Animated Activity Questionnaire; BMI=Body Mass Index; HOOS-PS= Hip disability and Osteoarthritis Outcome Score-Physical function Short form; KOOS= Knee injury and Osteoarthritis Outcome Score-Physical function Short form; OHS=Oxford Hips Score; OKS= Oxford Knee Score; NRS= Numeric Rating Scale; THA=total hip arthroplasty; TKA= total knee arthroplasty.

Table 2. A priori hypotheses and correlations for the analysis of construct validity and responsiveness of the Animated Activity Questionnaire (AAQ) in patients who underwent THA or TKA.

THA patients		
Hypotheses construct validity THA patients	Correlation coefficient	In accordance with hypotheses (yes/ no)
The total score of the AAQ correlates moderately (0.3-0.6) with the total score of the…..		
1. HOOS-PS at baseline.	0.54	Yes
2. OHS at baseline.	0.59	Yes
3. 30 Second Chair Test at baseline.	0.51	Yes
4. Fast Paced Walking Test at baseline.	0.52	Yes
5. Stair Climb Test at baseline.	0.59	Yes
Hypotheses responsiveness THA	Correlation coefficient	In accordance with hypotheses (yes/ no)
The change in the total score of the AAQ will have a correlation of at least 0.5 with the……		
6. GRS at 3 months.	0.24	No
7. GRS at 12 months.	0.27	No
The change in the total score of the AAQ will have a correlation of at least 0.3 with the……		
8. change in the HOOS-PS at 3 months.	0.48	Yes
9. change in the HOOS-PS at 12 months.	0.48	Yes
10. change in the OHS at 3 months.	0.57	Yes
11. change in the OHS at 12 months.	0.55	Yes
12. change in the 30 CST at 3 months.	0.37	Yes
13. change in the 30 CST at 12 months.	0.40	Yes
14. change in the FPWT at 3 months.	0.51	Yes
15. change in the FPWT at 12 months.	0.40	Yes
16. change in the SCT at 3 months.	0.69	Yes
17. change in the SCT at 12 months.	0.70	Yes
18. change in the average score of the performance-based tests at 3 months.	0.53	Yes

19. change in the average score of the performance-based tests at 12 months.	0.47	Yes
The change in the total score of the AAQ (0-3 months) will correlate at least 0.10 higher with the change in the..		
20. CST than with the changes in scores of the HOOS-PS.	**-** 0.11	No
21. FPWT than with the changes in scores of the HOOS-PS.	0.03	No
22. SCT than with the changes in scores of the HOOS-PS.	0.21	Yes
The change in the total score of the AAQ (0-12 months) will correlate at least 0.10 higher with the change in the		
23. CST than with the changes in scores of the HOOS-PS.	- 0.08	No
24. FPWT than with the changes in scores of the HOOS-PS.	- 0.08	No
25. SCT than with the changes in scores of the HOOS-PS.	0.22	Yes
TKA patients		
Hypotheses construct validity TKA patients	Correlation coefficient	In accordance with hypotheses (yes/ no)
The total score of the AAQ correlates moderately (0.3-0.6) with the total score of the……		
1. KOOS-PS at baseline.	0.59	Yes
2. OKS at baseline.	0.62	Yes
3. 30 Second Chair Test at baseline.	0.56	Yes
4. Fast Paced Walking Test at baseline.	0.53	Yes
5. Stair Climb Test at baseline.	0.62	Yes
Hypotheses responsiveness TKA	Correlation coefficient	In accordance with hypotheses (yes/ no)
The change in the total score of the AAQ will have a positive correlation of at least 0.5 with the….		
6. GRS at 3 months.	0.33	No
7. GRS at 12 months.	0.19	No
The change in the total score of the AAQ will have a positive correlation of at least 0.3 with the….		
8. KOOS-PS at 3 months.	0.39	Yes
9. KOOS-PS at 12 months.	0.39	Yes
10. OKS at 3 months.	0.51	Yes
11. OKS at 12 months.	0.53	Yes
12. 30 CST at 3 months.	0.33	Yes

13. 30 CST at 12 months.	0.37	Yes
14. FPWT at 3 months.	0.52	Yes
15. FPWT at 12 months.	0.43	Yes
16. SCT at 3 months.	0.60	Yes
17. SCT at 12 months.	0.53	Yes
18. change in the average score of the performance-based tests at 3 months.	0.47	Yes
19. change in the average score of the performance-based tests at 12 months.	0.39	Yes
The change in the total score of the AAQ (0-3 months) will correlate at least 0.10 higher with the change in the…..		
20. CST than with the changes in scores of the KOOS-PS.	0.06	No
21. FPWT than with the changes in scores of the KOOS-PS.	0.13	Yes
22. SCT than with the changes in scores of the KOOS-PS.	0.21	Yes
The change in the total score of the AAQ (0-12 months) will correlate at least 0.10 higher with the change in the…..		
23. CST than with the changes in scores of the KOOS-PS.	- 0.02	No
24. FPWT than with the changes in scores of the KOOS-PS.	0.04	No
25. SCT than with the changes in scores of the KOOS-PS.	0.14	Yes

Legend to Table 2: 30 SCT= 30 Second Chair Test; AAQ=Animated Activity Questionnaire; FPWT= Fast Paced Walking test; HOOS-PS= Hip disability and Osteoarthritis Outcome Score-Physical function Short form;KOOS-PS= Knee injury and Osteoarthritis Outcome Score-Physical function Short form; OKS=Oxford Knee Score; OHS=Oxford Hip Score; SCT=Stair Climb Test; THA=total hip arthroplasty; TKA=total knee arthroplasty .

Table 3. Spearman correlation coefficients (95% CI) between the Animated Activity Questionnaire (AAQ), HOOS-PS interval score, KOOS-PS interval score, Oxford Hip Score (OHS), Oxford Knee score (OKS) and performance-based tests in patients who underwent THA or TKA at baseline.

Baseline THA	AAQ	HOOS-PS	OHS	30 seconds Chair stand test	40 meter fast paced walk test	Stair climb test	Average score performance-based tests
AAQ	1.00 N=285	0.54 (0.45 – 0.62) N=276	0.59 (0.51 –0.66) N=276	0.51 (0.42 – 0.59) N=283	0.52 (0.43 – 0.60) N=283	0.59 (0.46 – 0.70) N=114	0.55 (0.41 - 0.67) N=113
HOOS-PS		1.00 N=293	0.72 (0.66 – 0.77) N=293	0.30 (0.19 – 0.40) N=286	0.28 (0.17 – 0.38) N=286	0.41 (0.25 – 0.55) N=125	0.40 (0.23 - 0.55) N=112
OHS			1.00 N=293	0.33 (0.22 – 0.43) N=286	0.35 (0.24 – 0.44) N=286	0.43 (0.28 – 0.56) N=125	0.41 (0.24 - 0.55) N=112
30 seconds Chair stand test				1.00 N=295	0.59 (0.51 – 0.66) N=294	0.61 (0.49 – 0.71) N=125	
40 meter fast paced walk test					1.00 N=295	0.65 (0.54 – 0.74) N=126	
Stair climb test						1.00 N=126	

TKA	AAQ	KOOS-PS	OKS	30 seconds Chair stand test	40 meter fast paced walk test	Stair climb test	Average score performance-based tests
AAQ	1.00 N=275	0.59 (0.51 – 0.66) N=269	0.62 (0.54 – 0.69) N=269	0.56 (0.47 – 0.64) N=273	0.53 (0.44 – 0.61) N=273	0.62 (0.48 – 0.73) N=100	0.53 (0.13 - 0.49) N=100
KOOS-PS		1.00 N=276	0.79 (0.74 – 0.83) N=276	0.37 (0.26 – 0.47) N=268	0.23 (0.11 – 0.34) N=268	0.36 (0.17 – 0.52) N=97	0.32 (0.37 - 0.66) N=96
OKS			1.00 N=276	0.33 (0.22 – 0.43) N=268	0.35 (0.24 – 0.45) N=268	0.41 (0.22 – 0.57) N=91	0.36 (0.17 - 0.52) N=96
30 seconds Chair stand test				1.00 N=274	0.56 (0.47 – 0.64) N=273	0.55 (0.40 – 0.67) N=101	
40 meter fast paced walk test					1.00 N=274	0.72 (0.61 – 0.80) N=101	
Stair climb test						1.00 N=101	

Legend to Table 3: THA=total hip arthroplasty; TKA= total knee arthroplasty; AAQ=Animated Activity Questionnaire; HOOS-PS= Hip disability and Osteoarthritis Outcome Score-Physical function Short form; KOOS-PS= Knee injury and Osteoarthritis Outcome Score-Physical function Short form; OHS=Oxford Hip Score; OKS=Oxford Knee score.

Table 4. Spearman correlation coefficients (95% CI) between change scores of the Animated Activity Questionnaire (AAQ), HOOS-PS interval score, Oxford Hip Score (OHS) Global Rating Score of change (GRS), and performance-based tests in patients after THA (3 and 12 months after surgery).

3 months	AAQ	HOOS-PS	OHS	GRS	30 seconds Chair stand test	40 meter fast paced walk test	Stair climb test	Average score performance-based tests
AAQ	1.00 N=206	0.48 (0.37 – 0.58) N=198	0.57 (0.47 – 0.66) N=198	0.24 (0.11 – 0.37) N=202	0.37 (0.24 – 0.48) N=202	0.51 (0.40 -0.61) N=205	0.69 (0.55 – 0.79) N=74	0.53 (0.34 - 0.68) N=73
HOOS-PS		1.00 N=280	0.64 (0.57 – 0.70) N=280	0.37 (0.26 – 0.46) N=280	0.26 (0.13 – 0.38) N=208	0.33 (0.20 – 0.45) N=210	0.56 (0.39 – 0.69) N=84	0.49 (0.29 – 0.65) N =72
OHS			1.00 N=280	0.51 (0.42 – 0.59) N=280	0.30 (0.13 – 0.38) N=208	0.38 (0.26 – 0.49) N=210	0.62 (0.47 – 0.74) N=84	0.53 (0.34 – 0.68) N =72
GRS				1.00 N=284	0.29 (0.16 – 0.41) N=212	0.16 (0.03 – 0.29) N=214	0.61 (0.46 – 0.73) N=84	
30 seconds Chair stand test					1.00 N=215	0.34 (0.22 – 0.45) N=215	0.53 (0.36 – 0.67) N=84	
40 meter fast paced walk test						1.00 N=218	0.57 (0.41 – 0.70) N=85	
Stair climb test							1.00 N=84	

12 months	AAQ	HOOS-PS	OHS	GRS	30 seconds Chair stand test	40 meter fast paced walk test	Stair climb test	Average score performance-based tests
AAQ	1.00 N=151	0.48 (0.34 – 0.60) N=142	0.55 (0.42 – 0.66) N=142	0.27 (0.11 – 0.41) N=147	0.40 (0.25 – 0.53) N=143	0.40 (0.25 – 0.53) N=143	0.70 (0.55 – 0.81) N=63	0.47 (0.25-0.65) N=61
HOOS-PS		1.00 N=221	0.73 (0.66 – 0.79) N=221	0.45 (0.34 – 0.55) N=221	0.32 (0.16 – 0.46) N=143	0.29 (0.13 – 0.43) N=145	0.50 (0.30 – 0.66) N=68	0.46 (0.23 – 0.64) N =60
OHS			1.00 N=230	0.46 (0.35 – 0.56) N=221	0.32 (0.17 – 0.46) N=145	0.23 (0.07 – 0.38) N=147	0.42 (0.21 – 0.60) N=70	0.42 (0.19 – 0.61) N =60
GRS				1.00	0.34 (0.19 – 0.48) N=148	0.03 (-0.13 – 0.19) N=150	0.36 (0.13 – 0.55) N=68	
30 seconds Chair stand test					1.00 N=153	0.31 (0.16 – 0.45) N=153	0.42 (0.24 – 0.60) N=70	
40 meter fast paced walk test						1.00 N=156	0.44 (0.23 – 0.61) N=72	
Stair climb test							1.00 N=72	

Legend to Table 4: THA=total hip arthroplasty; AAQ=Animated Activity Questionnaire; HOOS-PS= Hip disability and Osteoarthritis Outcome Score-Physical function Short form; OHS=Oxford Hip Score.

Table 5. Spearman correlation coefficients (95% CI) between change scores of the Animated Activity Questionnaire (AAQ), KOOS-PS interval score, Oxford Knee Score (OKS), Global Rating Score of change, and performance-based tests in patients after TKA (3 and 12 months after surgery).

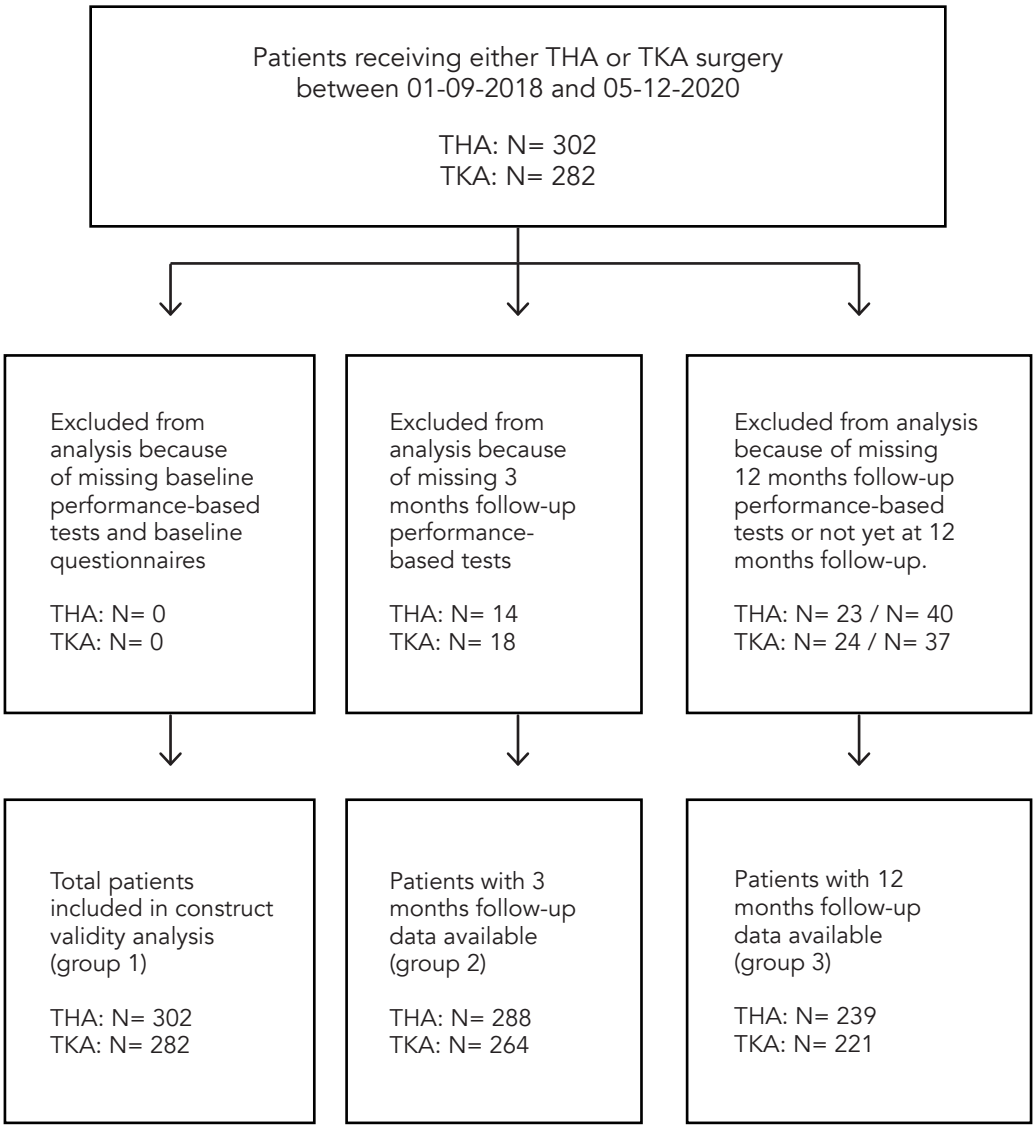
3 months	AAQ	KOOS-PS	OKS	GRS	30 seconds Chair stand test	40 meter fast paced walk test	Stair climb test	Average score performance-based tests
AAQ	1.00 N=204	0.39 (0.27 – 0.50) N=200	0.51 (0.40 – 0.61) N=200	0.33 (0.20 – 0.45) N=201	0.33 (0.20 – 0.45) N=200	0.52 (0.41 – 0.61) N=200	0.60 (0.42 – 0.73) N=69	0.47 (0.26 - 0.64) N=69
KOOS-PS		1.00 N=258	0.68 (0.61 – 0.74) N=257	0.27 (0.15 – 0.38) N=257	0.24 (0.11 – 0.37) N=200	0.22 (0.08 – 0.35) N=201	0.28 (0.04 – 0.49) N=68	0.28 (0.04 - 0.49) N=67
OKS			1.00 N=259	0.54 (0.45 – 0.62) N=257	0.25 (0.12 – 0.38) N=200	0.40 (0.28 – 0.51) N=201	0.35 (0.12 – 0.54) N=68	0.32 (0.09 - 0.52) N=67
GRS				1.00 N=258	0.11 (-0.03 – 0.25) N=201	0.32 (0.19 – 0.44) N=202	0.31 (0.08 – 0.51) N=68	
30 seconds Chair stand test					1.00 N=204	0.37 (0.25 – 0.48) N=203	0.31 (0.08 – 0.51) N=70	
40 meter fast paced walk test						1.00 N=205	0.51 (0.31 – 0.67) N=70	
Stair climb test							1.00 N=70	

12 months	AAQ	KOOS-PS	OKS	GRS	30 seconds Chair stand test	40 meter fast paced walk test	Stair climb test	Average score performance-based tests
AAQ	1.00 N=134	0.39 (0.23 – 0.53) N=123	0.53 (0.39 – 0.65) N=122	0.19 (0.02 – 0.35) N=126	0.37 (0.21 – 0.51) N=129	0.43 (0.28 – 0.56) N=131	0.53 (0.30 – 0.70) N=53	0.39 (0.13 – 0.60) N=53
KOOS-PS		1.00 N=201	0.68 (0.60 – 0.75) N=200	0.31 (0.18 – 0.43) N=199	0.22 (0.04 – 0.38) N=121	0.36 (0.20 – 0.51) N=123	0.20 (-0.08 – 0.45) N=51	0.26 (0.02 – 0.50) N=49
OKS			1.00 N=209	0.40 (0.28 – 0.51) N=199	0.25 (0.07 – 0.41) N=120	0.35 (0.18 – 0.50) N=122	0.30 (0.03 – 0.53) N=51	0.25 (0.03 – 0.50) N=49
GRS				1.00 N=204	0.16 (-0.02 – 0.33) N=124	0.14 (-0.04 – 0.31) N=126	0.18 (-0.10 – 0.43) N=52	
30 seconds Chair stand test					1.00 N=132	0.42 (0.27 – 0.55) N=132	0.38 (0.13 – 0.59) N=55	
40 meter fast paced walk test						1.00 N=134	0.53 (0.31 – 0.70) N=55	
Stair climb test							1.00 N=55	

Legend to Table 5: TKA= total knee arthroplasty; AAQ=Animated Activity Questionnaire; KOOS-PS= Knee injury and Osteoarthritis Outcome Score-Physical function Short form; OKS= Oxford Hip Score.

Figure

Figure 1. Flowchart of patients in a study on the validity, responsiveness and interpretability of the Animated Activity Questionnaire in THA and TKA patients.



Chapter 7

The impact of the COVID-19 pandemic on different aspects of the delivery of physical therapy after total hip or knee surgery: perspectives of patients and physical therapists

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Introduction

The lifetime risk of total hip or knee arthroplasty (THA/TKA) following a diagnosis of osteoarthritis is approximately 14% and 30% respectively (1). In the Netherlands 99% of the patients receive physical therapy (PT) after THA/TKA surgery, with an average frequency of one to two sessions per week and a duration of more than 12 weeks. The effectiveness of postoperative PT in improving function, range of motion and quality of life has been extensively demonstrated (2-6).

During the COVID-19 pandemic and ensuing lockdown, from 23rd of March 2020 until May 11th 2020, PT practices were closed and physical therapists were advised and supported by the Dutch Society for Physical Therapy (KNFG) to deliver their interventions by means of remote care, i.e. telephone, e-mail or video consultations (7). After practices were re-opened, physical therapists were still advised to provide remote care, work with personal protection equipment and keep 1.5 meter distance of the patients as much as possible (7). From February 2022 on, these advises are still given by the KNFG with the exception of remote care (8). Tele-rehabilitation showed to be promising in musculoskeletal PT during the COVID-19 pandemic (9).

So far, it remains unclear to what extent the COVID-19 pandemic, the temporary closure of practices and the advices on remote care have influenced the delivery of PT after THA/TKA. Although the number of surgeries decreased during the first wave, patients who were operated just before the first lockdown were in need of postoperative PT precisely in the period where PT practices were closed. Therefore, the aim of this study was to determine the impact of the COVID-19 pandemic on the delivery of PT after THA/TKA in the Netherlands, both from the perspectives of patients and their treating physical therapists.

Methods

Study design and setting

The present study on the impact of the COVID-19 pandemic on the delivery of PT after THA/TKA used data obtained in the context of a randomized controlled trial, as well as additional information gathered among patients and physical therapists participating in that trial during the COVID-19 pandemic.

Participants of the present study were selected from the intervention arm of the

PhysiotherApeutic Treat-to-target Intervention after Orthopaedic surgery study (PATIO) (Trial ID NTR7129) (10). Ethical approval was obtained from the Medical Ethics Committee of the Erasmus MC, Rotterdam, The Netherlands (NL61763.078.17). All participants gave informed consent in accordance with the Handbook for Good Clinical Research Practice of the World Health Organization and Declaration of Helsinki principles (11).

The protocol of the PATIO study was described earlier (10). In brief, the intervention concerned an optimized PT care pathway, where the content, frequency and duration of treatment were determined by the achievement of individual, functional milestones and treatment goals. All physical therapists delivering the intervention took part in a physical training. After the closure of the PT practices on March 23rd 2020, physical therapists who were treating patients from the intervention group were instructed by the PATIO study group to continue the delivery of the intervention according to the recommendations from the government and their professional organization. These recommendations concerned providing remote care such as telephone or video call, work with personal protection equipment and keep 1,5 meter distance of the patients as much as possible (7).
Patients and physical therapists

We selected patients from the intervention group of the PATIO study, because the characteristics of the PT treatment were monitored in detail for this group. Moreover, the selection was limited to those patients who had completed at least the baseline assessment of the PATIO study and of whom the physical therapist had provided information on the delivery of the intervention. Patients using PT from March 1, 2020 until the end period of this study (December 2021) were classified in the COVID period group and those using PT in the period before March 2020 were classified in the pre-COVID period group.

Assessments
Paper or electronic questionnaires were administered to patients preoperatively and 6 months after THA/TKA surgery. PT questionnaires were administered in both patients and physical therapists when the patient's PT treatment was completed.

Sociodemographic and disease characteristics of patients and physical therapists
The following sociodemographic information was collected at baseline: age, sex, height and weight to calculate the body mass index (BMI), treated joint (hip or knee), living condition (alone, with partner and/or kids), education (low, middle, high) (12) and the presence of comorbidities using a questionnaire developed by the Dutch

Central Bureau of Statistics (CBS) (13). In physical therapists, their years of work experience and specialization was collected.

Physical functional status

At baseline, physical functional status was assessed with short versions of the validated Dutch translation of the Hip disability and Osteoarthritis Outcome Score (HOOS-PS) (14) and Knee injury and Osteoarthritis Outcome Score (KOOS-PS) (15), respectively yielding a score ranging from 0 (severe functional impairments) to 100 (no functional impairments). Functional limitations in several daily activities and pain intensity were assessed by the Oxford Hip score (OHS) (16) or Oxford Knee Score (OKS) (17), with overall scores running from 0 to 48 with 48 being the best functional outcome. Hip and knee pain severity in rest and during activities in the past week were assessed by the Numeric Rating Scale (NRS) (18), with the score ranging from 0 (no pain) to 10 (worst pain imaginable).

Impact of COVID-19 pandemic on PT delivery

Patients and their physical therapists received a questionnaire on the PT treatment after the full completion of the PT treatment. This questionnaire included several questions about the frequency, duration and content of the given PT treatment and was based on previous research of Peter et al (19). Questions about duration and frequency of PT were reported by the physical therapists. Additionally, from May 2020 onwards questions were added regarding the possible impact of COVID-19 pandemic on different aspects of PT treatment.

Statistical analysis

Descriptive statistics (mean and standard deviation (SD) or percentage) were used to present the general characteristics of the study population, and the results of the questionnaires. Characteristics of patients, physical therapists and the PT treatment were stratified between the COVID-19 period group and the pre-COVID-19 period group. All analyses were performed using SPSS software, version 25.0. Armonk, New York: IBM Corporation.

Results

Baseline characteristics of the study population and their physical therapists are shown in table 1. Impact of COVID pandemic on PT treatment

Table 2 shows the patients and physical therapists perceptions of the impact of the COVID-19 pandemic on PT treatment. 12 (30.8%) of the THA and 4 of the TKA (10.0%) patients reported that they had received remote care during the COVID pandemic. Approximately half these patients would have preferred PT in practice.

Regarding the perspectives of physical therapists, it was found that if remote care was provided, physical therapists reported that most THA patients coped well and started working at home with an exercise schedule. In TKA patients, most physical therapists reported that they did not give the most optimal treatment because the patient had some difficulties to cope well with the remote care therapy.

Most physical therapists reported no changes in frequency of sessions in 22 (56.3%) THA and 28 (70%) TKA patients or in duration in weeks of treatment in 25 (64.1%) THA and 28 (70%) TKA patients due to COVID-19. Physical therapists reported in more than half of the patients no impact of COVID-19 on the total amount of sessions. In about 70% of the patients, physical therapists reported no changes in type of exercise.

Use of physical therapy before and during COVID-19 pandemic
Before and during the COVID-19 pandemic, most patients reported PT sessions in the practice of the PT (range 63%-80%). Physical therapists reported an average frequency of 2 times a week (range 47% - 67%), with the exception of the THA patients who were treated during COVID, where an average of 1 time per week was mostly reported (43.6%). In the THA pre-COVID group, the mean total PT sessions was 19 (± SD 20) and 23 (± SD 19) in the during COVID group. In TKA patients the mean total sessions was 26 (± SD 16) in the pre-COVID group and 34 (± SD 23) in the during-COVID group (table 3).

Discussion

Before and during the COVID-19 pandemic, most THA/TKA patients reported an average of 2 PT sessions per week in PT practices. The average number of PT sessions per patient was lower in the pre-COVID group compared to the COVID group, in both THA/TKA. The impact of COVID on frequency and duration of PT and type of exercises seemed limited. More THA patients received remote care during the COVID pandemic. Physical therapists reported that most THA patients coped well with remote care although these patients preferred PT in practice.

Our results on the average frequency and duration of postoperative PT in both the pre-COVID and COVID periods are in line with previous research of Peter et al. (19), although the present study showed somewhat lower numbers. Possible explanations might be our younger study population or the use of a treat-to-target protocol led to quicker termination of treatment. Only in THA COVID group patients we observed less total PT sessions per week compared to the study of Peter et al., which might be due to the restrictions of COVID-19 or the use of a treat-to-target PT protocol. We did not found these differences in TKA patients which might be explained by an on average faster recovery after THA surgery and the more complex rehabilitation process in TKA patients (20, 21).

Regarding the delivery of remote care in THA/TKA patients, previous research showed positive results compared to the usual face-to-face PT. Patients achieved similar or better outcomes regarding reduction in pain, muscle strength, and functional activities (9, 22-26)and it was found cost-effective (27, 28). Other studies showed that implementing tele-rehabilitation was adequate and feasible (29) and that home-based exercise appears effective to improve muscle- strength, endurance, power and balance during the COVID-19 pandemic (30). Patients who underwent THA/TKA during the COVID-period reported that the restrictions imposed by COVID-19 had limited their rehabilitation process due to limited access to PT, no face-to-face follow-up and the inability to exercise (31). Which is partially in line with our results where half of the patients prefer face-to-face PT.

Strengths of this study are its nationwide multicenter design, the stratified analysis of THA/TKA patients and both patient and physical therapists perspectives were able to be analyzed. A limitation of the study was the relatively small sample size. Selection bias may have occurred in our study due to several reasons. First, only patients in the PATIO study intervention group were selected. These patients followed a standardized, treat-to-target postoperative PT strategy which can influence the PT treatment. Secondly, it is possible that questionnaires were mostly filled in by patients/physical therapists with more dedication regarding the treatment.

Based on the results of our study we can conclude that the impact of COVID-19 on the delivery of PT seems limited. We only observed differences in the total amount of PT sessions between the pre-COVID and the COVID group. Specific questions related to the COVID-19 pandemic indicated that also within the COVID period most patients received treatment according to the protocol with regard to type, duration and frequency of PT. The impact of the changes on PT on the quality of care delivered was not covered in this study.

Tables and figures

Table 1. Baseline characteristics of patients participating in a study on postoperative physical therapy after THA or TKA and their treated physical therapists.

	THA patients		**TKA patients**		**Physical therapists**
	Pre-COVID period n=73	COVID period n=39	Pre-COVID period n=66	COVID period n=40	N=99
Age, years	64.8 (9.3)	66.5 (9.0)	66.4 (6.5)	66.4 (7.0)	-
Sex, female, n (%)	38 (52.1)	16 (41.0)	39 (59.1)	24 (60.0)	-
BMI, kg/m^2	27.2 (4.6)	26.7 (4.2)	29.1 (5.2)	30.0 (5.4)	-
Education, n (%)					
- low	27 (37.0)	15 (38.5)	34 (51.5)	17 (42.5)	-
- middle	19 (26.0)	15 (38.5)	22 (33.3)	11 (27.5)	
- high	27 (37.0)	9 (23.0)	10 (15.2)	12 (30.0)	
One or more Comorbidity/ Comorbidities, n (%)	57 (78.1)	28 (71.8)	51 (77.3)	27 (67.5)	-
HOOS/KOOS -PS (0-100),	40.8 (16.6)	40.0 (14.6)	42.8 (13.4)	46.1 (17.3)	-
OHS/OKS (0-48)	24.8 (8.8)	25.5 (7.7)	27.5 (7.1)	25.1 (8.0)	-
Pain NRS (0-10),					
- rest	5.1 (2.5)	4.8 (2.1)	4.3 (2.2)	5.2 (2.1)	-
- activity	3.8 (3.0)	3.3 (2.9)	6.6 (1.6)	7.0 (1.9)	
physical therapists Experience of treating THA/TKA patients, n (%)	-	-	-	-	
- 0-5 years					32 (32.3)
- 6-10 years					32 (32.3)
- 11-15 years					9 (9.1)
- 16-20 years					9 (9.1)
- > 20 years					17 (17.2)
physical therapists Type of specialization, Yes, n (%) †					
- manual					19 (19.2)
- children					1 (1.0)
- oncological/edema					2 (2.0)
- geriatric					2 (2.0)
- sports					19 (19.2)

Legend to Table 1:

BMI=Body Mass Index; HOOS-PS= Hip disability and Osteoarthritis Outcome Score-Physical function Short form; KOOS-PS= Knee injury and Osteoarthritis Outcome Score-Physical function Short form; NRS= Numeric Rating Scale; OHS=Oxford Hips Score; OKS= Oxford Knee Score; THA=total hip arthroplasty; TKA= total knee arthroplasty.

Data reported as mean (standard deviation)

† Type of specialization: multiple answers possible.

Table 2. Perspectives of patients undergoing THA or TKA and physical therapists on the impact of COVID-19 on PT treatment during the pandemic

	THA patients N=39		**TKA patients N=40**	
	Patients	Physical therapist	Patients	Physical therapist
Delivery of remote care due to COVID-19, n (%)	-		-	
-Total		12 (30.8)		7 (17.5)
-Telephone		6 (15.4)		3 (7.5)
-Video call		6 (15.4)		4 (10)
Preference for face-to-face treatment , n (%)				
-Yes		-		-
-No	5 (41.7)		2 (50.0)	
-No, however there were more possibilities in PT practice	5 (41.7) 2 (16.6)		2 (50.0) 0 (0.0)	
In case of remote care, perception that care was optimal , n (%)	-		-	
- Yes		8 (75.0)		2 (28.6)
- Somewhat		4 (25.0)		5 (71.4)
- No		0 (0.0)		0 (0.0)
Impact on frequency per week, n (%)	-		-	
-Yes, more treatments		-		1 (2.5)
-Yes, fewer treatments		13 (33.3)		9 (22.5)
-No changes		22 (56.3)		28 (70.0)
-Missing		4 (10.3)		2 (5.0)
Impact on duration, n (%)	-		-	
-Yes, longer period		9 (23.1)		7 (17.5)
-Yes, shorter period		1 (2.6)		3 (7.5)
-No changes		25 (64.1)		28 (70.0)
-Missing		4 (10.3)		2 (5.0)

Impact on total number of sessions, n (%)	-	-	
-Yes, considerably less treatments		1 (2.6)	2 (5.0)
-Yes, les treatments		8 (20.5)	8 (20.0)
-Yes, more treatments		5 (12.8)	2 (5.0)
-No		21 (53.8)	26 (65.0(
-Missing		4 (10.3)	2 (5.0)
Impact on duration of individual sessions, n (%)	-	-	
-Yes		2 (5.1)	5 (12.5)
-No		33 (84.6)	33 (82.5)
-Missing		4 (10.3)	2 (5.0)
Impact on content of treatment, n (%)	-	-	
-No changes in exercises		28 (71.8)	28 (70.0)
-Different exercises/therapy with same end goals		5 (12.8)	7 (17.5)
-Different exercises/therapy and harder to work on end goals		2 (5.1)	3 (7.5)
-Missing		4 (10.3)	2 (5.0)

Legend to Table 2:

PT= physical therapy; THA=total hip arthroplasty; TKA= total knee arthroplasty.

Table 3. Characteristics of physical therapy treatment before and after the COVID-19 pandemic, asked to physical therapists.

	THA patients		**TKA patients**	
	Pre-COVID n=73	During COVID n=39	Pre-COVID n=66	During COVID n=40
Location of PT, n (%)†				
Home	25 (34.2)	17 (43.6)	27 (40.9)	17 (42.5)
Practice of PT	46 (63.0)	31 (79.5)	47 (71.2)	31 (77.5)
Remote care	6 (8.2)	12 (30.8)	4 (6.0)	4 (10.0)
Other (hospital, rehabilitation center)	9 (12.3)	1 (2.6)	11 (16.7)	4 (10.0)
Frequency per week, n (%)				
<1	20 (27.4)	7 (17.9)	7 (10.6)	3 (7.5)
1	19 (26.0)	17 (43.6)	15 (22.7)	13 (32.5)
2	34 (46.6)	14 (35.9)	44 (66.7)	23 (57.5)
>=3	0 (0.0)	1 (2.6)	0 (0.0)	1 (2.5)
Duration (weeks), n (%)				
< 2	10 (13.7)	1 (2.6)	-	-
2-4	9 (12.2)	1 (2.6)	3 (4.5)	2 (5.0)
5-8	10 (13.7)	6 (15.4)	7 (10.6)	-
9-12	16 (21.9)	10 (25.6)	19 (28.8)	9 (22.5)
>12	28 (38.5)	21 (53.8)	37 (56.1)	29 (72.5)
Total number of treatment sessions, mean (SD)	19.56 (20.5)	22.92 (19.4)	26.33 (16.34)	34.4 (23.0)
Satisfaction with the result of treatment? (0-10), mean (SD) ‡	7.93 (2.2)	7.51 (3.0)	8.25 (1.6)	8.45 (1.1)

Legend to Table 3:

PT= physical therapy; THA=total hip arthroplasty; TKA= total knee arthroplasty.

† Location of PT: multiple answers possible.

‡ asked to patients.

Declaration

Ethics approval and consent to participate

The study has been reviewed and approved by the Medical Ethics Committee (registration code NL61763.078.17) of the XXX. This approval covered all study sites. All participants signed an informed consent form prior to start of the study.

Consent for publication

No individual person's data will be published, therefore consent for publication is not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

MG,WP, TVV and MR have contributed to the conception of the study. LG performed the analysis and wrote the manuscript. UY supported LG with conduction of analysis and writing. All authors were involved in the study design and revising the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

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Chapter 8

Impact of the COVID-19 lockdown on patient-reported outcome measures in Dutch hip and knee arthroplasty patients

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Abstract

Background and purpose: During the first COVID-19 lockdown elective surgery was greatly reduced. Prioritization of patients with greater need and expected benefit in terms of Quality of Life was advised. The lockdown also potentially affected follow-up outcomes. Therefore, our study compared patient-reported outcome measures (PROMs) retrieved during the lockdown of Dutch primary total hip and knee arthroplasty (THA, TKA) patients to previous years.

Patients and methods: We performed cross-sectional analyses using national data from the Dutch Orthopaedic Registry (LROI). All primary elective THA and TKA patients with preoperative or postoperative PROMs (EQ-5D-3L index, OHS/OKS) during the first COVID-19 lockdown between 23rd of March to 15th of July 2020 were included. Patients with PROMs during the same months in 2018 plus 2019 were used as control. Finally, 33,453 THA and 27,335 TKA patients were included. Patient characteristics were compared during versus before the lockdown. Subsequently, the lockdown effect on PROMs scores was analysed with multivariable linear regression.

Results: During the COVID-19 lockdown, THA and TKA patients preoperatively had a lower age and BMI, and more often had surgery in private clinics. Both preoperative PROMs in THA patients, but not in TKA patients, were worse (EQ-5D: Adjusted Mean Difference (AMD) -0.021, $p<0.001$) during the lockdown compared to prior years. Both postoperative PROMs in THA and TKA patients were better during the lockdown (12-month EQ-5D in THA: AMD 0.010, $p=0.003$; 12-month EQ-5D in TKA: AMD 0.013, $p<0.001$).

Interpretation: During the COVID-19 lockdown, THA patients had slightly worse preoperative PROMs, suggesting selection of patients with greater urgency. Postoperative PROMs in both THA and TKA patients differed minimally. Overall, the observed differences were likely not clinically relevant.

Introduction

In response to the SARS-CoV-2 (COVID-19) pandemic, extreme measures have been taken to contain the virus, most notable being national lockdowns and quarantine policies (1). Several studies noted an increase in psychological distress symptoms of e.g. anxiety feelings, and a decrease in Quality of Life in the general population following the pandemic and the measures taken (2-4). This effect increased with lower age, female sex, poor health status and low socio-economic status (SES) (5, 6). In most countries there were regional variations in infection rates, also observed in the Netherlands (7). People inhabiting places with higher infection rates might experience increased effects on mental and physical health as well (8).

In the Netherlands the first lockdown was instigated on the 16th of March 2020, which was relaxed 1st of June 2020. During the lockdown, large events were prohibited, and people were advised to stay at and work from home if possible. Also, non-essential shops and places including outpatient healthcare facilities such as physical therapists were closed. Large shifts in healthcare resources were needed and most elective orthopedic care was reduced to a minimum (9). The Dutch Orthopaedic Society issued a statement on the 1st of May 2020, to restrict elective arthroplasty to patients who have the largest need and expected benefit in terms of Quality of Life (10). Also, to minimize COVID-19 infection risks, healthier patients eligible for day treatment were preferred (11).

The lockdown in combination with the pandemic also likely resulted in a lower grade of physical activity and postoperative rehabilitation, negatively influencing the postoperative patient-reported outcome measures (PROMs) of these patients (12, 13). Reporting this impact has important implications regarding the assessment of effectiveness of interventions during a pandemic and the lockdown.

This study compared PROMs retrieved during the COVID-19 lockdown of primary THA and TKA patients registered in the Dutch Orthopaedic Registry (Dutch abbreviation: LROI) to previous years. We had the following hypotheses. First, preoperative PROMs are lower due to a selection effect based on urgency assessment. Second, especially early postoperative PROMs are lower due to the impaired rehabilitative process. Third, at all follow-up points the lockdown negatively affect PROMs e.g. through anxiety feelings. Specific subgroups which were possibly more affected by the COVID-19 lockdown were also analysed.

Methods

Dutch Orthopaedic Registry (LROI)

We used data from the LROI, which prospectively collects data on orthopedic interventions in the Netherlands. The LROI contains demographic and surgical information, and for arthroplasties additionally prosthesis characteristics. Data completeness is over 95% for primary THA and TKA patients (14). Since 2014 the Dutch Orthopaedic Society strongly recommends the collection of internationally validated general health and disease-specific PROMs in elective arthroplasty. PROMs are retrieved before surgery (at max. 182 days before surgery), at 3-month follow-up (63-110 days) in THA and at 6-month follow-up (154-210 days) in TKA, and at 12-month follow-up (323-407 days) in both. Preoperative PROMs are mostly completed at the outpatient clinic, whilst postoperative PROMs are completed either electronically after invitation via email, or with pen and paper. In 2018 and 2019, 63–66% of THA patients for osteoarthritis completed preoperative PROMs, whilst 34–42% completed both preoperative and postoperative PROMs. In TKA these rates were 55–61% and 30–40% respectively. During COVID-19 in 2020 response rates were in the same ranges (9).

Study design

We performed a retrospective cross-sectional study, and adhered to the STROBE guidelines. Primary THA and TKA patients for any elective indication were selected. Patients who filled out either pre- or postoperative PROMs between the 23rd of March and the 15th of July 2020 were included. This window allowed for a potential impact of the lockdown to reach its full extent. THA and TKA patients were analysed separately. This resulted in 6 COVID-19 lockdown groups (THA: preoperative, 3- and 12-month follow-up; TKA: preoperative, 6- and 12-month follow-up). Using the same inclusion window patients from 2018 plus 2019 were selected as control groups. COVID-19 groups were compared to the respective control groups, resulting in 6 cross-sectional comparisons.

Obtained data

The following patient characteristics were obtained: age, sex, BMI, Charnley score, ASA score, previous surgery of the joint, indication for joint replacement (osteoarthritis or non-osteoarthritis such as posttraumatic), and type of hospital (general, academic or private). Additionally, data on COVID-19 infection rate and SES were linked to registry data using patients' 4-digit postal codes. The Dutch Institute for Health and Milieu published COVID-19 infection rates in the Netherlands bi-weekly (15). The Netherlands is divided into 12 'provinces'. Each province was given an infection rate

score 1 through 5 calculated with 2-week intervals (1: ≤24, 2: 25-49, 3:50-74, 4: 75-99, 5: ≥100 infections per 100,000 inhabitants). This score was assigned to records based on the date the PROMs were filled in. Data on SES were obtained from the Dutch Institute of Social Research (16). For each 4-digit postal code area with more than 100 inhabitants, a numeric SES-score was created. The SES-score is calculated with multiple variables from a postal code area: mean income per household, % households with a low income, % unemployed inhabitants and % households with an on average low education. This method to approximate the individual SES score is considered a validated technique (17). The SES-score was categorized into 5 groups based on the quantiles. These groups were referred to as quintiles.

Patient-reported outcome measures

The EuroQol 5-Dimensions (EQ-5D-3L) questionnaire, Visual Analogue Scale (EQ-VAS), and 2 disease-specific questionnaires were obtained (18). For THA the latter were the Oxford Hip Score (OHS) and the short version of the Hip disability and Osteoarthritis Outcome Score (HOOS-PS), and for TKA these were the Oxford Knee Score (OKS) and the short version of the Knee disability and Osteoarthritis Outcome Score (KOOS-PS) (20-22). We selected the EQ-5D-3L and the Oxford set as our main outcome measures. For the EQ-5D-3L an overall index score was calculated using the Dutch National Value set (19).

Statistics

Patient characteristics of the COVID-19 groups were compared with the respective control groups using the chi-square and student t-test. The representativeness of responders was assessed by also comparing patient characteristics of each COVID-19 group to non-responders operated during the same period based on the inclusion window. The pattern of representativeness was compared to previous years (2018 plus 2019). Duplicate cases, i.e. patients who had their contralateral joint replaced as well, made up a small number of patients (THA: 5%, TKA: 6%) in the entire cohort. Given the present study design, they were not expected to affect results; therefore they were not removed.

Subsequently, PROMs retrieved during the COVID-19 lockdown were compared to control groups using multivariable linear regression analysis. Potential confounders were included based on the theoretical association with the exposure (COVID-19 lockdown) and the known association with outcomes (PROMs) (23). The analyses were adjusted for sex, BMI, ASA score, Charnley score, previous surgery of the joint, indication for joint replacement, type of hospital, and SES (24-27). If a PROM was statistically significantly associated with the COVID-19 group, interaction terms

between this group and specific high risk subgroups were used to explore whether the COVID-19 lockdown had a different effect in these subgroups. The subgroups which we explored were BMI >30, ASA ≥3, age >70, non-osteoarthritis indication for joint replacement, female sex, and SES quintile ≤2. Similarly, we investigated the effect of inhabiting a region with ≥50 COVID-19 infections per 100,000 inhabitants. Each interaction term was added individually to the regression analysis which was then assessed for fit and significance. If interaction terms were not relevant, i.e. resulted in a lower R2 (worsened model fit) and/or did not reach statistical significance, they were removed from the analyses. Robust 95% confidence intervals (CIs) were calculated to account for heteroscedasticity of the PROMs outcomes. The differences are presented as Adjusted Mean Differences (AMDs) with robust CIs and p-values. Clinical relevance was determined by comparing AMDs of the main analyses to currently accepted Minimal Clinically Important Differences (MCIDs). These have been reported to be 0.03 for the EQ-5D-3L index in musculoskeletal patients, 5.2 for the OKS and 4.8 for the OKS in arthroplasty patients (28, 29). Potential clinical relevance was confirmed if the CIs bounds exceeded the defined MCIDs. A p-value <0.05 was considered significant. All analyses were performed using SPSS (version 25, IBM Corp, Armonk, New York, United States of America).

Ethics, funding, and potential conflicts of interest

This study was based on registry data with an extensive protocol for legally conform data access, therefore no ethical approval additional to LROI permission was required. One of the authors (JB) has received funding from EuroQol for a PhD project including this study. The views expressed by the authors in this manuscript do not necessarily reflect the views of the EuroQol group.

Results

Included patients

There were 33,453 elective THA and 27,335 elective TKA patients eligible for inclusion (Figure 1). The number of patients at 6-month follow-up (TKA) and 12-month follow-up during the COVID-19 lockdown was similar to prior years. There were 35 to 50% fewer preoperative and 3-month follow-up (THA) patients.

Patient characteristics and representativeness

Characteristics of patients during the lockdown were compared to the control groups for THA and TKA separately (Table 1). Most notable differences occurred before surgery: during the lockdown both THA and TKA patients had a lower age and BMI,

and more often had surgery in private clinics. THA patients slightly more often had a non-osteoarthritis indication, and TKA patients slightly more often were male and had a Charnley score A/B1/B2 during the lockdown. At 6- and 12-month follow-up in TKA, and at 12-month follow-up in THA, patients more often had an ASA score III-IV. Other characteristics of patients with postoperative PROMs were comparable during the lockdown.
Characteristics of responders were also compared to non-responders for THA and TKA separately at each follow-up point (Tables 1-4, Supplementary data). The comparison of patterns confirmed that elective care was reduced during the lockdown and confirmed abovementioned differences in patient characteristics. Responders at all follow-up points were slightly younger, more often were male, more often had joint-replacement for the indication osteoarthritis, and had a better orthopedic (i.e. Charnley score) and general vitality (i.e. ASA score) scores. During the lockdown similar patterns emerged, except for type of hospital. In control years, preoperative responders had surgery in general hospitals more often, whilst during the lockdown they were more likely to have had surgery in private clinics.

PROMs

The estimated mean EQ-5D index for each comparison between PROMs retrieved during the COVID-19 lockdown and control groups is presented in Figure 2. In THA patients, the adjusted EQ-5D index and OHS were slightly worse during the COVID-19 lockdown (Table 2). In TKA patients, both PROMs were unchanged during the lockdown. For Adjusted Mean Differences in EQ-VAS and HOOS-PS/KOOS-PS see Table 5, Supplementary data.

In THA patients, at 3-month and 12-month follow-up the EQ-5D index and OHS were slightly better during the lockdown. In TKA patients, the EQ-5D index and OKS did not differ at 6-month follow-up, whilst at 12-month follow-up they were slightly better. All identified differences and CI bounds did not exceed predefined MCIDs.

Subgroup analyses

Several interaction terms reached significance, however, they were not consistent across PROMs nor follow-up points. Only in THA patients at 12-month follow-up the term for inhabiting a region with ≥50 infections per 100.000 inhabitants reached statistical significance in both PROMs. Higher EQ-5D index and OHS scores (EQ-5D AMD 0.014, CI 0.007 – 0.022; OHS AMD 0.93, CI 0.60 – 1.27) were counteracted (EQ-5D Interaction Term -0.012, CI -0.022 – -0.001; OHS Interaction Term -0.58, CI -1.03 – -0.13).

Discussion

Our study demonstrated only small differences in preoperative and postoperative PROMs retrieved during the COVID-19 lockdown compared to previous years in Dutch THA and TKA patients. In THA patients most preoperative PROMs were slightly worse during the lockdown, which was not the case in TKA patients. This suggests a selection effect based on urgency assessment reflected in preoperative PROMs in THA. In both THA and TKA patients, most postoperative PROMs were slightly better during the lockdown. Contrary to our hypotheses, this suggests that the rehabilitation process remained mostly unaffected, and that an overall negative lockdown effect was not observed. Identified differences and CI bounds of all PROMs used in this study did not exceed predefined MCIDs, and are likely not clinically relevant.

This study had several strengths. 2 additional area-based variables were linked to the LROI data set, namely SES and COVID-19 infection rate. Also, multiple PROMs were used at 3 measurement moments, and an extensive set of potential confounders were included. Finally, given the study design (national registry study) the results can be considered generalizable for Dutch orthopedics.

This study had the following limitations. First, in this cross-sectional study we did not explore the effect of the lockdown on the longitudinal change scores (i.e. difference between pre- and postoperative PROMs). These analyses would provide information on a different hypothesis, whether a lockdown effect before surgery could persist into recovery. Furthermore, due to privacy laws the area-based variables were not allowed to contain patient identifiable information. Therefore, we could not study whether regional differences in PROMs response percentage and representativeness occurred. Additionally, the response rate of PROMs is relatively low in the LROI. However, response rates remained unchanged during the lockdown. Lastly, although the lockdown in the Netherlands shared many similarities with other countries during the first COVID-19 wave, certain differences may still influence the generalizability of results to other countries.

Our study confirms the reduction in elective joint replacements during lockdown, and that a shift of orthopedic care from general hospitals to private clinics occurred during the first COVID-19 lockdown. Furthermore, younger patients with a lower BMI were selected for arthroplasty during the lockdown. Early on in the pandemic focus had shifted towards how to prioritize treatment with reduced capacity for elective surgery (30-32). As the formal announcement of the Dutch Orthopaedic Society was

made public halfway the first lockdown, it could reflect a shift in collective clinical opinion of Dutch orthopedic surgeons. They may have been aware of risk factors for worse COVID-19 infections such as high age and BMI, and (sub-)consciously selected candidates with a lower risk. A limitation of registry data is that we are unable to discern to what extent self-selection played a role, e.g. patients delaying the procedure themselves because of fear to become infected in the hospital.
Besides selection based on characteristics, we additionally found evidence of selection based on urgency. Even after adjustment, THA patients had worse preoperative EQ-5D index and disease-specific PROMs during the COVID-19 lockdown compared to previous years. In TKA patients similar PROMs scores during COVID-19 were observed compared to control years; we do not have a certain explanation for this contrast with THA patients.

We noted no difference or rather a slight improvement in most PROMs scores in both THA and TKA patients compared to previous years, an unexpected finding. This was already apparent at short-term (3- and 6-month for THA and TKA respectively), which indicates that the rehabilitation success was unaffected. All arthroplasty patients in the Netherlands receive an unsupervised exercise schedule after surgery, and generally receive postoperative outpatient exercise therapy subsequently. It is possible that unsupervised therapy was sufficient, a notion supported by contemporary systematic reviews (12, 13). However, this finding should be interpreted with caution. Although during the lockdown physical therapists had to close their physical practice, in approximately 25% of patients they continued via telemedicine, which is not recorded in the LROI (33). Moreover, many patients included at the short-term cross-sectional comparison will have had surgery sometime before the lockdown, and thus might have already initiated physical therapy.

A global scientific body reported severe psychological stress during the COVID-19 pandemic. This is also reflected in studies using the EQ-5D, where lower scores are found in different populations from different nationalities including Dutch, mainly driven by poorer scores in the pain/discomfort and the anxiety/depression (3, 4). The slightly higher postoperative PROMs indicate there was no direct negative effect of the lockdown in this Dutch orthopedic population. In THA patients, inhabiting a region with a COVID-19 high infection rate appeared to negate the improvement in EQ-5D and OHS during the lockdown. However, this effect was minimal and resulted in approximately equal scores compared to prior the lockdown, which we do not believe provides sufficient evidence of an effect of this interaction term. These findings are in line with a recent study on the impact of COVID-19 on PROMs in hand-wrist patients, which had a similar cross-sectional study design (34). Combined,

these results attest to the fact that the general and the orthopedic population do not necessarily experience the same impact of the COVID-19 lockdown.

A potential explanation for the discrepancy in EQ-5D index between the Dutch arthroplasty patient group and the general population is "response-scale heterogeneity", which refers to the difference in the way individuals interpret a response scale, i.e. a PROM. For instance, if a difference in health occurs between two groups, this may reflect a true difference in health or that the groups perceive the response scale differently due to psychological mechanisms (35). In this population, this may have been caused by feeling privileged during the lockdown: patients considered themselves lucky to have already had their hip or knee replacement before the pandemic hit.

In conclusion, we demonstrated PROMs scores in Dutch primary THA and TKA patients during the COVID-19 lockdown were hardly affected. Orthopedic surgeons were forced to delay elective surgery due to COVID-19 and also to identify the best candidates for surgery. The observed lower preoperative PROMs scores of THA patients during the COVID-19 lockdown could indicate a (sub-)conscious selection effect based on urgency. Postoperative PROMs in both THA and TKA patients differed minimally. Overall, differences found were likely not clinically relevant.

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Figures

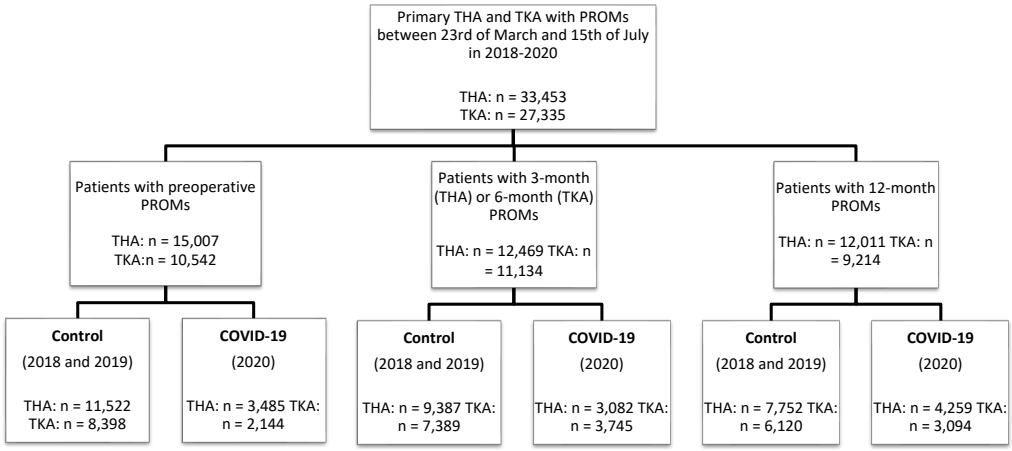


Figure 1: Flowchart of included primary THA and TKA patients with completed PROMs during defined inclusion windows. In a small number of patients with PROMs at multiple measurement points the postoperative follow-up PROM falls in an inclusion window in the subsequent year. Hence, the number of patients in the defined groups exceed the total number of patients.

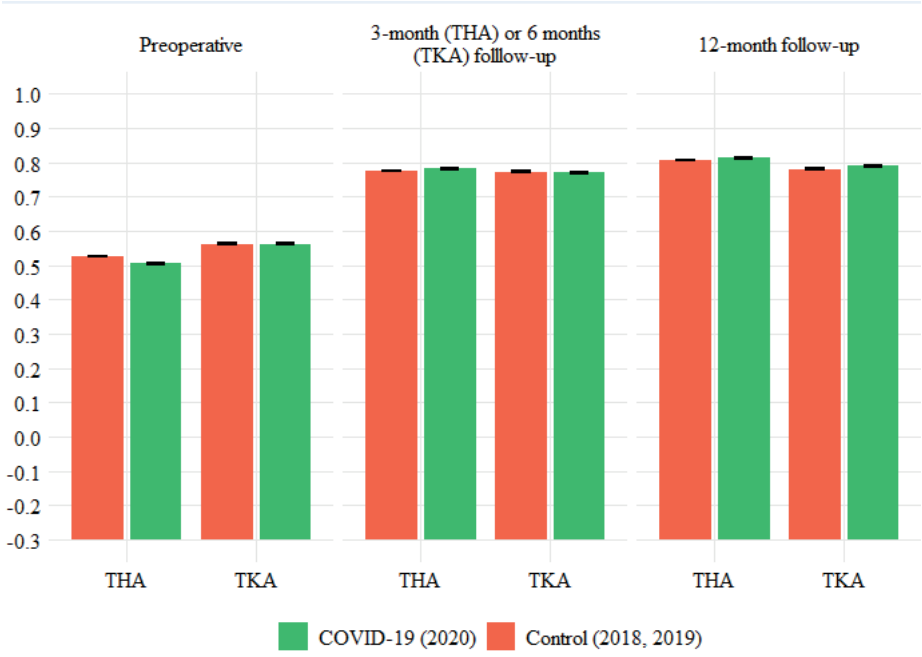
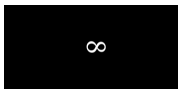


Figure 2: Estimated mean EQ-5D index scores for COVID-19 and control groups, for primary THA and primary TKA separately. A higher EQ-5D index score represents better health status. The error bars represent the 95% confidence intervals of the predicted mean; the upper and lower limit are very close to each other due to the large number of patients for each bar.

Tables

Table 1: Characteristics of primary THA patients with completed PROMs during inclusion windows

	Preoperative			3-month postoperative			12-month postoperative		
Factor	Control (n = 11,522)	COVID-19 (n = 3,485)	p-value	Control (n = 9,387)	COVID-19 (n = 3,082)	p-value	Control (n = 7,752)	COVID-19 (n = 4,259)	p-value
Age, mean (SD	69 (10)	68 (10)	0.006	69 (9.8)	68 (10)	0.05	69 (10)	69 (10)	0.4
BMI, mean (SD)	27.4 (4.6)	27.0 (4.3)	< 0.001	27.3 (4.5)	27.2 (4.3)	0.2	27.4 (4.5)	27.4 (4.5)	1
Female sex[a]	7,415 (64)	2,225 (64)	0.6	5,873 (63)	1,922 (62)	0.9	4,992 (64)	2,698 (63)	0.3
Previous surgery on the joint	475 (4.1)	158 (4.5)	0.3	344 (3.7)	109 (3.5)	0.7	288 (3.7)	164 (3.9)	
ASA classifi-cation[a]			0.1			0.2			< 0.001
I–II	9,018 (78)	2,772 (80)		7,558 (81)	2,515 (82)		6,394 (82)	3,327 (78)	
III–IV	2,504 (22)	712 (20)		1,829 (19)	565 (18)		1,358 (18)	932 (22)	
Type of hospital[a]			< 0.001			< 0.001			< 0.001
General	10,285 (89)	2,748 (79)		8,103 (86)	2,521 (82)		6,903 (89)	3,663 (86)	
Private	1,002 (8.7)	683 (20)		1,086 (12)	499 (16)		684 (8.8)	488 (11)	
Academic	235 (2.0)	54 (1.5)		198 (2.1)	62 (2.0)		165 (2.1)	108 (2.5)	
Indication[a]			< 0.001			0.8			0.6
Osteo-arthritis	10,696 (93)	3,160 (91)		8,727 (93)	2,860 (93)		7,196 (93)	3,940 (93)	
Non-osteo-arthritis	818 (7.1)	319 (9.2)		658 (7.0)	221 (7.2)		556 (7.2)	317 (7.4)	
Charnley classifi-cation[a]			0.1			0.3			0.6
A/B1/B2	10,975 (95)	3,304 (95)		8,986 (96)	2,930 (95)		7,406 (96)	4,059 (95)	



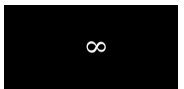
C	397 (3.4)	105 (3.0)		271 (2.9)	99 (3.2)		249 (3.2)	136 (3.2)	
N/A	146 (1.3)	58 (1.7)		127 (1.4)	50 (1.6)		95 (1.2)	62 (1.5)	
Socioeconomic status score[a]			0.3			0.01			0.8
3rd–5th quintile (highest)	6,357 (55)	1,954 (56)		5,404 (58)	1,707 (55)		4,382 (57)	2,407 (57)	
1st–2nd quintile (lowest)	5,058 (44)	1,497 (43)		3,853 (41)	1,349 (44)		3,302 (43)	1,830 (43)	
Regional COVID infection rate per 100.000[a]									
≤ 24	11,522 (100)	2,956 (85)	–	9,387 (100)	1,592 (52)	–	7,752 (100)	2,629 (62)	–
25 – 49	–	319 (9.2)		–	621 (20)		–	606 (14)	
50 – 74	–	80 (2.3)		–	346 (11)		–	413 (10)	
75 – 99	–	48 (1.4)		–	234 (7.6)		–	277 (6.5)	
≥ 100	–	49 (1.4)		–	256 (8.3)		–	312 (7.3)	

Data is presented as n (%), unless reported otherwise. The control groups were subsequently compared to the respective COVID-19 groups except for the variable infection rate.

[a] Numbers do not always add up due to missing or unknown values.

Table 2: Characteristics of primary TKA patients with completed PROMs during inclusion windows

	Preoperative			6-month postoperative			12-month postoperative		
Factor	Control (n = 8,398)	COVID-19 (n = 2,144)	p-value	Control (n =7,389)	COVID-19 (n = 3,745)	p-value	Control (n = 6,120)	COVID-19 (n = 3,094)	p-value
Age, mean (SD)	69 (8.9)	69 (8.5)	0.02	68 (8.4)	69 (8.4)	0.1	69 (8.7)	69 (8.5)	0.9
BMI, mean (SD)	29.7 (5.0)	27.0 (4.3)	0.1	29.4 (4.8)	29.5 (4.8)	0.3	29.7 (5.0)	29.8 (4.9)	0.5
Female sex[a]	5,390 (64)	1,308 (61)	0.006	4,458 (60)	2,291 (61)	0.4	3,819 (62)	1,946 (63)	0.6
Previous surgery on the joint	2,098 (25)	527 (25)	0.2	2,049 (28)	948 (25)	< 0.001	1,682 (27)	787 (25)	0.6
ASA classifi-cation[a]			0.3			0.003			< 0.001
I–II	6,322 (75)	1,636 (76)		5,930 (80)	2,916 (78)		4,912 (80)	2,340 (76)	
III–IV	2,075 (25)	504 (24)		1,459 (20)	829 (22)		1,208 (20)	754 (24)	
Type of hospital[a]			< 0.001			< 0.001			< 0.001
General	7,399 (88)	1,715 (80)		6,312 (85)	3,064 (82)		5,274 (86)	2,563 (83)	
Private	840 (10)	412 (19)		983 (13)	617 (16)		765 (13)	470 (15)	
Academic	159 (1.9)	17 (0.8)		94 (1.3)	64 (1.7)		81 (1.3)	61 (2.0)	
Indication[a]			0.3			0.1			0.1
Osteo-arthritis	8,117 (97)	2,056 (96)		7,199 (97)	3,626 (97)		5,957 (97)	2,990 (97)	
Non-osteo-arthritis	275 (3.3)	79 (3.7)		190 (2.6)	114 (3.0)		163 (2.7)	98 (3.2)	
Charnley classifi-cation[a]			0.006			0.5			0.6
A/B1/B2	8,016 (95)	2,074 (97)		7,081 (96)	3,602 (96)		5,860 (96)	2,950 (95)	
C	359 (4.3)	59 (2.8)		300 (4.1)	135 (3.6)		247 (4.0)	135 (4.4)	



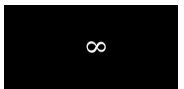
N/A	20 (0.2)	5 (0.2)		7 (0.1)	4 (0.1)		13 (0.2)	9 (0.3)	
Socio-economic status score[a]			0.2			0.2			1
3rd–5th quintile (highest)	4,404 (52)	1,162 (54)		4,009 (54)	1,978 (53)		3,273 (53)	1,637 (53)	
1st–2nd quintile (lowest)	3,926 (47)	967 (45)		3,304 (45)	1,731 (46)		2,807 (46)	1,400 (45)	
Regional COVID infection rate per 100.000[a]									
≤ 24	8,398 (100)	1,811 (84)	–	7,389 (100)	2,367 (63)	–	6,120 (100)	1,909 (62)	–
25 – 49	–	191 (8.9)		–	548 (15)		–	425 (14)	
50 – 74	–	50 (2.3)		–	338 (9.0)		–	284 (9.2)	
75 – 99	–	47 (2.2)		–	232 (6.2)		–	191 (6.2)	
≥ 100	–	31 (1.4)		–	225 (6.0)		–	228 (7.4)	

Data is presented as n (%), unless reported otherwise. The control groups were subsequently compared to the respective COVID-19 groups except for the variable infection rate.

[a] Numbers do not always add up due to missing or unknown values.

Table 3: Characteristics of primary THA patients who were operated in the same period based on the inclusion window in 2020 (COVID-19)

	Preoperative			3-month postoperative			12-month postoperative		
	Non-responders (n = 3,020)	Responders (n = 3,485)	p-value	Non-responders (n = 4,237)	Responders (n = 3,082)	p-value	Non-responders (n = 6,267)	Responders (n = 4,259)	p-value
Age, mean (SD)	69 (11)	68 (10)	0.02	69 (11)	68 (10)	< 0.001	70 (11)	69 (10)	< 0.001
BMI, mean (SD)	26.8 (4.7)	27.0 (4.3)	0.03	27.3 (4.7)	27.2 (4.4)	0.5	27.3 (4.7)	27.4 (4.5)	0.5
Female sex[a]	1,986 (66)	2,225 (64)	0.1	2,787 (66)	1,922 (62)	0.003	4,148 (66)	2,698 (63)	0.003
Previous surgery on the joint	177 (5.9)	158 (4.5)	0.02	207 (4.9)	109 (3.5)	0.005	313 (5.0)	164 (3.9)	0.002
ASA classifi-cation[a]			< 0.001			< 0.001			< 0.001
I–II	2,190 (73)	2,772 (80)		3,107 (73)	2,515 (82)		4,647 (74)	3,327 (78)	
III–IV	829 (27)	712 (20)		1,127 (27)	565 (18)		1,620 (26)	932 (22)	
Type of hospital[a]			< 0.001			< 0.001			< 0.001
General	2,569 (85)	2,748 (79)		3,810 (90)	2,521 (82)		5,516 (88)	3,663 (86)	
Private	347 (11)	683 (20)		320 (7.6)	499 (16)		562 (9.0)	488 (11)	
Aca-demic	104 (3.4)	54 (1.5)		107 (2.5)	62 (2.0)		189 (3.0)	108 (2.5)	

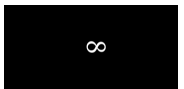


Indication[a]			< 0.001		< 0.001		< 0.001
Osteo-arthritis	2,115 (70)	3,160 (91)		3,411 (81)	2,860 (93)	5,112 (82)	3,940 (93)	
Non-osteoarthritis	901 (30)	319 (9.2)		824 (19)	221 (7.2)	1,150 (18)	317 (7.4)	
Charnley classification[a]			< 0.001		< 0.001		< 0.001
A/B1/B2	2,438 (81)	3,304 (95)		3,660 (86)	2,921 (95)	5,589 (89)	4,051 (95)	
C	88 (2.9)	105 (3.0)		128 (3.0)	99 (3.2)	160 (2.6)	136 (3.2)	
N/A	479 (16)	58 (1.7)		429 (10)	50 (1.6)	495 (7.9)	62 (1.5)	
Socio-economic status score[a]			0.2		0.9		0.1
3rd–5th quintile (highest)	1,648 (55)	1,954 (56)		2,353 (56)	1,707 (55)	3,371 (54)	2,407 (57)	
1st–2nd quintile (lowest)	1,347 (45)	1,497 (43)		1,850 (44)	1,349 (44)	2,723 (43)	1,830 (43)	

The PROMs responders were compared with the respective non-responders.
Data is presented as n (%), unless reported otherwise.
[a] Numbers do not always add up due to missing or unknown values.

Table 4: Characteristics of primary THA patients who were operated in the same period based on the inclusion window in 2018 plus 2019 (control)

	Preoperative			6-month postoperative			12-month postoperative		
Factor	Nonresponders (n = 1,857)	Responders (n = 2,144)	p-value	Nonresponders (n = 5,079)	Responders (n = 3,745)	p-value	Nonresponders (n = 4,608)	Responders (n = 3,094)	p-value
Age, mean (SD)	69 (9.2)	69 (8.5)	0.2	69 (8.8)	69 (8.4)	<0.001	70 (9.0)	69 (8.5)	<0.001
BMI, mean (SD)	29.6 (5.1)	29.5 (5.0)	0.6	29.6 (5.0)	29.5 (4.8)	0.2	30.1 (5.1)	29.8 (4.9)	0.01
Female sex[a]	1,187 (64)	1,308 (61)	0.06	3,212 (63)	2,291 (61)	0.05	3,083 (67)	1,946 (63)	<0.001
Previous surgery on the joint	446 (24)	527 (25)	0.7	1,074 (21)	948 (25)	0.001	941 (20)	787 (25)	<0.001
ASA classification[a]			0.2			<0.001			0.001
I–II	1,388 (75)	1,636 (76)		3,778 (74)	2,916 (78)		3,320 (72)	2,340 (76)	
III–IV	466 (25)	504 (24)		1,298 (26)	829 (22)		1,287 (28)	754 (24)	
Type of hospital[a]			< 0.001			<0.001			<0.001
General	1,470 (79)	1,715 (80)		4,301 (85)	3,064 (82)		3,974 (86)	2,563 (83)	
Private	342 (18)	412 (19)		677 (13)	617 (16)		533 (12)	470 (15)	
Academic	45 (2.4)	17 (0.8)		101 (2.0)	64 (1.7)		101 (2.2)	61 (2.0)	



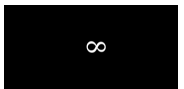
Indication[a]			0.006			0.1		0.1
Osteo-arthritis	1,750 (94)	2,056 (96)		4,879 (96)	3,626 (97)		4,418 (96)	2,990 (97)	
Non-osteo-arthritis	102 (5.5)	79 (3.7)		189 (3.7)	114 (3.0)		175 (3.8)	98 (3.2)	
Charnley classification[a]			0.003			0.2		0.04
A/B1/B2	1,762 (95)	2,061 (96)		4,870 (96)	3,588 (96)		4,419 (96)	2,932 (95)	
C	72 (3.9)	59 (2.8)		174 (3.4)	135 (3.6)		150 (3.3)	135 (4.4)	
N/A	16 (0.9)	5 (0.2)		14 (0.3)	4 (0.1)		14 (0.3)	9 (0.3)	
Socioeconomic status score[a]			1			0.4		0.1
3rd–5th quintile (highest)	1,009 (54)	1,162 (54)		2,596 (51)	1,978 (53)		2,303 (50)	1,637 (53)	
1st–2nd quintile (lowest)	841 (45)	967 (45)		2,360 (46)	1,731 (46)		2,116 (46)	1,400 (45)	

The PROMs responders were compared with the respective non-responders. Data is presented as n (%), unless reported otherwise.

[a] Numbers do not always add up due to missing or unknown values.

Table 5: Characteristics of primary TKA patients who were operated in the same period based on the inclusion window in 2020 (COVID-19)

	Preoperative			6-month postoperative			12-month postoperative		
Factor	Nonresponders (n = 8,653)	Responders (n = 8,398)	p-value	Nonresponders (n = 9,786)	Responders (n = 7,389)	p-value	Nonresponders (n = 9,130)	Responders (n = 6,120)	p-value
Age, mean (SD)	69 (9.2)	69 (8.9)	0.7	69 (9.2)	68 (8.4)	< 0.001	69 (9.6)	69 (8.7)	< 0.001
BMI, mean (SD)	29.9 (5.2)	29.7 (5.0)	0.01	29.7 (5.0)	29.4 (4.8)	< 0.001	30.0 (5.2)	29.7 (5.0)	0.001
Female sex[a]	5,521 (64)	5,390 (64)	0.6	6,188 (63)	4,458 (60)	< 0.001	6,009 (66)	3,819 (62)	< 0.001
Previous surgery on the joint	1,921 (22)	2,098 (25)	0.01	2,322 (24)	2,049 (28)	< 0.001	2,272 (25)	1,682 (27)	< 0.001
ASA classification[a]			0.1			0.01			< 0.001
I–II	6,604 (76)	6,322 (75)		7,695 (79)	5,930 (80)		6,912 (76)	4,912 (80)	
III–IV	2,047 (24)	2,075 (25)		2,089 (21)	1,459 (20)		2,215 (24)	1,208 (20)	
Type of hospital[a]			< 0.001			< 0.001			< 0.001
General	6,999 (81)	7,399 (88)		8,251 (84)	6,312 (85)		7,903 (87)	5,274 (86)	
Private	1,463 (17)	840 (10)		1,321 (13)	983 (13)		970 (11)	765 (13)	
Academic	191 (2.2)	159 (1.9)		214 (2.2)	94 (1.3)		257 (2.8)	81 (1.3)	
Indication[a]			0.1			< 0.001			< 0.001

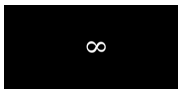


Osteo-arthritis	8,324 (96)	8,117 (97)		9,415 (96)	7,199 (97)	8,752 (96)	5,957 (97)	
Non-osteoarthritis	325 (3.8)	275 (3.3)		316 (3.2)	190 (2.6)	376 (4.1)	163 (2.7)	
Charnley classification[a]			< 0.001			< 0.001		0.04
A/B1/B2	8,332 (96)	7,984 (95)		9,394 (96)	7,053 (96)	8,750 (96)	5,843 (95)	
C	263 (3.0)	359 (4.3)		321 (3.3)	300 (4.1)	310 (3.4)	247 (4.0)	
N/A	32 (0.4)	20 (0.2)		39 (0.4)	7 (0.1)	31 (0.3)	13 (0.2)	
Socio-economic status score[a]			0.6			< 0.001		< 0.001
3rd–5th quintile (highest)	4,388 (51)	4,404 (52)		5,002 (51)	4,009 (54)	4,541 (50)	3,273 (53)	
1st–2nd quintile (lowest)	3,984 (46)	3,926 (47)		4,609 (47)	3,304 (45)	4,409 (48)	2,807 (46)	

The PROMs responders were compared with the respective non-responders. Data is presented as n (%), unless reported otherwise.
[a] Numbers do not always add up due to missing or unknown values.

Table 6: Characteristics of primary TKA patients who were operated in the same period based on the inclusion window in 2018 plus 2019 (control)

	Preoperative		**3-/6-month postoperative**		**12-month postoperative**	
Factor	AMD (CI)	p-value	AMD (CI)	p-value	AMD (CI)	p-value
Total Hip Arthroplasty	n = 15,007		n = 12,469		n = 12,011	
Without interaction terms						
EQ-5D index[a]	–0.021 (–0.029 to –0.013)	< 0.001	0.008 (0.001 to 0.015)	0.03	0.010 (0.003 to 0.016)	0.003
With interaction terms	no relevant interaction terms					
BMI > 30 **EQ-5D index**[a]			–0.019 (–0.035 to – 0.002) 0.012 (0.005 to 0.020)	0.02 0.002		
Infections ≥ 50 per 100.000 **EQ-5D index**[a]					– 0.012 (–0.022 to –0.001) 0.014 (0.007 to 0.022)	0.03 < 0.001
Without interaction terms						
OHS[a]	–0.95 (–1.30 to –0.60)	< 0.001	0.44 (0.13 to 0.74)	0.005	0.71 (0.42 to 1.00)	< 0.001



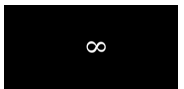
With interaction terms	no relevant interaction terms		no relevant interaction terms			
Infections ≥ 50 per 100.000 **OHS**[a]					–0.58 (–1.03 to –0.13) 0.93 (0.60 to 1.27)	0.01 < 0.001
Total Knee Arthroplasty	n = 10,542		n = 11,134		n = 9,214	
Without interaction terms						
EQ-5D index[a]	–0.003 (–0.012 to 0.007)	0.6	0.000 (–0.007 to 0.007)	1.0	0.013 (0.006 to 0.021)	< 0.001
With interaction terms	–[b]		–[b]		no relevant interaction terms	
Without interaction terms						
OKS[a]	–0.03 (–0.36 to 0.41)	0.9	0.12 (–0.22 to 0.47)	0.5	0.45 (0.07 to 0.83)	0.02
With interaction terms	–[b]		–[b]		no relevant interaction terms	

The PROMs responders were compared with the respective non-responders. Data is presented as n (%), unless reported otherwise.

[b] Numbers do not always add up due to missing or unknown values.

Table 7: Adjusted mean differences (AMD) with 95% confidence intervals (CIs) of EQ-5D index and OHS/OKS during the COVID-19 lockdown compared with the control periods.

	Preoperative		**3-/6-month postoperative**		**12-month postoperative**	
Factor	AMD (CI)	p-value	AMD (CI)	p-value	AMD (CI)	p-value
Total Hip Arthroplasty	n = 15,007		n = 12,469		n = 12,011	
Without interaction terms						
EQ-VAS[a]	0.11 (–0.71 to 0.93)	0.8	2.16 (1.40 to 2.92)	< 0.001	3.11 (2.38 to 3.85)	< 0.001
With interaction terms	–[c]		no relevant interaction terms		no relevant interaction terms	
Without interaction terms						
HOOS-PS[b]	2.15 (1.43 to 2.87)	< 0.001	–0.38 (–1.00 to 0.24)	0.2	–0.77 (–1.35 to –0.20)	0.009
With interaction terms			–[c]		no relevant interaction terms	
BMI >30 **HOOS-PS**[b]	–1.88 (–3.60 to –0.16) 2.60 (1.78 to 3.41)	0.03 < 0.001				
SES 1st –2nd quintile (lowest) **HOOS-PS**[b]	–1.55 (–3.00 to –0.09) 2.82 (1.88 to 3.76)	0.04 < 0.001				
Total Knee Arthroplasty	n = 10,542		n = 11,134		n = 9,214	

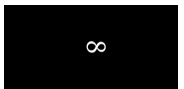


Without interaction terms:						
EQ-VAS[a]	0.76 (–0.20 to 1.73)	0.1	1.82 (1.08 to 2.57)	< 0.001	1.92 (1.06 to 2.79)	< 0.001
With interaction terms:	–[c]				no relevant interaction terms	
ASA ≥3 **EQ-VAS**[a]			2.74 (0.82 to 4.67) 1.23 (0.42 to 2.05)	0.005 0.003		
Age >70 **EQ-VAS**[a]			2.47 (0.98 to 3.96) 0.64 (–0.36 to 1.64)	0.001 0.2		
Without interaction terms:						
KOOS-PS[b]	0.28 (–0.49 to 1.04)	0.5	0.49 (–0.09 to 1.06)	0.1	–0.77 (–1.48 to –0.07)	0.03
With interaction terms:	–[c]		–[c]		no relevant interaction terms	

Analyses were adjusted for age, sex, BMI, previous surgery on the operated joint, indication, ASA score, Charnley classification, type of hospital, and socio-economic status score.
a A higher EQ-5D index, OHS/OKS represents an improvement.
b Interaction terms were not analyzed in non-significant associations.

Table 8: Adjusted mean differences (AMD) with 95% confidence intervals (CIs) of EQ-VAS and HOOS-PS/KOOS-PS during the COVID-19 lockdown compared with the control periods.

	Preoperative		**3-/6-month postoperative**		**12-month postoperative**	
Factor	AMD (CI)	p-value	AMD (CI)	p-value	AMD (CI)	p-value
Total Hip Arthroplasty	n = 15,007		n = 12,469		n = 12,011	
Without interaction terms						
EQ-VAS[a]	0.11 (–0.71 to 0.93)	0.8	2.16 (1.40 to 2.92)	< 0.001	3.11 (2.38 to 3.85)	< 0.001
With interaction terms	–[c]		no relevant interaction terms		no relevant interaction terms	
Without interaction terms						
HOOS-PS[b]	2.15 (1.43 to 2.87)	< 0.001	–0.38 (–1.00 to 0.24)	0.2	–0.77 (–1.35 to –0.20)	0.009
With interaction terms			–[c]		no relevant interaction terms	
BMI >30 **HOOS-PS**[b]	–1.88 (–3.60 to –0.16) 2.60 (1.78 to 3.41)	0.03 < 0.001				
SES 1st –2nd quintile (lowest) **HOOS-PS**[b]	–1.55 (–3.00 to –0.09) 2.82 (1.88 to 3.76)	0.04 < 0.001				
Total Knee Arthroplasty	n = 10,542		n = 11,134		n = 9,214	



Without interaction terms:						
EQ-VAS[a]	0.76 (–0.20 to 1.73)	0.1	1.82 (1.08 to 2.57)	< 0.001	1.92 (1.06 to 2.79)	< 0.001
With interaction terms:	–[c]				no relevant interaction terms	
ASA ≥3 **EQ-VAS**[a]			2.74 (0.82 to 4.67) 1.23 (0.42 to 2.05)	0.005 0.003		
Age >70 **EQ-VAS**[a]			2.47 (0.98 to 3.96) 0.64 (–0.36 to 1.64)	0.001 0.2		
Without interaction terms:						
KOOS-PS[b]	0.28 (–0.49 to 1.04)	0.5	0.49 (–0.09 to 1.06)	0.1	–0.77 (–1.48 to –0.07)	0.03
With interaction terms:	–[c]		–[c]		no relevant interaction terms	

Analyses were adjusted for age, sex, BMI, previous surgery on the operated joint, indication, ASA score, Charnley classification, type of hospital, and socio-economic status score.

[a] A higher EQ-VAS represents an improvement.

[b] A lower HOOS-PS/KOOS-PS represents an improvement.

[c] Interaction terms were not analyzed in non-significant associations.

Chapter 9

General discussion

General discussion

Total Hip and Knee Arthroplasties (THA and TKA) are widely performed surgical procedures improving pain, physical function and quality of life of people with end-stage hip and knee osteoarthritis (OA). Postoperative physical therapy (PPT) is commonly used to enhance recovery, but there are several knowledge gaps regarding its delivery. A number of these are addressed in the current thesis, with the PhysiotherApeutic Treat-to-target Intervention after Orthopaedic surgery (PaTIO) study as the core of this thesis. The ultimate aim is to improve post-operative recovery and patient-centred care following THA and TKA. Specifically, the current thesis focused on:

- The association between the duration of current PPT and postoperative recovery after THA and TKA;
- The added value of an integrated PPT care trajectory with a treat-to-target approach, focusing on individualized milestones as compared to usual care;
- The usefulness of an innovative outcome measure—the Animated Activity Questionnaire (AAQ)—for monitoring recovery in patients after THA or TKA; and
- The impact of the COVID-19 pandemic on postoperative recovery and physical therapy (PT) delivery.

Duration of PPT and its association with recovery after THA and TKA

Our study on the actual provision of PPT found that patients with poorer outcomes after THA or TKA, and thus likely to have a greater need of PT due to insufficient recovery, had a longer use of PPT than those with better outcomes. Longstanding use of PPT could, apart from slower recovery from the surgery, also be related to the presence of comorbidities (1). Previous studies on this topic are scarce, with one cross-sectional study in patients after THA or TKA finding that a higher number of comorbidities was linked to worse results in terms of pain, physical function, and quality of life (2). In our study, the role of comorbidities with respect to their impact on the relationship between physical recovery on the duration of PPT was not consistent across THA and TKA patients. In THA patients the existence of non-musculoskeletal comorbidities modified the associations between recovery and the duration of PPT, whereas in TKA patients nor the existence of comorbidities, severity or their frequency modified associations between recovery and the duration of postoperative PT. With respect to the PTs' management of comorbidities in the clinical trial described in this thesis (the PaTIO study),
the intervention protocol specifically included adjustments to PT treatment based on the presence of relevant comorbidities. However, the PTs' responses to the presence

and severity of comorbidities were neither monitored in the intervention nor the control group. As such we do not have a clear understanding of how treatments were adapted to address these comorbidities. In future research into PPT in THA and TKA, the role of PTs' competences regarding the management of comorbidities may need more attention, e.g. by recording if they have taken part in a training on comorbidity-adjusted exercises in OA (3-5) and the monitory of any clinical decisions related to comorbidities during treatment. This ensures that PPT is individualized, incorporating appropriate knowledge to address both the primary condition and comorbidities, optimizing the treatment plan.

Regarding the study on physical recovery and use of PT after THA and TKA provided valuable insights into the long term use of PPT in patients with prolonged recovery. It is noteworthy that the study was based on data from an existing multicenter cohort study on the outcomes of THA and TKA, and as such, the data were not specifically gathered to monitor the quality, accessibility, or efficacy of PPT services. The data in that cohort study are largely overlapping with the mandatory requirements of the Dutch Orthopaedic Association (NOV) and the Dutch Arthroplasty Register (LROI), that were implemented to enhance the quality and safety of orthopedic care. To ensure the feasibility of such a data collection, the information to be gathered is necessarily limited. An interesting opportunity would be to establish a linkage between various available datasets and registries, such as the LROI and a registry that specifically records data on the use of physical therapy, specifically the National Physiotherapy Database (Landelijke Database Fysiotherapie, LDF) (6). Linking data from the LROI and LDF would enable integration of surgical and rehabilitation information, allowing for a more comprehensive understanding of the entire recovery process. Such integration could help the identification of areas for improvement and create new opportunities for high-quality, multidisciplinary research. Potential research questions could be aimed at exploring how different rehabilitation programs affect long-term recovery, identifying factors that predict rehabilitation success and uncovering gaps in current treatments.

The following observation must be taken into account when considering PPT following THA or TKA. In the Netherlands, neither the current Dutch national PT guideline for the management of hip and knee OA (7) nor the guideline on THA and TKA from the Dutch Orthopaedic Association (8, 9) provide detailed recommendations on the delivery of PPT. Likewise, no quality indicators for PPT following THA or TKA are available. This situation is different from e.g. Canada, where both a specific PPT guideline (10) and a related set of quality indicators (10, 11) have been developed. The latter includes process-oriented indicators that focus on key aspects

of rehabilitation, such as a comprehensive assessment including pain, physical examinations, performance-based tests, and the evaluation of participation and current physical activity levels as well as the actual provision of treatment, guidance and support. By using standardized tools, these indicators enable effective monitoring and delivery of rehabilitation care, ensuring a comprehensive and structured approach to patient recovery after THA and TKA (10, 11). The development of detailed practice recommendations on the provision of PPT following THA and TKA and related quality indicators in the Netherlands could enhance a comprehensive insight into the PT process, enable meaningful comparisons, and improve the overall quality of care.

Optimizing PPT: Evaluation of the effectiveness of an integrated PPT care trajectory with a treat-to-target approach

While numerous studies have investigated the effectiveness of different regimens of PT following THA or TKA (12, 13), none have examined whether an intervention involving personalized milestones would be more (cost-) effective. Our outcomes were assessed with a generally accepted set of questionnaires and performance tests. Besides these, we used the AAQ to investigate the effect. We demonstrated the potential of the AAQ as an innovative tool for monitoring recovery in THA and TKA patients. It successfully met 100% of predefined hypotheses for construct validity, establishing it as a valid measure of physical function in both patient groups. With regard to responsiveness, the performance of the AAQ was sufficient in TKA patients but limited in THA patients, suggesting the need for caution when interpreting changes in physical function over time. The findings of the study may be related to the methodology employed, and further replication of the study is warranted to explore these findings in greater depth, In particular, further validation is needed to refine its application, especially in THA patients. Nevertheless, the promising results suggest that the AAQ can be valuable in remote or virtual care settings after THA or TKA, allowing clinicians to assess physical function without requiring in-person tests, and offering insights into specific patient activities that are not captured by traditional patient reported outcome measures (PROMs).

Regarding the added value of a personalized approach to PPT after THA or TKA, the PaTIO study showed that a such a strategy was not more effective than usual care. There are several potential explanations why we did not find a difference in outcomes between the two groups in the PaTIO study. For instance, although we administered a generally accepted set outcome measures for this patient group and type of intervention, including questionnaires, performance tests and the AAQ, these may not have been sensitive enough to discriminate between the intervention and control condition. It remains to be established to what extent a patient-specific

outcome measure, administered frequently to capture the achievement of milestones - particularly in the first weeks of treatment—would have been able to catch any differences related to the potentially greater emphasis on the achievement of personal goals and milestones between the two groups. Examples of such tools are the Patient-Specific Complaint (PSC) score (14) or the McMaster Toronto Arthritis Patient Preference Disability Questionnaire (MActar) (15). However, it must be noted that these instruments often require an interview, whereas the frequent administration of such instruments would only feasible with a version that can be completed by patients themselves. For that purpose, user-friendly methods for their administration and completion would be needed, such as the use of text messages to be answered by study participants.

Another possible explanation for the lack of effect concerns the treatment fidelity of the PPT intervention, in terms of protocol and dosage adherence, quality of delivery, and participant adherence (16). In general, the monitoring of these specific aspects in the intervention group during the conduct of the trial was limited and may have been insufficient. Therefore, it cannot be ruled out that, despite all efforts, the treatment was not sufficiently personalized as compared to regular care. Also, it is possible that the PPT treatment in the control group was relatively well tailored to the individual, due to e.g. the presence of orthopaedic primary care PT networks, using standardized protocols. Due to limited information on the delivery of PPT in the control group, we cannot further explore the extent of personalization in that arm of the trial. Regarding the quality of the intervention, it should also be noted that during the course of our RCT, a significant global event occurred, namely the COVID-19 pandemic. During the COVID-19 pandemic, the number of THA and TKA procedures performed in the Netherlands decreased substantially (17). While elective surgeries for OA decreased, the proportion of acute THA surgeries increased, for instance for hip fractures (17). Care was primarily shifted to outpatient clinics (ZBCs) rather than academic and non-academic centers. This shift to ZBCs was particularly important for the PaTIO study, as a significant proportion of our target population was no longer treated at the participating hospitals, and thus inclusion rates of the trial dropped. However, although in general the number of THA and TKA decreased during the pandemic, our study on the impact of COVID-19 suggested that, if provided, the number of PT sessions during the pandemic likely did not differ substantially compared to the pre-COVID period. Nevertheless, the pandemic could have had an impact on our study in different ways. The first possible impact was related to the design of our study, where randomization of patients was done on the hospital level. It occurred that the inclusion of patients in the usual care group was largely completed at the time of the pandemic, whereas enrolment of patients from hospitals randomised

to the intervention group continued during and after the pandemic. Second, although it appeared that the pandemic did not have a major impact on the delivery of the intervention, this was only concluded from a few parameters (impact on delivery, frequency and duration of PT). Thereby, it cannot be ruled out that the unusual circumstances during the pandemic affected other, unknown aspects of treatment in that period, that could have led to insufficient delivery of the intervention. This is all the more relevant as more patients in the intervention group were treated during the COVID-19 period compared to those in the usual care group.

Regarding the lack of contrast between the intervention and control groups, it was further observed that nearly all patients in the usual care group utilized PT, which aligns with our expectations. This relatively high use is attributable to the structure of the Dutch healthcare system, where PT is reimbursed from the basic insurance. Although the first 20 sessions of PPT are not covered, most patients have supplementary insurance that reimburses a substantial number of those initial sessions, creating a situation with no or little constraints to start and continue treatment (18). This opportunity may have conflicted with the intention of the intervention to continue PT only as long as it was deemed clinically necessary. The resulting relatively high number of PT sessions in the intervention groups may have contributed to a lack of contrast between the groups, whereas we expected the number of PT sessions to decrease. As limitation or prohibition of PT in either the intervention or control group is challenging under the current reimbursement conditions, research aiming to enhance postoperative rehabilitation should probably focus on alternative rehabilitative strategies rather than the head-to-head comparison of PPT regimens. Such approaches could include thorough education and instruction before and during hospitalization, supported by a rehabilitation app, remote consultation services or the delivery of group-based interventions. Such strategies could potentially reduce the need for individual face-to-face contacts (14, 19-21), with the latter only be offered to patients at risk for delayed functional recovery as selected by a comprehensive preoperative and early postoperative screening .
The studies presented in this thesis included observational research and a RCT where two PPT approaches were compared. Thereby, this thesis provides no insight into the added value of PPT as such. Several systematic reviews on the effectiveness of different PPT strategies following THA or TKA have been performed (12, 13, 22, 23). Overall, these systematic reviews suggest that PT interventions are effective, although their general conclusions were based on studies with low to moderate levels of evidence. The two most recent reviews (12, 13) concluded that in patients undergoing THA (13), PPT interventions were found to improve physical function, hip muscle strength, pain and hip flexion range of motion. Whereas in TKA patients (12) PPT

interventions enhanced physical function, knee range of motion and less pain during short-term follow up. Again these general conclusions were based on studies with low to moderate levels of evidence. Notably these reviews (12, 13) included studies with considerable variation in PPT interventions and control conditions, complicating reliable comparisons across studies. While cost-effectiveness was addressed as well, the limited number of RCTs (THA n=1, TKA n=2) and again the heterogeneity of the interventions prevented definitive conclusions. In addition, none of the included cost-effectiveness trials adopted a societal perspective and the varying health economic perspectives and methods used make comparisons with the PaTIO study challenging. In the PaTIO study we found no differences in cost-effectiveness between our integrated PPT care trajectory with a treat-to-target approach and usual PPT.

In all, with the conduct of trials with interventions delivered and evaluated over a prolonged period after surgery, it must be acknowledged that demonstrating the added value of any intervention on top of the overall effect of surgery becomes more difficult over time. In that respect, focusing on the early postoperative period to examine whether an intervention involving personalized milestones would be (cost-) effective would likely be more informative.

Given the overall gaps in the evidence, the delivery of PPT after THA and TKA warrants future studies to optimize the provision of PPT, addressing the appropriate selection of patients as well as the optimal content and duration, and the role of the PT in the identification of patients with delayed recovery. Moreover, alternative rehabilitative strategies, including educational apps and other forms of digital instruction and guidance should be considered. With the design of such studies, collaboration among multidisciplinary stakeholders, including orthopedic surgeons, physical therapists, patients, researchers, registry organizations and health care insurers, will be crucial to ensure appropriate care for all patients undergoing THA or TKA.

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Summary

Total Hip and Knee Arthroplasties (THA and TKA) are widely performed surgical procedures improving pain, physical function and quality of life of people with end-stage hip and knee osteoarthritis (OA). Postoperative physical therapy (PPT) is recommended by guidelines as an effective intervention to enhance recovery. The present thesis focused on several aspects of PPT, including the relationship between recovery after THA or TKA and the use of PPT, the (cost)effectiveness of an optimized PPT strategy, the validity and responsiveness of the Animated Activity Questionnaire (AAQ) in the follow-up of patients after THA and TKA, and the delivery of PPT.

To address the relationship between recovery and PPT usage after THA or TKA, an observational study described in **Chapter 2** used data from a large, ongoing multi-center prospective cohort study of OA patients undergoing THA or TKA (Leiden Osteo Arthritis Study, LOAS). Data from 1289 THA and 1333 TKA patients showed that the majority received PPT, with over 50% of all patients continuing PT for 12 weeks or more. Poorer recovery, as measured by Hip Disability and Osteoarthritis Outcomes Score / Knee Injury and Osteoarthritis Outcomes Score (HOOS/KOOS) subdomains, was associated with longer PT use in both groups. As a relatively large proportion of the patients undergoing THA or TKA has one or more comorbidities, which may influence recovery, the role of comorbidities was further explored. In patients with THA, non-musculoskeletal comorbidities were found to modify the associations between recovery and the duration of postoperative PT. In patients with a non-musculoskeletal comorbidity, the impact of physical recovery on the risk of long term PT was smaller than in the patients without musculoskeletal comorbidity. In patients with TKA comorbidity did not modify any association between recovery and duration of PPT. Overall, the findings suggest that duration of PT use is related to the patients' recovery needs, whereas in patients with THA comorbidities may influence that relationship negatively.

Despite the proven general association between recovery after THA or TKA and duration of PPT, there appears to be substantial practice variation in its delivery—not only with respect to duration but also in terms of timing or content. This variation raises questions about the optimal approach to maximize patients' recovery and efficient use of resources. To investigate whether better tailoring of PPT to individual, functional treatment goals improves recovery after THA or TKA, a randomized controlled trial (RCT) comparing an optimized PPT strategy with usual care was set up. **Chapters 3, 4 and 5** describe the development of the study protocol and the

effectiveness and cost-effectiveness of the optimized PPT strategy compared to usual care, respectively.

The study protocol in **Chapter 3** includes the methodology for a nationwide, cluster RCT comparing a personalized, treat-to-target PPT approach with usual care in patients undergoing THA or TKA. PPT is delivered by specially trained physical therapists (PTs) working in selected primary care practices in the vicinity of the intervention hospitals. The intervention is structured into clearly defined phases, each with specific start and end points. Within each phase, milestones are discussed and achieved. These milestones determine whether to proceed to the next phase, adjust the therapy, or discontinue it. Hospitals are randomized 1:1 to the intervention or usual care condition. PTs treating patients with THA or TKA from the hospitals randomized to the intervention group follow a mandatory training of 2 hours. Key elements of the personalized treat-to-target PPT protocol are a personalized, time contingent program (clear start and stop moments) and comprising evidence-based treatment components, such as muscle strengthening and functional exercises, to achieve the functional milestones. Assessments are at baseline, 3, 6, 9 and 12 months (performance tests only at baseline, 3 and 12 months.) The primary outcome of the trial is the HOOS/KOOS- Physical function Short Form at 3 months. Secondary outcomes re the Oxford Hip Score and Oxford Knee Score (OHS/OKS), a global numeric rating scale (NRS) of change, performance-based tests including the 30 seconds Chair-Stand Test, 40 meter (m) (4x10m) Fast Paced Walk Test, the Stair Climb test, and the AAQ For the economic analysis, cost questionnaires including the use of healthcare and other costs are administered, and patients complete the EuroQol 5-Dimensions (EQ-5D-5L) and the EQ-Visual Analog Scale (VAS) to compute Quality Adjusted Life Years (QALYs). Analyses are on intention-to-treat basis, by means of Generalized Estimating Equations (GEE), taking into account all time points. The economic analysis included the intention-to-treat principle using cost-effectiveness acceptability curves from healthcare and societal perspectives.

The results of the trial are presented in **Chapter 4.** Eighteen hospitals were randomized, eleven to the intervention and seven to usual care. There were 624 patients in total (312 THA and 312 TKA) who participated in the trial (for THA and TKA: 156 intervention, 156 usual care). On average, THA patients received 20 and 19 PPT sessions in the intervention and control groups, respectively, and TKA patients 29 and 32 PPT sessions. Both THA and TKA patients experienced improvements in functional outcomes, quality of life, and pain following surgery. However, our personalized, treat-to-target PPT intervention did not show superior benefits in enhancing these outcomes compared to standard care.

The economic analysis is described in **Chapter 5.** The 1-year societal costs favored usual care, but were not significantly different from the intervention group, by €1219 for THA patients (95% CI: €-413 to €2852) and €926 for TKA patients (95% CI: €-562 to €2415). QALYs were non-significantly higher in the control group for THA patients by 0.01 (EQ-5D-5L: 95% CI -0.20 to 0.04; EQ-VAS: 95% CI -0.01 to 0.03), with no differences between intervention and control TKA patients (EQ-5D-5L: 95% CI -0.03 to 0.03; EQ-VAS: 95% CI -0.02 to 0.02). For a willingness-to-pay threshold of €50,000 per QALY, there is a less than 50% probability that the intervention is cost- effective compared to usual care. Overall, it was concluded from the economic analysis that there were no differences in QALYS neither in costs to substantiate the delivery of either the intervention or usual care.

Chapter 6 describes an analysis of the validity and responsiveness of the AAQ in patients included in the abovementioned RCT. Construct validity was assessed by means of testing hypotheses about expected correlations between the AAQ and the comparators. Responsiveness was assessed by means of testing hypotheses about expected correlations between change in AAQ and change in the scores of the comparators. We considered the AAQ as valid and responsive for THA and TKA separately if at least 75% of the results were in accordance with the hypotheses (at least 15 of the 20 hypotheses). In total, 302 patients with THA and 282 with TKA were included in construct validity analysis. For the 3 months and 12 months follow-up, 288 THA and 264 TKA patients and 239 THA and 221 TKA patients were included, respectively. All 10 hypotheses for construct validity were confirmed. Responsiveness criteria were met in 75% of cases for TKA patients and 70% for THA patients. It was concluded that the AAQ is a valid tool for assessing physical functioning in both THA and TKA patients. While responsiveness was sufficient for TKA patients, it was somewhat limited for those who underwent THA.

The COVID-19 pandemic significantly disrupted the delivery of PPT, especially during the initial lockdown in the Netherlands (March 23 – May 11, 2020), when PT practices were closed. In **Chapter 7** the impact of the COVID-19 pandemic was explored from the perspectives of both patients and their treating physical therapists. Data was used from the intervention group of our cluster RCT in 18 hospitals, comparing a treat-to-target intervention versus usual care in 624 patients undergoing primary THA or TKA. In total, 73 THA patients who received PT before COVID-period and 39 THA patient who received PT during COVID were included. For TKA the inclusion numbers were 66 TKA patients and 40 TKA patients, respectively. Characteristics of the PTs were measured after completion of the PT treatment with an assessment including years of experience of PT, the use of PT, location of PT, frequency of PT, duration of

PT and total number of PT treatment sessions. Additionally, from May 2020 onwards questions were added regarding the possible impact of COVID-19 pandemic on different aspects of PT treatment. There were 99 PT questionnaires included in this study. According to the survey, more THA patients (30.8%) than TKA patients (10.0%) reported receiving remote care during COVID. Physical therapists reported that THA patients generally coped well with remote care, while TKA patients faced more challenges. Despite pandemic-related constraints, and partial remote delivery, most PTs indicated no major changes in PT frequency, duration, or exercise type. The average number of PT sessions was higher during the COVID period for both THA and TKA patients, whereas PTs reported no changes in frequency or duration of PT sessions during COVID. In about 70% of the patients, physical therapists reported no changes in type of exercise. It was concluded that the impact of COVID-19 on the delivery of PPT seemed limited with respect to the number of sessions, with the exception of less PT sessions in the group of patients receiving PPT in the pre-COVID period than in the COVID period. Overall, it was found that within the COVID period most patients received treatment according to the protocol with regard to type, duration and frequency of PT.

Regarding the impact of the COVID-19 pandemic on patient-reported outcome measures in THA and TKA patients, the study presented **in Chapter 8** explored whether the pandemic affected patient-reported outcomes (PROMs) after THA or TKA. Using national data from the Dutch Arthroplasty Register (LROI), PROMs from patients operated between March and July 15, 2020 (lockdown period) were compared to those from the same period in 2018 and 2019 (pre-COVID). PROMs collected in THA patients were the EuroQol 5-Dimensions (EQ-5D-3L) questionnaire, EQ-visual analogue scale (EQ-VAS), the Oxford Hip Score (OHS) and the short version of the Hip disability and Osteoarthritis Outcome Score (HOOS-PS). In TKA patients these PROMs were the EQ-5D-3L, EQ-VAS, the Oxford Knee Score (OKS) and the short version of the Knee disability and Osteoarthritis Outcome Score (KOOS-PS). In total, data from over 33,000 THA and 27,000 TKA patients were analyzed. There were 28,661 pre-covid patients included and 10.826 patients during the COVID-19 period. During the lockdown, THA and TKA patients were significantly younger and more often underwent surgery in private clinics. The preoperative PROMs of THA patients were slightly , yet statistically significant, worse during the lockdown , indicating a possible prioritization of more urgent cases. For TKA patients, there were no differences in preoperative PROMs scores. Regarding the postoperative PROMs at 12 months, these were statistically significantly better in the COVID period as compared to previous years for both THA and TKA patients. However, despite these statistical differences, the magnitude of change was small and likely not clinically relevant.

It was concluded that during the COVID-19 lockdown, THA patients had slightly worse preoperative PROMs, suggesting selection of patients with greater urgency. Postoperative PROMs in both THA and TKA patients differed minimally. Overall, the observed differences were likely not clinically relevant

In **Chapter 9,** the findings from the studies described in Chapters 2-8 are discussed in the context of the literature and developments in research, healthcare and society.

Nederlandse samenvatting

Totale heup- en knieprothesen (THA en TKA) zijn veelvoorkomende chirurgische ingrepen die de pijn, fysieke functie en levenskwaliteit van mensen met vergevorderde heup- en knie-artrose verbeteren. Postoperatieve fysiotherapie (PPT) wordt door richtlijnen aanbevolen om het herstel te bevorderen. Het voorliggende proefschrift richt zich op verschillende aspecten van PPT, waaronder de relatie tussen herstel na THA of TKA en het gebruik van PPT, de (kosten)effectiviteit van een geoptimaliseerde PPT-strategie, de validiteit en responsiviteit van de Animated Activity Questionnaire (AAQ) in de follow-up van patiënten na THA en TKA, en de levering van PPT.

In **hoofdstuk 2** wordt een observationele studie beschreven die de relatie tussen herstel en het gebruik van PPT na THA of TKA onderzocht, gebruikmakend van gegevens uit de grote, lopende, multicenter prospectieve cohortstudie van artrosepatiënten (Leiden Osteoarthritis Study, LOAS). Gegevens van 1289 THA- en 1333 TKA-patiënten toonden aan dat de meerderheid PPT ontving, waarbij meer dan 50% van de patiënten de fysiotherapie 12 weken of langer voortzette. Slechter herstel, gemeten met de Hip Disability and Osteoarthritis Outcomes Score / Knee Injury and Osteoarthritis Outcomes Score (HOOS/KOOS) subdomeinen, was geassocieerd met een langer gebruik van fysiotherapie in zowel de THA als TKA groep. Omdat een relatief groot aantal patiënten met THA of TKA één of meerdere comorbiditeiten heeft die het herstel kunnen beïnvloeden, werd de rol van comorbiditeiten verder onderzocht. Bij THA-patiënten bleek dat niet-musculoskeletale comorbiditeiten de relatie tussen herstel en de duur van de postoperatieve fysiotherapie modificeerden. Patiënten met een niet-musculoskeletale comorbiditeit vertoonden een kleiner effect van fysiek herstel. Dit resulteerde in een hoger risico op langdurig fysiotherapiegebruik in vergelijking met patiënten zonder musculoskeletale comorbiditeit. Bij TKA-patiënten had comorbiditeit geen invloed op de relatie tussen herstel en de duur van de PPT. Over het algemeen suggereert de studie dat de duur van fysiotherapie gerelateerd is aan de herstelbehoeften van de patiënt, maar dat comorbiditeiten bij THA-patiënten deze relatie negatief kunnen beïnvloeden. Hoewel er een algemeen verband is tussen herstel na THA of TKA en de duur van PPT, blijkt er aanzienlijke variatie in de praktijk, zowel wat betreft de duur als de timing en inhoud van de behandeling. Deze variatie roept vragen op over de optimale aanpak om het herstel van patiënten te maximaliseren en middelen efficiënt te gebruiken.

Hoofdstukken 3, 4 en 5 beschrijven een gerandomiseerde gecontroleerde studie (RCT) die de effectiviteit en kosteneffectiviteit van een geoptimaliseerde PPT-strategie vergelijkt met de gebruikelijke zorg.

Hoofdstuk 3 beschrijft het protocol van de studie, een cluster-RCT waarin een gepersonaliseerde, doelgerichte PPT-aanpak wordt vergeleken met de gebruikelijke zorg bij patiënten die een THA of TKA ondergaan. Fysiotherapie zal worden geleverd door speciaal opgeleide fysiotherapeuten in geselecteerde eerstelijnszorgpraktijken nabij de interventieziekenhuizen. De interventie is opgedeeld in duidelijk gedefinieerde fasen met specifieke start- en eindmomenten, waarin mijlpalen worden besproken en behaald. Het protocol bevat evidence-based behandelingscomponenten zoals spierversterkende en functionele oefeningen. De primaire uitkomstmaat is de HOOS/KOOS-Physical Function Short Form na 3 maanden. Secundaire uitkomstmaten zijn onder andere de Oxford Hip Score en Oxford Knee Score (OHS/OKS), de EuroQol 5-Dimension (EQ-5D-5L) en de EQ-Visual Analog Scale (VAS).

In **hoofdstuk 4** worden de resultaten van de PaTIO trial gepresenteerd. Er namen 624 patiënten deel (312 THA en 312 TKA), waarbij de interventiegroep gemiddeld 20 (THA) of 29 (TKA) PPT-sessies ontving, en de controlegroep respectievelijk 19 en 32 sessies. Zowel patiënten na een THA als TKA vertoonden verbeteringen in functionele uitkomsten, kwaliteit van leven en pijn na de operatie. Echter, onze gepersonaliseerde, treat-to-target PPT-interventie bleek geen grotere voordelen te bieden bij het verbeteren van deze uitkomsten in vergelijking met de gebruikelijke zorg.

Hoofdstuk 5 behandelt de economische analyse. De totale maatschappelijke kosten na één jaar waren niet significant verschillend tussen de interventie- en controlegroep voor zowel THA- als TKA-patiënten. De QALY's waren iets hoger in de controlegroep voor THA-patiënten, maar het verschil was niet klinisch relevant. Het werd geconcludeerd dat er geen verschillen waren in kosten of QALY's die het gebruik van de interventie boven de gebruikelijke zorg rechtvaardigden.

Hoofdstuk 6 bespreekt de validiteit en responsiviteit van de AAQ bij de patiënten uit de RCT. De AAQ bleek een valide en responsief meetinstrument voor fysieke functie bij zowel THA- als TKA-patiënten, hoewel de responsiviteit bij THA-patiënten enigszins beperkt was.

Hoofdstuk 7 onderzoekt de impact van de COVID-19-pandemie op de levering van PPT. Tijdens de lockdown werden fysiotherapiepraktijken gesloten, maar de meeste

fysiotherapeuten gaven aan dat de frequentie, duur en het type oefeningen niet significant veranderden. De gemiddelde aantal fysiotherapiesessies was zelfs hoger tijdens de COVID-periode dan voor de pandemie. Er werd geconcludeerd dat de impact van COVID-19 op de levering van PPT relatief beperkt was.

Hoofdstuk 8 onderzoekt de impact van de COVID-19-pandemie op de patiënt gerapporteerde uitkomstmaten (PROMs) van THA- en TKA-patiënten. Het onderzoek toonde aan dat patiënten die tijdens de lockdown werden geopereerd, iets jonger waren en vaker in privéklinieken werden behandeld. De postoperatieve PROMs na 12 maanden waren statistisch significant beter in de COVID-periode, hoewel de verandering klinisch niet relevant was.

In **hoofdstuk 9** worden de bevindingen uit de voorgaande hoofdstukken besproken in de context van de literatuur en de ontwikkelingen in de zorg en de maatschappij.

Curriculum vitae

Lichelle Groot is geboren op 26 juni 1990 te Rijswijk, Zuid-Holland. Zij groeide deels op in Rijswijk en daarna in Steenbergen, Noord-Brabant. In 2007 Behaalde zij haar HAVO diploma te Roncalli scholengemeenschap Bergen op zoom. Aansluitend startte zij met haar HBO studie Oefentherapie Cesar in Utrecht. Tijdens haar studie oefentherapie heeft ze onder andere 2 minors gevolgd namelijk, Cardiopulmonaire beperkingen & Neurorevalidatie & wetenschap. Haar Senior stages waren een Intramurale stage longrevalidatiecentrum in Heideheuvel te Hilversum en een kinderoefentherapie stage in een particuliere praktijk voor kinderen met een motorische achterstand. Zij sloot haar studie af met een scriptie waarin ze onderzoek deed naar COPD en bewegen. Na enkele jaren als oefentherapeut Cesar en medewerker zorgdeclaratie bij een zorgverzekering te hebben gewerkt, besloot ze haar ambities te volgen. In 2016 voltooide ze haar pre-master Gezondheidswetenschappen aan de VU Amsterdam. In 2017 volgde haar masterdiploma gezondheidswetenschappen met de specialisatie preventie en volksgezondheid aan de VU Amsterdam. Tijdens haar master in 2017 deed zij haar wetenschapsstage bij het RIVM, waar ze kwantitatief onderzoek naar pijnpatronen over de volwassen leeftijd heen uitvoerde. Het artikel werd later gepubliceerd en won een internationale prijs. Aansluitend aan haar studie startte zij met haar promotieonderzoek, een samenwerking tussen het ErasmusMC en het LUMC. Haar promotieonderzoek werd vanuit de afdeling Orthopedie en Sportgeneeskunde van het Erasmus MC en de afdelingen orthopedie, revalidatie en fysiotherapie van het LUMC gecoördineerd. Zij heeft een grote landelijke studie uitgevoerd onder 18 ziekenhuizen en vele fysiotherapiepraktijken om meer inzicht te krijgen in de (kosten)-effectiviteit van postoperatieve fysiotherapie na een totale heup of knie prothese. Lichelle Groot heeft sinds 2020 een geregistreerd partnerschap met Yorrick Bakker. Samen met hun kinderen Noah (2020) en Lynn (2022) wonen zij in Utrecht. Lichelle is momenteel werkzaam als wetenschapscoördinator in het wetenschapscentrum in het Canisius Wilhelmina ziekenhuis (CWZ) in Nijmegen.

PhD portfolio

Name PhD student: L. Groot
Erasmus MC Department: Orthopaedics and sports medicine
PhD Period: 01-01-2018 t/m 01-0-1-2023

	Date	Workload (ECTS)
General courses		
BROK (Basic course Rules and Organisation for Clinical researchers)	24-05-2018	1,5
BROK Recertification	14-03-2024	1,5
CPO-course: Patient Oriented Research	26-04-2019	0.3
Scientific integrity	23-07-2019	0.3
Biomedical English Writing	Oct. – Nov. 2021	2.0
Endnote course	28-09-2021	0.2
Biostatistical Methods II: Regression models	25-11-2019 tm 06-12-2019	4.3
Analysis of repeated measurements course (Boerhaave nascholing)	31-05-2021 tm 09-06-2021	1.5
opleiding Economische Evaluaties van Medische Interventies ME-TA	30-06-2021 t/m 02-07-2021	1.0
Personal leadership	December 2021 (9-3-12 en 17-12	1.0
Seminars and workshops		
ROGO- dag (Regionale Opleiding Groep Orthopedie)	21-11-2018	0.3
LUMC / OLVG research afternoon	05-07-2019	0.1
Educational trainings day Leading the Change (LTC)	10-01-2020	0.1
Workshop presenting by Anne Gehring	21-07-2020	0.3
All educational moments Wednesday morning department of orthopaedics & sports medicine Erasmus MC	01-01-2018 t/m 01-01-2023	2.0
All journal clubs for 5 years during departments meetings	01-01-2018 t/m 01-01-2023	2.0
ROGO – day	10-11 2021	0.3
Educational trainings day LTC	9-12-2021	0.1
Workshop Visual Communication	26-11-2021	0.1
Educational trainings day LTC	12-01-2023	0.1
Oral Presentations		
Presentatie studie tijdens onderwijs afdeling orthopedie	07-11-2018	1.0

WECO Erasmus MC project presentative	07-01-2019	1.0
Science day Wetenschapsdag orthopedie (oral presentation)	16-1-2019	1.0
Dag van de fysiotherapie congres (Invited speaker - oral presentation)	16-11-2019	1.0
Pitch jaarcongress NOV – onderwerp Lokale hoofdonderzoeker	30-01-2020	1.0
Wetenschapsdag EMC 2021	13-01-2021	1.0
NOV voorjaarscongres – update PATIO studie presenteren	21-05 -2021	1.0
LOAS studie tijdens LUMC ortho overleg	02-08-2021	1.0
EFORT Lisboa (poster presentation)	22-06-2022 t/m 24-06-2022	1.0
NOV jaarcongress (Invited speaker - oral presentation)	25-05-2023 – 26-05-2023	1.0
Congresses		
NOV year congress 's-Hertogenbosch	25-01-2018 tm 26-01-2018	1.0
NOV congress Rotterdam	09-10-2018 tm 10-10-2018	1.0
NOV year congress 's-Hertogenbosch	24-01-2019 tm 25-01-2019	1.0
Science day KNGF	27-03-2019	1.0
Science day EMC	15-01-2020	0.3
NOV congress 's-Hertogenbosch	30-01-2020 tm 31-01-2020	1.0
NOV congress Online	21-05-2021	1.0
NOV congress Leeuwarden	07-10-2021 tm 08-10-2021	1.0
Science day EMC	28-09-2022	0.3
NOV congress Utrecht	06-10-2022 & 07-10-2022	1.0
NOV Year congress Utrecht	25-05-2023 – 26-05-2023	1.0
Teaching		
Teaching medical students during master research	06-2021 tm 07-2021	1.0
Supervising		
Supervizing Eline schippers with the execution of the trial and contacting all centers about potentials inclusion or included patients	09-2020 - 01-2021	5.0
Supervizing Umit Yildiz with data collection, analysis of the data and writing of an article regarding physiotherapy during corona time	01-2021 – 05 -2021	5.0
Supervizing Isabelle knaapen with the execution of the trial, data collection and the sample within the intervention physiotherapy practices	12-2021 – 10-2022	5.0

List of publications

Groot L, Gademan M, van Loon D, Peter WF, Vlieland TV, Reijman M, group Ps. PhysiotherApeutic Treat-to-Target Intervention after Total Hip and Knee Arthroplasty Does Not Improve Outcomes Compared to Usual Physical Therapy: The PATIO Study. J Arthroplasty. 2025.

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Submitted
Groot L, M.G.J Gademan, dr. W.F. Peter, T.P.M. Vliet Vlieland, M. Reijman, W. B. van den Hout, on behalf of the PaTIO study group. Cost effectiveness analysis of a physiotherApeutic Treat-to-target Intervention after total hip and knee arthroplasty: A comparison of personalized treatment and usual care therapy in a randomized control trial: The Patio study.

Groot L, W.F. Peter, T.P.M. Vliet Vlieland, M. Reijman, C.B. Terwee, M. G.J Gademan and on behalf of the PATIO study group. Validity and responsiveness of the Animated Activity Questionnaire for assessing activity limitations in patients after total hip or total knee replacement.

Dankwoord

Mijn interesse in het menselijk bewegen en de gezondheid van het bewegingsapparaat ontstond tijdens mijn opleiding tot oefentherapeut Cesar. Tijdens deze studie raakte ik steeds meer gefascineerd door de vraag waarom we doen wat we doen: waarom bepaalde beweegpatronen ontstaan, hoe klachten van het bewegingsapparaat zich ontwikkelen en op welke manier we mensen het beste kunnen ondersteunen in hun herstel en gezondheid. Deze nieuwsgierigheid naar de achterliggende mechanismen en de behoefte om verder te kijken dan alleen de praktijk, brachten mij ertoe om Gezondheidswetenschappen te gaan studeren en mij verder te verdiepen in onderzoek. Het samenkomen van mijn passie voor bewegen, mijn achtergrond in de oefentherapie en mijn interesse in wetenschappelijk onderzoek vormden uiteindelijk de basis voor dit proefschrift. Op de voorkant van dit proefschrift staat een veer. Een verwijzing naar veerkracht, iets wat ik de afgelopen jaren regelmatig nodig heb gehad. Er is in de afgelopen jaren behoorlijk wat gebeurd en soms werd de veer daardoor flink uitgerekt. Misschien zelfs verder dan ik vooraf voor mogelijk had gehouden. Maar hoe ver een veer ook wordt uitgerekt, uiteindelijk kan hij weer terugveren. Juist in de momenten waarop de veer het meest werd uitgerekt, heb ik ervaren hoe belangrijk het is om de juiste mensen om je heen te hebben. Mensen die je opvangen, je kracht geven, je soms even terugbrengen naar de basis en je helpen om weer verder te gaan. Deze veer staat voor mij daarom niet alleen voor mijn eigen veerkracht, maar ook voor de mensen die mij de afgelopen jaren hebben geholpen om steeds weer terug te veren. Wie had ooit gedacht dat ik, vanuit de HAVO, uiteindelijk een proefschrift zou verdedigen? Deze reis heeft mij laten zien dat nieuwsgierigheid je soms op onverwachte paden brengt, maar ook dat je niet alles alleen hoeft te kunnen en dat de juiste mensen om je heen je helpen om steeds weer verder te gaan. Want niets is onmogelijk. Maar één ding is zeker: dit proefschrift heb ik niet alleen geschreven en deze mijlpaal had ik nooit alleen kunnen bereiken. Daarom wil ik graag de mensen bedanken die mij tijdens deze bijzondere reis hebben begeleid, gesteund en geïnspireerd.

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Lieve **Noah en Lynn**, en dan jullie, mijn twee lieve kinderen. Noah, inmiddels bijna 6 jaar, en Lynn, net 4 jaar. Jullie hebben een groot deel van mijn promotietraject van dichtbij meegemaakt. Jullie begrepen waarschijnlijk niet precies waar mama al die jaren mee bezig was, maar jullie weten wel heel goed dat mama een onderzoeker is en een boek aan het schrijven was met héél veel informatie. En altijd zo lief vragen hoeveel ik in mijn boek had geschreven wanneer jullie terugkwamen van de dierentuin of een ander uitje als mama aan haar proefschrift werkte. Die oprechte interesse vond ik ontzettend bijzonder en lief. Jullie hebben mij geleerd dat er naast onderzoek, werk, deadlines en proefschriften nog veel belangrijkere dingen zijn. Een knuffel, een verhaaltje voor het slapen gaan, samen spelen of gewoon even lekker thuis zijn. Jullie zorgden ervoor dat mijn werk altijd weer in perspectief kwam en dat er genoeg momenten waren waarop mijn proefschrift even helemaal niet belangrijk was.

Dank jullie wel voor alle knuffels, kusjes, gezelligheid en vooral voor wie jullie zijn. Ik ben ontzettend trots dat ik jullie mama mag zijn. Blijf vooral altijd zo nieuwsgierig als jullie nu zijn, blijf vragen stellen, ontdekken en je verwonderen over de wereld om jullie heen. Wie weet waar die nieuwsgierigheid jullie later allemaal nog brengt. En nu mijn proefschrift af is, hebben jullie weer wat vaker een mama die met alle aandacht naar jullie verhalen luistert.