Physical activity after total hip arthroplasty

PhD Thesis

Jakob Vangen Nordbø

2025

Illustration by Hellevik studio

UNIVERSITY
OF OSLO

Series of dissertations submitted to the
Faculty of Medicine, University of Oslo

ISBN 978-82-348-0796-1

Cover: UiO.
Print production: Graphic center, University of Oslo.

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Acknowledgements

Performing this thesis has been an exciting journey, accompanied by several people whom I highly appreciate.

I am deeply grateful to my principal supervisor, Asbjørn Årøen, for challenging me into research. You always believed in me and guided me with wisdom. I am grateful for our discussions over these years and for your availability. Furthermore, I have had the privilege of working with three outstanding co-supervisors: Truls Martin Straume-Næsheim, "the strategist"; Einar Andreas Sivertsen, "the clever one"; and Geir Hallan, "who knows everything". Your expertise and support have been indispensable. I am likewise grateful to biostatistician Anne Marie Fenstad, whose expertise in statistical matters and provision of data in all three thesis articles have been invaluable.

The randomised controlled trial (RCT) was led by PhD candidate Odd-Einar Svinøy and his principal supervisor Gunvor Hilde at OsloMet. I am deeply grateful that you let me into your team. Your high standard and systematic work have taught me what it takes to complete an RCT. I will also thank my co-authors of article 2: Are Hugo Pripp, May Arna Risberg, Astrid Bergland, and Pål Oliver Borgen, whose collaboration and expertise enriched the work.

I want to thank my incredible teammates in the hip section at Ahus, whom I admire and learn from every day: Christian Pollmann, Aron Adelved, and Nehat Mecinaj, as well as my leader, Stefan Bartels, who encouraged me to become a hip surgeon and has always supported me. I am also grateful to the orthopaedic department at Ahus, under the leadership of Inge Skråmm and Jan Rune Mikaelsen, for providing me with the opportunity to perform hip surgery during my PhD.

The University of Oslo funded the PhD education, and the research projects received grants from Ortomedic AS and the Eckbos legate. As a research fellow at Campus Ahus, I have had the pleasure of collaborating with insightful colleagues who have greatly expanded my scientific understanding: Per-Henrik Randsborg, Rune Bruhn Jakobsen, Guri Ranum Ekås, and Stein Erik Utvåg. I am also thankful to Sigurd Årøen and Noah Straume-Næsheim for their assistance with data plotting and the distribution of questionnaires.

Completing a PhD becomes a way of life, with evenings and weekends spent at the office. I am deeply grateful to my friends for their support and care, helping me to keep balance in life. I also highly appreciate the care and assistance provided by my parents-in-law, Signe and Stein, and my parents, Pauline and Jon Inge, during busy periods.

Finally, I am deeply grateful to my wife, Hanna, for being my love and my friend. You always listen, ask questions, and you are always interested. Moreover, you have acted as my 'fifth supervisor'. As an expert in Stata, you have taught me almost everything I know. You are both smart and caring, and I am so lucky to have you. I also want to thank our three sons: Jon, Thov, and Bror. You are the most valuable gifts in my life. Thank you for being patient and for supporting me just by being who you are.

Abbreviations

AktivA	Active with osteoarthritis
ASA class	American Society of Anesthesiologists Classification
BMI	Body Mass Index
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
DAG	Directed Acyclic Graph
EQ-5D-5L	Five-level-Euro-Qol five-dimension
EQ-VAS	EQ-5D Visual Analog Scale
FCI	Functional Comorbidity Index
HHS	Harris Hip Score
HOOS	Hip Disability and Osteoarthritis Outcome Score
HR	Hazard Ratio
HUNT3	The Trøndelag Health Study, the third wave
HUNT LPA questionnaire	The Trøndelag Health Study -Leisure time physical activity questionnaire
HXLPE	Highly Cross-Linked Polyethylene
IQR	Interquartile Range
ITT	Intention To Treat
LMM	Linear Mixed Models
MAR	Missing At Random
MCAR	Missing Completely At Random
MI	Multiple Imputation
MNAR	Missing Not at Random
NAR	Norwegian Arthroplasty Register
OA	Osteoarthritis
OARSI	Osteoarthritis Research Society International
OR	Odds Ratio
PMMA	Polymethylmethacrylate
PP	Per Protocol
PROM	Patient Reported Outcome Measure
REC	Regional Committee for medical and health Ethics
RCT	Randomized Controlled Trial
RSA	Radiostereometric Analysis
SD	Standard Deviation
THA	Total Hip Arthroplasty
TUG	Timed Up & Go
UCLA score	University of California, Los Angeles Activity score
UHMWPE	Ultra-High Molecular Weight Polyethylene
6 MWT	6 Minute Walk Test

Articles in the thesis

Article 1

Patients with total hip arthroplasty were more physically active 9.6 years after surgery: a case-control study of 429 hip arthroplasty cases and 29,272 participants from a population-based health study.

Nordbø JV, Straume-Næsheim TM, Hallan G, Fenstad AM, Siversten EA, Årøen A.

Acta Orthop. 2024 May 30:95:268-274. doi: 10.2340/17453674.2024.40815

Article 2

The effect of prehabilitation for older patients awaiting total hip replacement. A randomized controlled trial with long-term follow-up

Svinøy OE, Nordbø JV, Pripp AH, Risberg MA, Bergland A, Borgen PO, Hilde G.

BMC Musculoskelet Disord. 2025 Mar 6;26(1):227. doi: 10.1186/s12891-025-08468-4

Article 3

Physical activity and the risk of aseptic loosening after total hip arthroplasty: a case-control study from the Norwegian Arthroplasty Register

Nordbø JV, Straume-Næsheim TM, Hallan G, Fenstad AM, Siversten EA, Årøen A.

BMC Musculoskelet Disord. 2025 Jul 4;26(1):639. doi: 10.1186/s12891-025-08865-9

Thesis at a glance

Study	Aim	Material	Main findings
1	To assess the long-term physical activity level after THA and compare these levels to a control group from a population-based health study.	Case-control study of 429 THA cases from the NAR and 29,272 controls from the HUNT3.	Patients with THA reported a higher level of physical activity 9.6 years after surgery compared to a control group like the normal population.
2	To evaluate whether a prehabilitation program consisting of exercises and education in patients with hip osteoarthritis awaiting THA improved gait speed 3 months after surgery.	Randomized controlled trial of 98 patients with hip OA > 70 years and HHS < 60.	Prehabilitation did not improve gait speed after THA, but prehabilitation improved gait speed before THA. Patients improved their gait speed after THA independently from prehabilitation.
3	To determine if patients who underwent revision surgery for aseptic loosening of their THA had higher physical activity levels before the revision compared to unrevised control patients.	Case-control study of 77 THA cases revised due to aseptic loosening and 429 unrevised THA controls.	Physical activity did not increase the risk of aseptic loosening in THAs containing HXLPE with a mean follow-up time of 9.1 years.

THA; Total Hip Arthroplasty, NAR; Norwegian Arthroplasty Register, HUNT3; The Trøndelag Health Study, the third wave, OA; Osteoarthritis, HHS; Harris Hip Score, HXLPE; Highly Cross-Linked Polyethylene

Thesis summary

Thesis summary (Engelsk versjon av sammendrag)

Physical activity is health-enhancing and improves quality of life. Patients with osteoarthritis (OA) in the hip often experience inactivity due to pain and joint stiffness. There is no cure for OA, thus, when conservative treatment fails, the only available treatment is surgery: total hip arthroplasty (THA). In THA, the native hip joint is replaced by an artificial joint. While THA is known to reduce pain and improve function, the physical activity level that patients achieve after THA is less well understood. Physical activity has been associated with THA wear and implant loosening. THA wear leads to particle debris, which induces a foreign body reaction. This foreign body reaction involves a local inflammatory response that causes bone resorption around the implant, potentially leading to implant loosening. Thus, the recommendations on physical activity after THA have been somewhat restrictive. However, in 1998, an improvement was made to the bearing surface of the cup: highly crosslinked polyethene (HXLPE). As HXLPE is more resistant to wear, revision surgery due to implant loosening has been remarkably reduced; thus, HXLPE has become the standard bearing surface of a THA. Given the increasing number of THA procedures being performed on younger patients, as well as an ageing population that is living longer, updated perspectives on physical activity after THA are warranted. This thesis aimed to explore the physical activity levels that patients attain after THA, to determine whether these levels can be improved through prehabilitation, and to assess whether high physical activity levels pose a risk for aseptic loosening of implants with HXLPE.

In the first study, we investigated the physical activity level attained by individuals with THA on average 9.6 years after surgery. We compared it to a matched control group from a population-based study, the HUNT3, using a case-control design. Furthermore, we calculated whether these physical activity levels met health-enhancing guidelines. In the second study, we designed a randomised controlled trial (RCT) in patients aged 70 years or older awaiting THA, to find out if a preoperative physiotherapist-guided training and educational program called prehabilitation improved postoperative activity levels. Patients were randomly assigned to either prehabilitation or usual care, and the primary outcome, gait speed, was

compared after the intervention and at 3, 6, and 12 months after surgery. In the third study, we investigated whether the level of physical activity was associated with reoperation due to aseptic loosening of implants with HXLPE at an average follow-up of 9.1 years. In a case-control design, revised and unrevised THA patients, aged 40 – 75 years at the time of surgery, were identified in the Norwegian Arthroplasty Register and asked retrospectively about their physical activity level at their best condition after the primary surgery. This peak physical activity level was compared between groups and analysed for the risk of later revision due to aseptic loosening of the THA.

Individuals with THA aged 50 to 90 years reported higher physical activity levels than the controls from HUNT3. 63% of individuals with THA reported physical activity levels meeting health-enhancing guidelines, compared to 39% in the control group. Prehabilitation in older patients awaiting THA did not improve gait speed after THA compared to usual care. However, pre-post operative physical performance increased in both groups. Furthermore, prehabilitation improved gait speed before THA surgery compared to usual care. Peak physical activity levels after primary THA were not higher in individuals revised due to aseptic loosening compared to unrevised control patients. In multivariate regression analyses, a high physical activity level was not associated with aseptic loosening of the implant.

This thesis extends the understanding of physical activity levels after THA. Patients with end-stage hip osteoarthritis who undergo THA may attain a physical activity level that meets health-enhancing guidelines. Since physical activity is associated with independence among the elderly, and physical activity levels increased after THA in OA-patients over 70 years, THA should be considered essential for improving the quality of life, even among the elderly. Prehabilitation for patients awaiting THA should not be prescribed routinely, as it does not improve postoperative activity levels. However, patients facing a waiting time for surgery may be offered prehabilitation to prevent preoperative deterioration. As physical activity was not associated with aseptic loosening of implants with HXLPE, individuals with THA should be encouraged to embrace the health benefits of physical activity rather than facing restrictions due to concerns about implant wear and loosening. However, HXLPE has only

existed for two decades, and results need to be confirmed on prospectively collected physical activity levels at longer follow-up in the years to come.

Sammendrag av avhandlingen (Thesis summary, Norwegian translation)

Fysisk aktivitet bidrar til god livskvalitet og forebygger sykdom. Hofteleddsartrose er en tilstand preget av smerter og stivhet som fører til redusert fysisk aktivitet. Det finnes ingen kur mot artrose, slik at når smertelindring og trening ikke gir ønsket effekt, er kirurgisk behandling med hofteprotese det eneste behandlingstilbudet. Ved innsettelse av en hofteprotese blir det naturlige hofteleddet erstattet med et kunstig ledd. Selv om hofteprotesen er kjent for å redusere smerte og forbedre hoftefunksjonen, vet vi mindre om hvilket fysisk aktivitetsnivå pasientene oppnår etter operasjonen. Fysisk aktivitet har vært assosiert med slitasje og løsning av hofteprotesen. Årsaksmekanismen er en lokal betennelsesrespons på slitasjepartikler som fører til bentap rundt protesen. Dette bentapet kan forårsake at protesen løsner. På grunn av sammenhengen mellom fysisk aktivitet og proteseløsning har aktivitetsanbefalingene vært tilbakeholdne. I 1998 ble protesen forbedret med en slitesterk overflate kalt «høygradig kryssbundet polyethylene» (HXLPE). I Norge startet vi å bruke HXLPE i 2005. Siden HXLPE gir redusert slitasje på protesen, har antallet reoperasjoner på grunn av proteseløsning blitt redusert, og HXLPE har blitt standarden. I dag opererer vi yngre pasienter med hofteprotese enn tidligere, samtidig som folk lever lenger med protesen. Siden fysisk aktivitet er viktig i alle livsfaser mener vi det er et behov for økt kunnskap om fysisk aktivitet etter operasjon med hofteprotese. Målet med denne avhandlingen var å undersøke hvilket fysisk aktivitetsnivå individer med hofteprotese når, om disse nivåene kan forbedres gjennom prehabilitering, og vurdere om et høyt aktivitetsnivå utgjør en risiko for løsning av hofteproteser med HXLPE.

I den første studien undersøkte vi fysisk aktivitetsnivå hos individer med hofteprotese gjennomsnittlig 9.6 år etter operasjonen og sammenlignet dette med en kontrollgruppe fra befolkningsundersøkelsen HUNT3 med et kasus-kontroll-design. Videre vurderte vi om disse aktivitetsnivåene oppfylte helsefremmende retningslinjer. I den andre studien gjennomførte vi en randomisert kontrollert studie for å finne ut om et fysioterapeutledet trenings- og utdanningsprogram før operasjonen, kalt prehabilitering, kunne forbedre aktivitetsnivået etter operasjonen. Vi inkluderte pasienter over 70 år med hofteleddsartrose ventende på

hofteprotese. Pasientene ble tilfeldig trukket til prehabilitering eller vanlig behandling. Vi målte ganghastighet som utfallsmål ved inklusjon, etter intervensjonen og 3, 6 og 12 måneder etter operasjonen. I den tredje studien undersøkte vi om fysisk aktivitetsnivå var assosiert med aseptisk løsning av hofteproteser med HXLPE. Ved hjelp av et kasus-kontroll-design identifiserte vi reviderte og ikke-reviderte individer med hofteprotese, i alderen 40–75 år på operasjonsdagen, i det norske hofteproteseregisteret med gjennomsnittlig 9.1 års oppfølgingstid. Pasientene ble spurt retrospektivt om sitt aktivitetsnivå «da de var på sitt beste» etter primæroperasjonen. Dette toppnivået av fysisk aktivitet ble sammenlignet mellom gruppene, og risikoen for senere revisjon på grunn av aseptisk løsning av protesen ble analysert.

Resultatene viste at individer med hofteprotese i alderen 50 til 90 år rapporterte høyere fysiske aktivitetsnivåer enn kontrollene fra HUNT3. Hele 63 % av individene med hofteprotese oppga aktivitetsnivåer som oppfylte helsefremmende retningslinjer, sammenlignet med 39 % i kontrollgruppen. I den randomiserte kontrollerte studien hadde prehabilitering blant eldre pasienter som ventet på hofteprotese ingen signifikant effekt på ganghastighet etter operasjonen sammenlignet med kontrollgruppen. Begge grupper viste imidlertid økning i ganghastighet etter operasjonen og prehabiliteringen forbedret ganghastigheten før operasjonen sammenlignet med vanlig behandling. Toppnivåene av fysisk aktivitet med hofteprotese var ikke høyere hos individer som senere ble revidert på grunn av aseptisk løsning, sammenlignet med ikke-reviderte pasienter. Fysisk aktivitet var derfor ikke assosiert med aseptisk løsning av hofteproteser med HXLPE.

Denne avhandlingen bidrar til økt kunnskap om fysisk aktivitet blant individer med hofteprotese. Pasienter med hofteleddsartrose som opereres med protese, kan oppnå aktivitetsnivåer på høyde med helsefremmende retningslinjer. Siden fysisk aktivitet er assosiert med selvstendighet blant eldre, og det fysiske aktivitetsnivået økte etter hofteproteseoperasjon hos pasienter over 70 år, bør hofteprotesen betraktes som essensielt for å forbedre livskvaliteten, selv for eldre. Det bør ikke rutinemessig foreskrives prehabilitering for pasienter som venter på hofteprotese, da det ikke forbedrer aktivitetsnivået etter operasjon. Pasienter med lang ventetid til operasjon kan imidlertid tilbys prehabilitering for å forhindre forverring før operasjonen. Fysisk aktivitet var ikke

assosiert med aseptisk løsning av hofteproteser med HXLPE. Individer med hofteprotese bør derfor oppmuntres til å være fysisk aktive og dra nytte av helsefordelene ved fysisk aktivitet, i stedet for å la seg begrense av bekymringer om slitasje og løsning av protesen. Det er viktig å merke seg at HXLPE bare har eksistert i to tiår. Da folk lever lenge med protesen er det derfor nødvendig å studere assosiasjonen mellom fysisk aktivitet og proteseløsning i årene som kommer.

Introduction

Osteoarthritis of the hip

Osteoarthritis (OA) is the most common joint disease, affecting more than 520 million people worldwide (1). It involves primary structural changes in the cartilage, with subsequent pathology in subchondral bone and surrounding tissue, leading to joint destruction (2). The knee is the most frequently affected joint, followed by the hand and the hip (2). In a Swedish register data study, the prevalence of physician-diagnosed OA of the hip was 5.8% in the population aged 45 years and older (3). OA patients experience pain as the most disabling symptom, which often leads to reduced physical functioning and is associated with an excess of comorbidity and mortality (2). Possible explanations for the excess mortality of OA in the lower limb joints include reduced levels of physical activity (4). There is no cure for OA, but exercise treatment (AktivA), weight loss and pain medication constitute conservative treatment (2). When conservative treatment fails, joint replacement surgery may be warranted.

AktivA

The Active with Osteoarthritis (AktivA) model is a Norwegian program with standardised training exercises and education for patients with OA of their knee or hip joints (5). In the AktivA model, physiotherapists are certified through a one-day course on how to implement the AktivA program and utilise an electronic quality register. Patients are trained for 6-12 weeks, with guided sessions at least twice a week to improve muscular strength, balance and functional stability. In the AktivA quality register, patients report outcome measures at inclusion and after 3, 12 and 24 months. In 2020, Holm et al. published results on the first 6,245 patients registered since the study's inception in 2016 (6). After three months, patients experienced reduced pain, improved quality of life, and increased physical activity levels, and this effect was sustained throughout the two-year observational period.

Total hip arthroplasty (THA)

The hip is a ball-and-socket joint, with the femoral head moving inside the acetabulum, allowing for great freedom of movement. Besides the opportunity for movement, the hip

joint bears the weight of the body as part of the lower extremity in the upright position. This combination of movement and weight-bearing is vulnerable to joint disease, which can induce pain, such as osteoarthritis. Since there is no cure for osteoarthritis, the demand for hip replacement surgery has become essential to alleviate joint pain and enable patients to regain the ability to walk (2). Hip replacement surgery was developed throughout the 1890s and the beginning of the 20th century, but the final breakthrough was made by Sir John Charnley in Wrightington, UK, in 1961. Charnley presented the low-friction total hip arthroplasty (THA) as we know it today, a femoral stem with a metal head in an acetabular socket made of polyethene (7) (Figure 1). Currently, THA is a successful treatment with 90% reporting little to no residual pain following recovery (8, 9), with a 10-year implant survival free of reoperation at 96% (10). Common causes of reoperation include periprosthetic joint infection, relapsing dislocations where the femoral head dislocates from the acetabular cup, periprosthetic fracture, or aseptic loosening of the implant (10). In Norway, the annual number of reported primary THAs in 2024 was 11,337 (5.6 million inhabitants) (10, 11). 66% of patients having THA were women. The mean age at the time of surgery was 70 years in women and 67 years in men. The lifetime risk of primary THA in Norway is up to 16% for women(12).

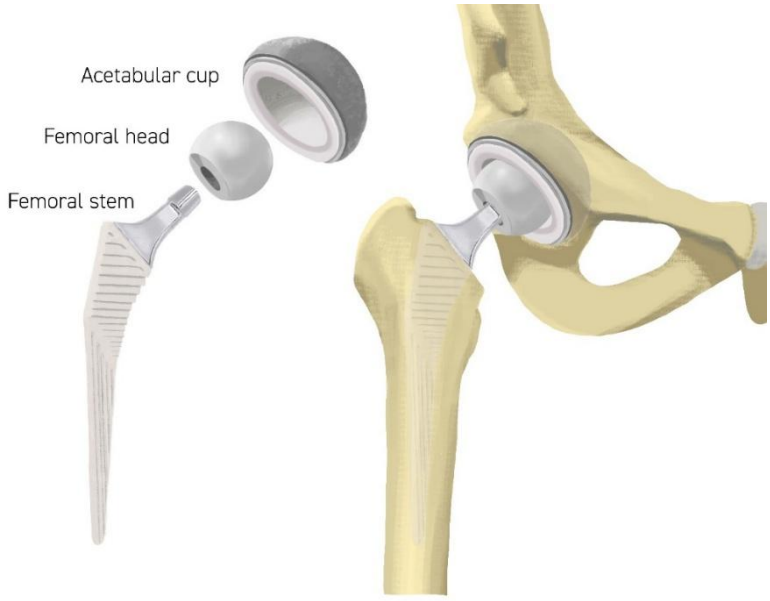


Figure 1,
Illustration of a total hip arthroplasty: a femoral stem with a metal head in an acetabular socket of polyethylene

Illustration by Hellevik studio

The THA presented by Charnley was a monoblock stem and head in a monoblock cup. Since then, the THA has evolved into a modular system, allowing for the choice of a preferred articulating head and liner after the cup and stem are fixed. The liner represents the new socket of the joint. As the head is made of metal or ceramics, the liner, generally consisting of polyethylene, becomes the fretting part of the THA. With the low-friction THA, Charnley aimed to make a long-lasting construct. He was introduced to ultra-high molecular weight polyethylene (UHMWPE) in 1962, whose strength, promoting lubricity and wear resistance, turned out to be a success in a THA (13). However, in the following decades, wear of UHMWPE became a challenge because the multidirectional movement in the THA ruptures the long-chained molecules of UHMWPE. By linking the molecules together, the wear was reduced. The first generation of this improved UHMWPE, introduced in 1998, was named highly cross-linked polyethylene (HXLPE). The last commercially available change of HXLPE, from 2007 to 2008, is the vitamin E-stabilised HXLPE (VEPE), which addresses the structural weakening of HXLPE caused by oxidation. So far, VEPE and HXLPE show similar *in vivo* performance (14).

The fixation of the stem and cup is either with cement or cementless. The cement is polymethylmethacrylate (PMMA), which is polymerised from powder and fluid into a hardening dough applied into the acetabulum or femoral canal before insertion of the implant. PMMAs' compression strength makes it suitable for fixing weight-bearing implants (15). The femoral stem is fixated into the bone cement by two different concepts, the composite beam and taper-slip stem. The composite beam (e.g. Lubinus SP2) has an anatomically adapted shape and a certain roughness that is bonded to the cement. In contrast, the doubled taper-slip stem (e.g. Exeter) allows for subsidence of the polished stem into the hardened cement (16). Cementless implants are fixated with an immediate mechanical fixation, followed by a process of healing into the bone. Thus, the surface of the cementless implant is porous, grit blasted or coated with hydroxyapatite to induce bone ingrowth (17). In early generations of both cementless and cemented stems, some designs were associated with higher revision rates due to aseptic loosening (18). However, today the revision rates between implants due to aseptic loosening are reduced and similar whether cement is used or not (10, 19). Aseptic loosening is described in more detail on page 19.

Nevertheless, elderly women often have osteoporotic bones and should not receive cementless femoral stems due to an increased risk of periprosthetic fractures (20).

Lastly, there are different surgical approaches to the hip joint used to perform the THA. The main approaches are: the anterior (between sartorius and tensor fascia lata (TFL)), anterolateral (between TFL and gluteus medius), lateral (through gluteus medius) and posterior approach (behind gluteus medius) (21). In a study published by the Norwegian Arthroplasty Register (NAR) in 2014, Amlie et al. found that patients operated through the lateral approach reported limping twice as often as those operated through the anterior or posterior approach (22). At the time of the study, the lateral approach was the most frequently used in Norway. In the following years, Norwegian surgeons reported a shift from the lateral to the posterior approach (23). However, Mjåland et al. found no difference between the surgical approaches in terms of the risk of revision due to any cause (24).

The Norwegian Arthroplasty Register

During the first decades of THA surgery, several implants were produced and adopted into clinical practice. The need for quality surveillance of THA surgery led to the establishment of arthroplasty registers. In Norway, the Norwegian Arthroplasty Register (NAR) was established in 1987 by the Norwegian Orthopaedic Association (25). Surgeons from all hospitals in Norway report primary and revision THA on a questionnaire, which is stored in the register's office located at the Department of Orthopaedic Surgery, Haukeland University Hospital, in Bergen. The coverage of reported procedures in Norway is high, with 97% of primary and 91% of revision THAs, compared to data from the Norwegian Patient Register (2019-2020)) (23). Demographic variables, such as patients' age, sex, American Society of Anesthesiologists (ASA) score, indication for surgery, and previous surgery to the hip, are recorded. Of the THA-related variables, surgical approach, fixation method, implants used, use of antibiotics, antithrombotics, and medication to prevent blood loss are registered, in addition to the duration of surgery and type of ventilation system in the operating theatre. After revision surgery, the indication for revision surgery is reported in one or more of the following categories: infection, dislocation, fracture, aseptic loosening, osteolysis, pain only, or other reasons. Thus, complications leading to revision surgery are captured. In 2017, the NAR included patient-reported outcome measures (PROMs) preoperatively, with intended

follow-up at 1, 6, and 10 years after the index surgery. PROMS expands the possibility of surveillance by incorporating patients' experiences of pain and functionality, as well as activities of daily living and physical activity. Besides the annual report produced by the NAR, the register serves as a source for research. Several studies are published annually, and the NAR has produced 36 PhD degrees since 1987.

Aseptic loosening of THA

Aseptic loosening of the THA means loosening of the stem and/or the cup, with the absence of an infection. Risk factors influencing the development of aseptic loosening are patient-related, such as activity levels or genetics, implant-related, including prosthesis design or the bearing couple, and surgical-related, including surgical technique or the placement of prosthesis components (26). Aseptic loosening of the THA has been the most frequent cause for revision surgery registered in the NAR since 1987 until now. However, there has been a decline in the number of revisions due to aseptic loosening: the proportion of such revisions was 74% in 1987-99 compared to 29% in 2023 (23). Additionally, in the same period, the 10-year risk for all-cause revision surgery declined from approximately 11% to 4%. The reduction of aseptic loosening of THA coincides with the reduced wear rate of HXLPE. In a systematic review, Prock-Gibbs et al. compared osteolysis and revision rates due to aseptic loosening up to 15 years of follow-up between patients with HXLPE and those with conventional polyethene (UHMWPE). HXLPE demonstrated less osteolysis and aseptic loosening in both young and elderly patients, regardless of whether the fixation was cemented or cementless (19). Polyethylene wear debris induces an inflammatory response, which can lead to bone loss and implant loosening (27). Thus, fewer wear particles, as seen in HXLPE, lead to less osteolysis. However, wear particles in HXLPE are smaller than those seen in UHMWPE but may cause an increased specific biological response (27). Thus, it is essential to study implant loosening also in THAs with HXLPE, particularly with longer follow-up periods due to the lower wear rate. Accordingly, in the present thesis, we evaluated whether physical activity was associated with implant loosening, with the longest follow-up possible, using THA with HXLPE, in the country.

Figure 2, An illustration of a well-fixed stem into the femur (green), and a loose stem (red) as seen in aseptic loosening with a clear space, osteolysis, around the stem.

Illustration by Hellevik studio

Physical activity

Physical activity and health related benefits

Physical activity is associated with an improved quality of life, including enhanced physical function, better mental health, and disease prevention (28). In a systematic umbrella review, Kraus et al. describe an inverse dose-response relationship between self-reported physical activity and all-cause and cardiovascular mortality, as well as cardiovascular disease (29). E.g. Moore et al. showed a reduced mortality risk already at low levels of leisure time physical activity compared to no physical activity (HR 0.81 (95% CI 0.79-0.83)) (30). Furthermore, the most physically active responders had an even greater effect with reduced mortality risk of HR 0.59 (95% CI 0.57-0.61). In a meta-analysis of accelerometer-measured physical activity in 36,383 individuals with a mean age of 62.6 years, Ekelund et al. found a similar pattern with decreasing mortality risk at increasing physical activity levels. Thus, the 2021 European Society of Cardiology (ESC) guidelines on cardiovascular disease prevention recommend at least a moderate level, 150 - 300 minutes a week of moderate-intensity or 75 - 150 minutes a week of vigorous-intensity, of aerobic physical activity. The least active individuals have the greatest potential for improvement (31). As patients with OA in their hip experience pain and inactivity, and total hip arthroplasty is the only treatment for end-stage hip OA, it is important to know how to improve physical activity after THA.

Physical activity after THA

Despite improvements in pain, physical function, and quality of life, the first year after THA, physical activity levels show a different pattern (32). The increase is only slight to moderate in the first year but appears to increase in subsequent years (33). Low-impact sports such as walking and cycling are commonly performed after THA. Hiking, a medium-impact sport, was performed by 40% of patients after THA. High-impact sports, such as jogging, were reported in less than 10% of participants (33). There are case reports of THA patients participating in high-impact activity sports without damaging their THA (34). However, few studies report on running or jogging after THA (35). For example, Abe et al. reported on 13 joggers with no signs of adverse effects at a 5-year follow-up after THA (36). To perform sports that require strength and coordination of the hips, previous experience in such sports is believed to be essential to prevent trauma and aid in a more controlled loading of the joint (37). Accordingly, while jogging is reported to load the joint 5 times the body weight (xBW), and walking up to 3.3 xBW, an episode of stumbling is reported to load the hip joint at 9 xBW (38).

Most patients wish to return to a pre-pathological level of physical activity or meaningful activities. Barriers to higher physical activity levels are related to limited information on its safety (39). In a systematic review on predictors of physical functioning after THA, preoperative BMI above 28 to 35 kg/m^2, age above 60 to 75 years, increased comorbidity, poor physical function and poor mental health were associated with poor postoperative functional outcome (40).

One method to evaluate the achieved level of physical activity after THA is to compare it to a control group. Knowledge of physical activity levels after THA is important for the preoperative shared decision-making between the surgeon and patient, considering the indication for THA. Current studies comparing physical activity levels in primary THAs with the normal population are small with varying results (41-44). Thus, we aimed to address this in the present thesis by comparing physical activity levels in THA patients with a population as close as possible to the normal population.

Considering physical activity recommendations after THA, physical activity levels and sports have been assessed on their risk for implant wear, dislocation or periprosthetic fracture (45). In an umbrella review, Sowers et al. proposed that low-impact activities, including walking, swimming, and cycling, should be permitted. In contrast, moderate-impact activities, such as hiking, dancing, or downhill skiing, should be allowed with experience. High-impact sports such as jogging or contact sports were not recommended (37). However, in a recent survey among 150 members from the European Hip Society, most surgeons allowed jogging or running 6 months after THA (46). Thus, the authors conclude that European surgeons are mitigating restrictions to sports after THA. This mitigation may be a result of the previously mentioned increased THA survival, with fewer reoperations due to aseptic loosening of THA with HXLPE compared to UHWMPE. Thus, it raises questions about the association between physical activity and aseptic loosening of the THA.

Physical activity and aseptic loosening of THA

Physical activity is associated with aseptic loosening in THA with conventional polyethylene (UHWMPE) (47, 48). The increased risk of aseptic loosening is probably due to wear-induced osteolysis or repetitive mechanical loading (37). However, a systematic review on THA with HXLPE indicated that patients engaging in high physical activity did not have an increased risk of aseptic loosening at a mean follow-up of 2 to 8.2 years (49). Moreover, in a review of HXLPE studies with a follow-up of > 15 years, physical activity was still not associated with increased wear (50). However, as reoperations due to aseptic loosening are less frequent in THA with HXLPE (19), only a few participants in the aforementioned reviews underwent reoperation. Thus, studies with larger sample sizes at longer follow-ups are warranted.

Prehabilitation

In a systematic review on interventions to improve physical activity behaviour after THA, Mooiweer et al. found few studies with diverse conclusions in terms of effect, concluding that more research is needed (51). Prehabilitation is a systematic program of interventions executed before surgery to enhance the surgical outcome (52). While OA-patients often experience pain relief and improved physical function after THA surgery, it is not always so (8), and improvement in physical activity the first year after surgery is sparse (32). Furthermore, the referral to surgery may include months or even years of waiting, which

provides an opportunity for the patients to prepare. Prehabilitation provided to OA patients before joint replacement surgery typically includes an exercise program and, in some cases, education (53). Education may include information on OA, the importance of physical activity, and weight reduction when appropriate. Strengthening exercises in prehabilitation are described with a wide variety in the literature according to supervised or unsupervised sessions, length of intervention (2-12 weeks), and content (mode, intensity, frequency and duration of exercise) (53, 54). This makes it hard to conclude on the effect of prehabilitation. In a recent systematic review and meta-analysis, Punnoose et al. conclude that prehabilitation results in improved physical function before surgery, but there is inconsistent evidence regarding postoperative improvements (53). However, the mean age of the OA patients in the studies was generally <70 years. Older patients with OA perform lower physical activity levels than younger patients (55), giving them a greater possibility of improvement. Thus, studies on prehabilitation in older OA patients are warranted.

Thesis Aims

The aim of this thesis was to explore the physical activity levels that patients attain after THA, to determine whether these levels can be improved through prehabilitation, and to assess whether such physical activity levels pose a risk for aseptic loosening of the implant.

The specific aims of the three studies were:

1) To assess the long-term physical activity level after THA and compare these levels to a control group from a population-based health study.

2) To evaluate whether a prehabilitation program consisting of exercises and education in patients awaiting THA improved postoperative gait speed.

3) To determine if patients who underwent revision surgery for aseptic loosening of their THA had higher physical activity levels before the revision compared to unrevised control patients.

Illustration by Hellevik studio

Materials and methods

Study design

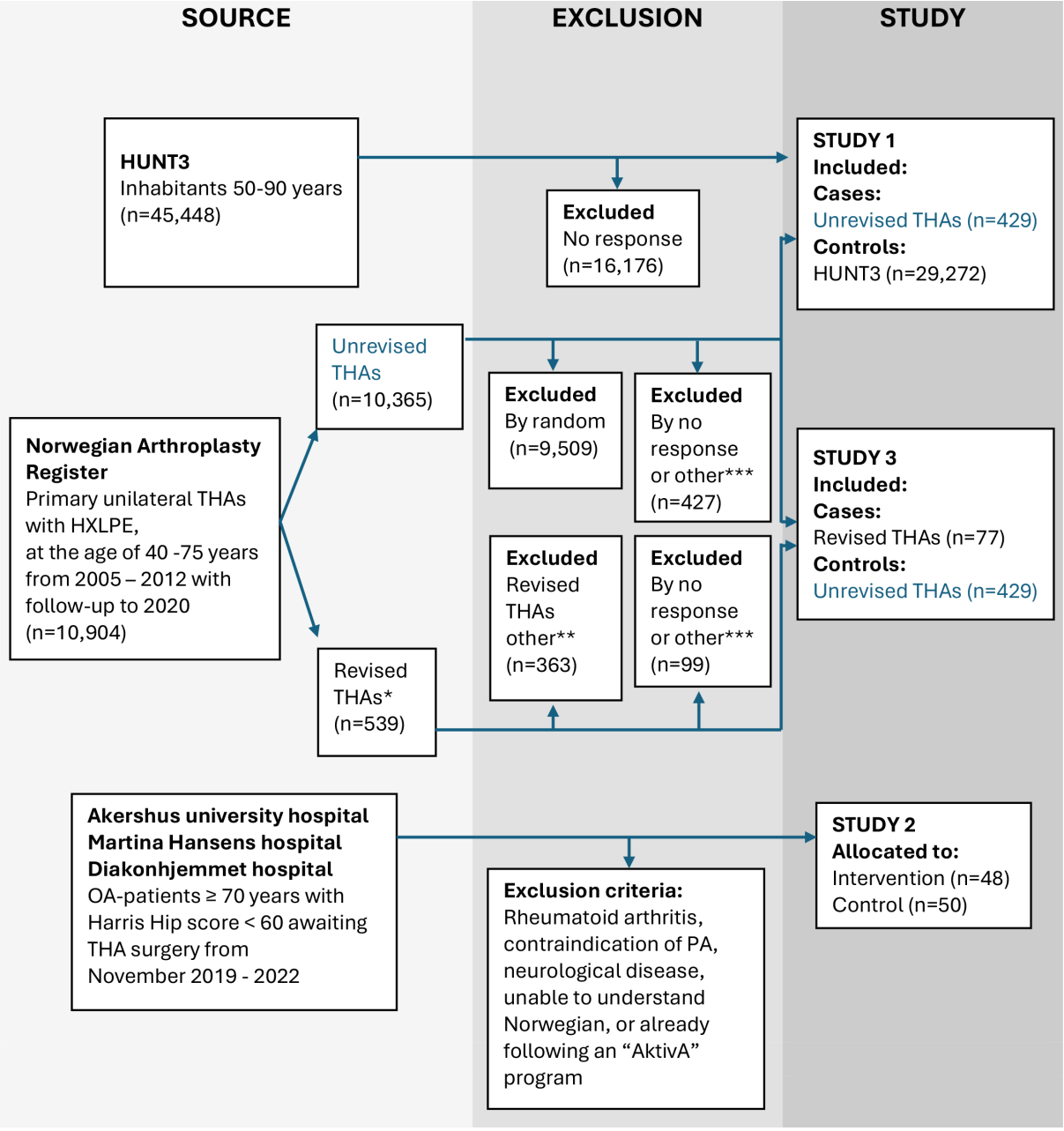
Table 1, Study design and data characteristics of the thesis articles

Study	Design	Analysis category	Data collection	Data type	Checklist
1	Case-control study	Observational	Prospective outcome	PROMS	STROBE
2	Randomized controlled trial	Experimental	Prospective oucome	Objective tests PROMS	CONSORT
3	Case-control study	Observational	Retrospective exposure	PROMS	STROBE

The thesis contains both observational and experimental study designs. In Study 1, we asked, “How physically active are people with Total hip arthroplasty compared to others?” and conducted a case-control study. In Study 2, we asked, “What is the effect of prehabilitation on physical activity levels after THA?”. Thus, we conducted a randomised controlled trial on patients awaiting THA with a training program, AktivA, as the intervention. Finally, we used the case-control design again in Study 3. The study question was “Is physical activity a risk factor for aseptic loosening of a THA?”. Thus, physical activity level was measured retrospectively as an exposure for the outcome: the risk of revision due to aseptic loosening.

Study population

Figure 3, flowchart of the thesis study populations



* Revised THA due to any cause

** Revised due to other reasons than aseptic loosening (infection, implant dislocation etc.)

*** No reply, declined, moved, non-compliant or deceased

HUNT3; The Trøndelag Health Study, the third wave, THA; Total hip arthroplasty, HXLPE; Highly Cross-Linked Polyethylene, OA; Osteoarthritis, PA; physical activity

HUNT3

The Trøndelag Health Study (The HUNT Study) is a large, ongoing health study conducted in central Norway (56). All inhabitants aged 20 and older are invited, and data have been collected longitudinally since 1984. Initially, HUNT focused on studying arterial hypertension, diabetes, and tuberculosis screening. However, its scope has since expanded to include a wide range of data collected through questionnaires, measurements such as blood pressure and body mass index, blood samples, and further tests in sub-groups (57). As a result, the HUNT Study is well-suited for examining epidemiological concerns related to biology, lifestyle, and disease incidence. The HUNT surveys are conducted at 10-year intervals and are named sequentially. To date, four waves have been completed: HUNT1 (1984-1986), HUNT2 (1995-1997), HUNT3 (2006-2007), and HUNT4 (2017-2019). Starting with HUNT2, adolescents were also invited to participate in the Young-HUNT Study. At the planning stage of this study 1, HUNT4 was not complete, so HUNT3 was chosen as the source.

The Norwegian Arthroplasty Register

The Norwegian Arthroplasty Register (NAR) is presented in the Introductory section, page 18.

Akershus University Hospital, Martina Hansens Hospital and Diakonhjemmet Hospital

Akershus university hospital (Ahus), Martina Hansens Hospital (MHH) and Diakonhjemmet Hospital are in the southeastern region of Norway. Ahus and Diakonhjemmet function as regional hospitals for 605,000 and 150,000 inhabitants, respectively (58, 59). MHH is a specialist hospital in orthopaedic surgery and rheumatology and receives patients from across the country (60). In 2023, the number of primary THAs performed was 783 at MHH, 315 at Ahus, and 235 at Diakonhjemmet.

Study intervention

As Studies 1 and 3 were observational, the only intervention conducted in this Thesis is the intervention in Study 2. The intervention in Study 2 involves the AktivA program, as explained in the introductory section of the Thesis on page 15. Participants trained 3 to 4 times a week for a duration of 45 to 60 minutes, over a period of 6 to 12 weeks. Large

muscle groups around the hip were trained. The physiotherapists tailored a training program to each participant in the intervention group. The most common exercises used in the training program are illustrated in Figure 4.

Figure 4, Examples of exercises from AktivA conducted in the intervention of study

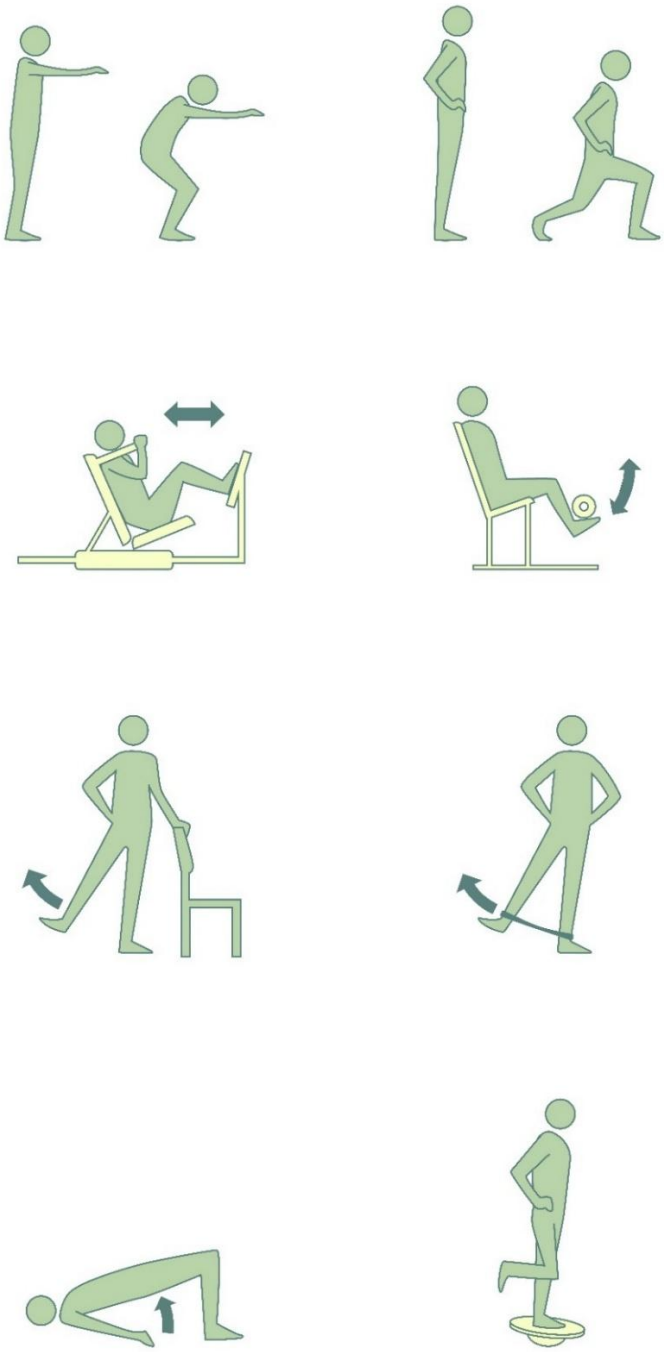


Illustration by Hellevik studio

Variables, demographic and outcome

Overview

Table 2 lists the demographic variables and outcome measures used in the different studies.

The outcome measures are briefly explained in the following section.

Table 2, Variables, demographic and outcome, by study

Study	Demographic variables	Collected outcomes		
		Patient reported outcome	Clinician based outcome	Performance based outcome
1	Age Sex BMI	HUNT LPA questionnaire		
2	Age Sex BMI Education ASA class FCI	HOOS EQ-VAS	Harris Hip Score	40 meter fast paced walk test 30 second Chair test Stair climb test Timed up and go test 6 minute walk test
3	Age Sex ASA class Indication Surg. Approach Fix. Method	UCLA activity score HOOS EQ5D		

BMI; Body mass index, ASA class; American Society of Anaesthesiologists physical status classification, FCI; Functional comorbidity index, HUNT LPA questionnaire; The Trøndelag Health Study Leisure time physical activity questionnaire, HOOS; The Hip Disability and Osteoarthritis Outcome Score, EQ5D; Euroqol 5-dimension questionnaire, UCLA score; University of California, Los Angeles activity score

Demographic variables

Besides age, sex, and Body Mass Index (BMI), education was categorised by level: primary, secondary, or tertiary. Indications for surgery included Osteoarthritis, Hip dysplasia, Femoral neck fracture (acute or sequelae), Rheumatoid arthritis, Bechterew's disease, Calve-Legg-Perthes disease, proximal epiphysiolysis of the femur, and other conditions.

Surgical approach contained Anterior (Smith-Petersen), Anterolateral, Lateral, or Posterior.

The fixation method contained Cemented, Cementless, Hybrid, or Reversed Hybrid. As

measures of comorbidity, we used the ASA class and the Functional Comorbidity Index. To understand the information given by these scales, we will give a brief explanation of their creation and use.

ASA class

ASA class or ASA score is an abbreviation for the American Society of Anaesthesiologists' physical status classification. It was invented in 1941 as a grading system to describe a patient's preoperative condition (61, 62). It is grading comorbidity from 1 (healthy) to 6 (moribund) (63). Patients with higher ASA class have a higher risk of mortality, morbidity such as cardiovascular disease, renal failure, infections, etc., and readmissions after surgery. The Norwegian Arthroplasty Register (NAR) utilises the ASA classification as a preoperative comorbidity measure, enabling comparisons of surgical outcomes across countries. In 2021, 6 national registries and 1 US healthcare organisation registry found a strong association between ASA class and the 1-year mortality risk after total hip arthroplasty (THA) (64).

Functional comorbidity index

The Functional Comorbidity Index (FCI) is an 18-item list of diagnoses that participants mark to indicate their current conditions (65). The score is calculated as the number of comorbidities and exhibits a stronger correlation with greater variation in physical function compared to simpler comorbidity indexes, such as the Charlson index (66).

Clinician based outcome

Harris Hip Score

A Harris Hip Score (HHS) ≤ 60 points was used as an inclusion criterion in Study 2. HHS is a widely used clinician-based outcome measure that assesses hip conditions and the results of hip surgery (67). The original version was provided by W.H. Harris in 1969 in patients with traumatic arthritis following dislocation and acetabular fractures (68). HHS has later been proven suitable to detect changes in patients with osteoarthritis in the hip (69), and to evaluate the outcome of THA (70). The score is a 0–100-point worst-best questionnaire with items covering pain (0-44 points), function (0-47 points), absence of deformity (0-4 points), and range of motion (0-5 points). Harris evaluated an HHS < 70 points as poor. In Oslo University Hospital, an HHS < 60 points has been used as an advisory criterion to recommend

THA in patients with osteoarthritis for three decades (71). Published minimal clinically important improvement in HHS after THA at 16-18 points, corresponding with “somewhat better now”, and moderate improvement at 40 points corresponding with “much better now”, supports this threshold of 60 points (72).

Patient reported outcome (PROM)

HUNT Leisure time Physical Activity (LPA) questionnaire

HUNT has developed its own questionnaire to measure the frequency, intensity, and duration of leisure-time physical activity during a week; the HUNT LPA questionnaire (presented in the methods chapter of Article 1). The outcome can be calculated into an index or categorised into levels of physical activity, including inactive, low, moderate, and high physical activity. The questionnaire is validated against objective physical activity measures, such as treadmill exercise testing and ActiReg, a device that measures body movements to calculate energy expenditure (73). The questionnaire demonstrates acceptable test-retest reliability and validity, particularly for high-intensity physical activity, and is recommended for use in epidemiological research. In Study 1, we used the HUNT LPA questionnaire and calculated categories of physical activity, as well as their ability to meet general physical activity recommendations.

UCLA activity score

The UCLA activity score, first published by H. C. Amstutz et al. in 1984, was developed by the University of California, Los Angeles, to evaluate physical activity after hip arthroplasty surgery (74). It is a one-item 10-level scale, where participants are asked to rate their physical activity level from 1 (wholly inactive) to 10 (highly physically active). The outcome score is calculated as the group mean or median, or categorised into groups: 1-4 (inactive), 5-7 (moderately active), or 8-10 (highly active) (75). The scale was validated against pedometer data in 1998 (76), and has since been considered reliable, without floor effects, for THA and TKA patients, making it appropriate for assessing physical activity levels in patients undergoing total joint arthroplasty (77). Today, it is the most commonly cited one-item questionnaire on physical activity after THA (33). In Study 3, the UCLA activity score was

collected retrospectively as the primary exposure measure for revision surgery due to aseptic loosening of the implant (Appendix Article 3).

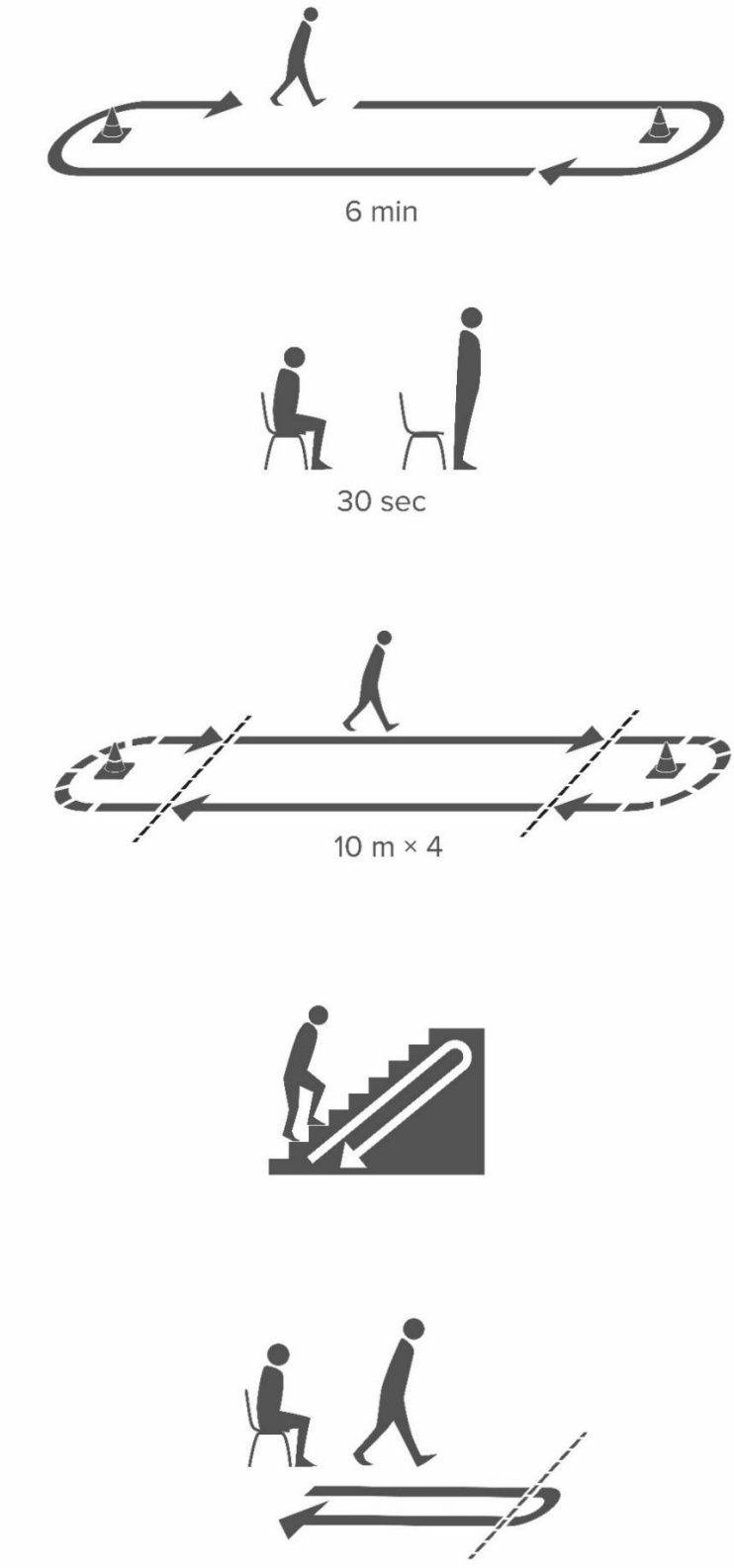
EQ5D, EQ-VAS and HOOS

EQ5D is a generic questionnaire designed to assess health-related quality of life. It was developed by the EuroQol group, an international network of researchers, and comprises five items: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (78). We used the 5-level version, with options ranging from 'no' to 'extreme problems' as answers to each item. The answers are calculated into an index based on value sets made for different regions. However, in Norway, there is no available value set; thus, we used the 3-level UK value set through a crosswalk algorithm (79, 80). EQ5d is widely used and valid for studying musculoskeletal conditions (81). We used EQ5D retrospectively, together with EQ VAS and HOOS, as secondary exposure measures for revision surgery due to aseptic loosening of the implant in Study 3. The EQ VAS (Visual Analogue Scale) is a supplement to EQ5D. Participants rate their general health on a 0 to 100 scale (where 0 is the worst and 100 is the best). The Hip Disability and Osteoarthritis Outcome Score (HOOS) is a hip-specific 40-item questionnaire distributed into the 5 subscales: pain, symptoms, activity of daily living, sports, and hip-related quality of life. Each subscale is calculated on a 0 to 100 scale (worst to best) (82). HOOS is validated as a patient-reported outcome after THA (83). In addition to being used in Study 3, EQ VAS and HOOS were used as outcome measures in Study 2.

Performance based outcome

The five performance-based outcomes recommended to evaluate patients with hip and knee OA by “Osteoarthritis Research Society International” (OARSI) are the 40-meter fast-paced walk test, 30-second Chair test, Stair climb test, Timed Up and Go test and the 6-minute walk test (84) (Figure 5). We used these tests as outcome measures in Study 2, whereas the 40-meter fast-paced walk test was used as the primary outcome measure. The 40-meter fast-paced walk test is a short-distance walking activity which predicts 3-year incidence of physical function and mortality (85, 86). The five test are illustrated in figure 5.

Figure 5, The five performance-based outcomes recommended to evaluate patients with hip and knee OA by the "Osteoarthritis Research Society International" (OARSI)



6 minute walk test: The participants are asked to walk safely as fast as possible on a course preferably > 20 m. A resting and walking aid is allowed.
Outcome: distance walked in meter (m).

30 second Chair test: The participants, sitting in a chair with arms crossed over their shoulders, are told to stand up and sit down as many times as possible within 30 seconds.
Outcome: number of fully stands (n).

40 meter fast paced walk test:
The participants are asked to walk as fast and safely as they can along a 4 x 10 m distance. Timing starts and stops every 10 m. A walking aid is allowed.
Outcome: walking speed (m/s).

Stair climb test: The participants walk up and down stairs from one floor to another. Suitable step height at 16-20 cm is recommended.
Outcome: time used from start to end (s)

Timed up and go test: The participants start by sitting in a chair, then rise and walk at a regular pace to a mark 3 m in front of the chair, return, walk back, and finally sit down again.
Outcome: time (s)

Illustration by Hellevik studio

Statistical analyses

Table 3, Statistical analyses, by study

Study	Analyses			
	Descriptive	Outcome	Handling missing data	Sample size calculation
1	Chi-square t-test	Logistic regression	Single imputation Multiple imputation	No
2	Chi-square t-test	Linear mixed models	Multiple imputation	Yes
3	Chi-square t-test Mann-Whitney U test	Logistic regression	None	Yes

Analyses

Descriptive data were compared between groups using the Chi-square test for categorical data and the t-test for continuous data in all three studies. The UCLA score, EQ5D index, EQ-VAS, and HOOS sub-scores were not expected to be normally distributed. Thus, they were presented with median and interquartile range, and a non-parametric test, the Mann-Whitney U test, was utilised for comparison between groups. However, as parametric tests are robust and may tolerate skewed distributions, we used them in the analyses of the study outcome. This allowed us to adjust for confounders in multiple regression analyses.
We used logistic regression in the primary analyses of the outcome in Studies 1 and 3.

The linear mixed model (LMM) is a method that handles observations with more than one follow-up measurement (87). In Study 2, measurements were conducted at baseline, post-intervention (before surgery), 6 weeks after surgery, and at 3-, 6-, and 12 months after surgery. Thus, the LMM was used for analyses of the outcome.

Missing data

If there was no systematic difference between missing and observed data or the systematic difference could be explained by the observed data, we considered the use of a multiple imputation (MI) technique (88). We used MI in Studies 1 and 2, and additionally, single imputation in Study 1.

Sample size estimations

In study 1, we did not perform a sample size estimation. This was partly due to the large case and control groups, whose size was considered sufficient, and partly because we failed to detect a meaningful clinical difference in the outcome variable.

In Study 2, we used a meaningful difference in gait speed of 0.1 m/s between groups, with a standard deviation of 0.2 m/s, as reference values for sample size calculation (89). With 5% significance level and 80% statistical power, we needed 120 participants. Unfortunately, the COVID-19 pandemic slowed recruitment of participants, and the sample size was subsequently recalculated to 98 participants.

In Study 3, we calculated the sample size based on a difference in the UCLA activity score of 0.92 as the least meaningful clinical difference and 2 as the standard deviation (90, 91). With these values at a 5% significance level and 80% statistical power, we needed 148 participants, 74 in each group.

Summary of results

Study 1

Patients with THA (n = 429) were more physically active, with a mean of 9.6 (SD 1.6) years after surgery, than a control group from a population-based health study, HUNT3 (n = 29,701). The mean age in cases with THA was 71.6 (SD 7) years compared to 64.3 (SD 10) in the controls. While sex distribution was equal between groups, body mass index (BMI) was slightly lower in the cases, with a BMI of 26.3 (SD 3). 245 (63%) of cases and 10,803 (39%) of controls reported a moderate to high level of physical activity, meeting the health-enhancing recommendations for physical activity. In logistic regression analyses adjusted by age, sex and BMI, THA patients were still more physically active than the control group. The result was confirmed by both single and multiple imputation analyses on missing observations of physical activity.

Study 2

Prehabilitation in older patients awaiting THA did not improve physical activity levels after THA compared to usual care. Participants in the intervention group (n=48) had a mean age of 76.8 (SD 4.4) years and a baseline HHS of 48.0 (SD 9.7), compared to 76.3 (SD 4.7) years and HHS 47.6 (SD 7.4) in the control group (n=50). After a median intervention length of 11 weeks (range, 4-20 weeks), patients in the intervention group had higher gait speed than the controls (mean difference, 0.15 m/s; 95% CI, 0.02 to 0.28). However, at the primary endpoint, 3 months after surgery, or at later follow-ups, this difference did not persist. Additionally, secondary outcomes did not reveal any differences between groups at follow-ups after THA. Despite the lack of between-group differences, both groups showed improvement in gait speed at all follow-up visits after THA. The improvement was highest at 12 months after THA, with 0.36 m/s in the intervention group and 0.22 m/s in the control group, compared to baseline measures.

Study 3

THA patients revised due to aseptic loosening, the cases (n=77), reported lower physical activity levels at their best condition after primary surgery (UCLA score mean 6.3 (SD 2.0))

compared to unrevised THAs, the controls (n=429) (UCLA mean 7.2 (1.9)). The mean age at the time of primary surgery was 61.0 (SD 8) years in cases, compared to 62.0 (SD 7) years in controls. Time from primary THA to revision surgery ranged from 50 days to 12 years, with a mean of 4.5 years. We analysed the physical activity levels in the cases over time, from primary to revision surgery, and found higher physical activity levels in patients who had a longer time to revision. However, the physical activity levels in the latest quartile, 7.3–12 years from primary surgery to revision, were still not higher than in unrevised controls. Logistic regression analyses of the retrospective peak physical activity on the risk of revision surgery did not reveal any association between physical activity and increased revision risk (OR 0.8, 95% CI 0.7-0.9). Adjustments for possible confounders did not change the conclusion.

Discussion of main findings

With the increasing number of hip arthroplasties performed and patients' growing demands for quality of life, this thesis addresses some important questions regarding physical activity following a "modern" THA with HXLPE. The physical activity level in individuals with THA, approximately 10 years after surgery, was higher than in a control group representing a normal population. Furthermore, a majority of those with THA reported a physical activity level that met the general recommendations (Study 1). A prehabilitation program consisting of exercises and education in patients awaiting THA did not improve gait speed after THA compared to no prehabilitation. However, prehabilitation improved gait speed before surgery. Moreover, all patients increased their gait speed regardless of prehabilitation 1 year after surgery (Study 2). Patients who underwent revision surgery for aseptic loosening of their THA had lower physical activity levels before the revision compared to unrevised control patients. Thus, with a mean follow-up at 9.1 years after primary surgery, physical activity was not a risk factor for aseptic loosening in THAs with HXLPE (Study 3).

Physical activity level after THA

In 2021, Mooiweer et al. published a systematic review on the amount and type of physical activity and sports after THA (33). Most studies in the review reported physical activity levels using one-item questionnaires, such as the UCLA Activity Score. 21 studies reported UCLA scores between 5.5 and 7, with a minimum of 1 year follow-up after THA, which correlates to regular participation in moderate activities. However, this thesis aimed to provide additional knowledge about the increased physical activity level after THA by comparing it to a large control group at a longer follow-up. Study 1 showed that patients with THA were more physically active 9.6 years after THA than age-matched controls from the large HUNT population. Although this result may be biased by the selection of OA patients eligible for THA and by healthier responders among the THA cases, the responders in the HUNT study also represented a healthier sample than the non-responders (92). On the contrary, Wagenmakers et al. found no difference in physical activity between patients with THA 3.3 years postoperative and a normal population of healthy counterparts (44).

Furthermore, in a European survey, 61% of adults reported fulfilling health-enhancing physical activity guidelines, which is closer to our THA population's rate at 63% than the HUNT3 population's rate at 39% (93). Thus, the probability of reaching health-enhancing physical activity guidelines depends on the selection of the tested populations. We believe that the reference population of HUNT3, which consists not only of healthy individuals, is more likely to be representative of a normal population. Thus, it is reasonable to conclude that patients with THA can achieve a physical activity level comparable to, or even surpassing, that of the normal population.

Another method to consider the outcome after THA is to compare the results of the operated leg with those of the non-operated leg, making each patient their own control. In a rehabilitation study that compared maximal strength training and conventional physiotherapy following THA, Winther et al. showed that the strength of the operated leg exceeded that of the non-operated leg after 1 year (94). In fact, maximal strength training showed improvements exceeding those of the non-operated leg as early as 3 months after surgery. Thus, it is reasonable to conclude that the individual can resume their pre-pathological physical activity level after THA, enabling them to perform physical activity as desired. A conclusion that supports our finding of individuals with THA being physically active.

The improvement of physical activity after THA was also seen in Study 2, where gait speed in the old THA population improved in line with Danish and American reference values 1 year after surgery (95, 96). Also, TUG values improved from the 75th percentile to the 25th percentile of TUG values of a Norwegian reference population (97). In the elderly population, it is crucial to manage activities of daily living (ADLs) to maintain independence. As gait speed is associated with independence in dressing and bathing (86), the older THA population in Study 2 likely improved their independence by increasing gait speed after THA.

The extended knowledge of physical activity levels after THA brought by this thesis is important for inactive OA patients considering THA surgery, and for the surgeons guiding them.

Prehabilitation in patients awaiting THA

Prehabilitation in the elderly population with end-stage OA in their hip did not improve physical activity levels after THA (Study 2). In our study, the prehabilitation training program was designed to last 8-12 weeks. This was adjusted to 6-12 weeks because some patients were offered surgery earlier than expected. Furthermore, as the participants had end-stage OA and suffered from pain, they struggled to perform exercises at the intended intensity, despite most participants attending to more than 80% of the planned sessions. A shorter prehabilitation period than intended and the reduced exercise intensity question the quality of the conducted prehabilitation. Besides, it raises the question of whether an average OA patient scheduled for THA surgery is suited for prehabilitation at all. As several systematic reviews exist on prehabilitation before THA surgery, the topic is thoroughly documented (53, 98-100). Heterogeneity of interventions and outcomes, and low quality of evidence, make it unclear whether prehabilitation improves physical activity levels post THA. In Article 2, we described this inconsistency by evaluating several studies based on their performance-based outcomes. However, most prehabilitation studies are conducted on patients in their mid-sixties. As physical performance declines with age (Study 1), we wondered if an older population would be more likely to benefit from prehabilitation. Only two studies have included older participants, with a mean age of over seventy years. These studies were clearly underpowered with 21 and 30 participants. In the first study, Hoogeboom et al. found no effect of prehabilitation (101). However, the study suffered from selection bias, with only 21 out of 62 eligible patients willing to participate. As unwillingness to participate was due to logistical considerations, Oosting et al. attempted to address this by creating a home-based exercise program twice a week for 3 to 6 weeks (102). Although the sample was underpowered (n = 30), training at home was considered feasible in the older population, and the intervention group showed some improvements in physical performance measures after THA. In our study, we included old patients, ≥ 70 years, with severe symptoms of hip OA, HHS ≤ 60, and aimed for an appropriate sample size with a more extended intervention period. Nevertheless, we did not find any effect of prehabilitation in THA cases. Unfortunately, our study suffered from a drop-out of 27% at the primary end point 3 months after THA which questions the power of the analysis. This is furtherly discussed in the methodological consideration chapter at page 55. However, the interpretation of the lacking prehabilitation effect after THA must be considered in light of the overall improvement in

gait speed in both the intervention and control group. Thus, what seemed to matter to these patients was to have the THA.

The intervention group showed an improvement in gait speed before surgery compared to the control group. This preoperative effect was also found in a systematic review on prehabilitation of hip OA patients with reduced pain and improved function in 8 studies, and improved muscle strength of hip abductors in 2 studies (53). Thus, we concluded that prehabilitation is an option to prevent deterioration in OA patients with involuntary prolonged latency to surgery.

Physical activity and the risk of aseptic loosening after THA

At the planning phase of study 3, to our knowledge, no study had addressed the question, "Is physical activity a risk factor for aseptic loosening in a THA with HXLPE?" RSA studies of HXLPE had shown promising results, including reduced wear (103). However, physical activity recommendations after THA were still based on studies with the previous conventional PE (UHMWPE) (47, 48), thus, the recommendations tended to be restricted due to the association between physical activity and wear of the implant (19, 51). Since HXLPE is the most commonly used bearing couple in THAs (10), and it is important for people with THA to be as physically active as they desire, we considered it essential to investigate the association between physical activity and aseptic loosening of THAs with HXLPE. As expected, we found no association between high physical activity levels and aseptic loosening in THA cases with HXLPE.

Moreover, recent studies on THA with HXLPE have shown no association between a high physical activity level and aseptic loosening, with follow-ups ranging from 4.5 to 8.2 years (104-106). Our study extended this finding by including THAs with a mean follow-up of 9.1 years and by including a higher number of revised patients. Although we cannot draw conclusions based on retrospective observational studies, it is reasonable to believe that THAs with HXLPE can tolerate high physical activity levels due to their low wear rate. Furthermore, in a recent systematic review of wear, osteolysis and aseptic loosening following THA with HXLPE in young patients, four studies reported physical activity levels

(50). The studies, which had over 15 years of follow-up, did not reveal an increased wear associated with high physical activity levels.

Despite an increasing number of studies showing no association between high physical activity levels and wear of THAs with HXLPE, a systematic review from February 2025 concludes that patients with THA should be counselled to maintain moderate physical activity levels, based on three older studies on revision rates of THA with conventional PE (107). Furthermore, a study published in August 2024 concluded that there is an increased revision risk of THAs in patients with intensive physical activity levels, without discriminating between PE and HXLPE (108). Thus, such studies prove the necessity of research like ours, on the association between physical activity and THA with HXLPE. Nevertheless, as it is important for people at all ages to gain the health-related benefits of physical activity, recommendations of physical activity after THA should emphasize the possibility of being physically active without fearing implant wear and loosening.

Finally, even if the low wear rate of HXLPE implants is promising at 15-year follow-up, there are some theoretical concerns. As mentioned in the introduction chapter, HXLPE was introduced in 1998, which limits the possible follow-up time. In his review on long-term follow-up in young patients with THA, Deans et al. discuss the possibility of a different bioreactivity profile of HXLPE wear particles (50). Furthermore, Rames et al. found osteolysis on CT scans around 9 out of 26 cementless acetabular cups in young patients with HXLP liners at 16 years of follow-up (109). However, the patients exhibited no clinical symptoms related to the osteolysis and had a low wear rate. Additionally, Kim et al. found no signs of osteolysis in CT scans of 133 patients at 17.1 years of follow-up (110). Thus, despite the promising results of low wear rates and reduced revision surgery due to aseptic loosening in THAs with HXLPE liners, this technology has only existed for 27 years and needs to be evaluated at longer follow-up in the years to come.

Methodological considerations

General methodological considerations

Case-control study design

In epidemiology, the research question may fit different designs. Designs have pros and cons that must be considered. Primarily, the designs have been ranked by their ability to show causal inference. In “Handbook of Epidemiology”, Ahrens et al. list the different designs by their ability to corroborate causality (Table 4) (111)

Table 4, Reasoning in different types of epidemiological study

Study type	**Reasoning**
Ecological study	Descriptive; association on group level may be used for development of broad hypotheses
Cross-sectional study	Descriptive; individual association may be used for development and specification of hypotheses
Case-control study	Increased prevalence of risk factor among diseased may indicate a causal relationship
Cohort study	Increased risk of disease among exposed indicates a causal relationship
Intervention study	Modification (reduction) of the inference rate of the disease confirms a causal relationship

Ahrens et al. 2005. Handbook of Epidemiology

The strength of a case-control design lies in its simplicity, making it easy and inexpensive. Moreover, and perhaps most importantly, it enables the study of rare conditions in large populations (112). The weakness lies in the selection of cases, in contrast to randomised groups, which allows confounders to make the cases different from the controls. When the retrospective design is used, cases will be associated with different exposures due to their experience with the condition, unlike the" healthy" controls. This is called recall bias.

Results from a case-control study may indicate a causal relationship (Table 4). However, the association between chocolate consumption and the number of Nobel laureates in a country is probably not proof of chocolate's ability to enhance cognitive functions (113). Thus, to determine the probable causality of an association, Bradford Hill published some viewpoints referred to as the Bradford Hill criteria in 1965 (114). According to three of the criteria, an association should be replicable by different persons in different places, should have a dose-response relationship, and should have a plausible explanation of the causal mechanism. This argumentation is referred to as probabilistic causation (115). Due to probabilistic causation argumentation, the associations found in Studies 1 and 3 may indicate a causal relationship. In Study 1, increased physical activity levels after THA are reasonable due to the reduction of pain and improvements in physical function. In study 3, the reduced wear of HXLPE makes the THA less vulnerable to particle reaction and aseptic loosening.

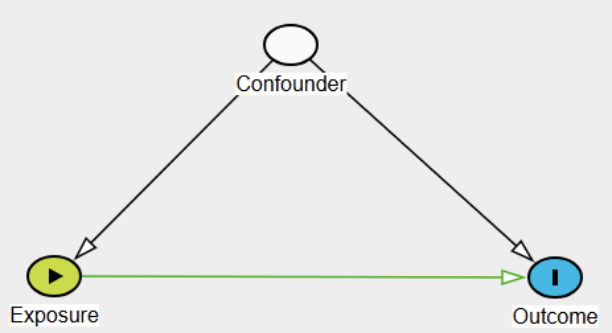
Method for causal inference

To understand the analyses performed in Studies 1 and 3, a theory of causal inference is necessary. It is a model designed to calculate the causality in the association between an exposure of interest and an outcome. For example, in Study 1, we aimed to determine whether having a hip arthroplasty is associated with self-reported physical activity. As Studies 1 and 3 are observational, participants are not randomly assigned; thus, there might be variables associated with the participants that are not randomly distributed between cases and controls. If these variables are associated with both the exposure and outcome, they are referred to as confounders (Fig. 6a). For example, in Study 1, age is a confounder because it increases the likelihood of undergoing an arthroplasty and decreases the ability to be physically active. If the cases are older people with a low level of physical activity and the controls are young and physically active individuals, the association between having a hip arthroplasty and being physically active would be negative due to age. This is called confounding bias. To address this, a causal design named Directed Acyclic Graph (DAG) has been introduced (112). It is named acyclic because the direction of the graph starts at the exposure and ends at the outcome, rather than the other way around. Thus, it points in the causal direction and aims to address variables that affect the relationship between the exposure and outcome, and to identify which variables affecting the causal relationship

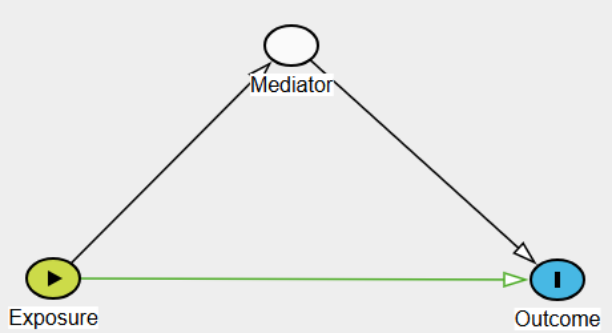
should be adjusted for in the statistical analysis. Thus, a confounder is a variable that should be controlled for in the analysis.

However, two kinds of variables should not be adjusted for in the analysis. The first is a variable called mediator (Fig. 6 b). Some of the effects of exposure on the outcome may be mediated through another variable, the mediator. Thus, the mediator can inform us about the underlying cause of the association, or at least explain some of its components (116). However, adjusting for mediators could "adjust away" some of the association between exposure and outcome, and should not be performed unless for a purpose. For example, in Study 1, the association between THA and physical activity may be due to pain reduction. Thus, pain reduction is a mediator. The second type of variable to be aware of is called a collider. A collider is associated with both the exposure and outcome (Fig. 6c). For example, in Study 1, both having an arthroplasty and being physically active are associated with, and "collide in", quality of life. If quality of life is controlled for in the regression analysis, the association between THA and physical activity is biased (117).

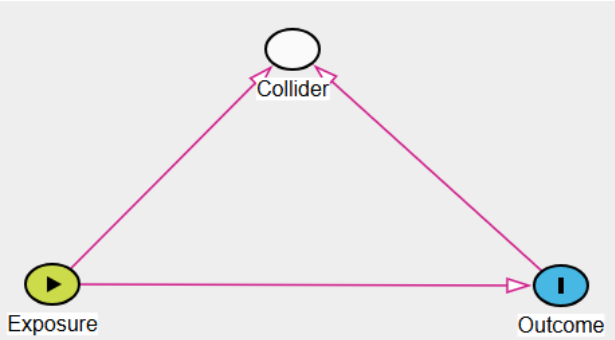
Figure 6, Directed acyclic graphs (DAGs) illustrating a) confounder, b) mediator, and c) collider:



a) confounder



b) mediator



c) collider

Illustrations are drawn at www.dagitty.net

Logistic regression analyses

When analysing the effect of an exposure on an outcome in observational studies, one must use a method that handles the possible influence that confounders might have on the exposure-outcome association. Such adjusted analysis is called regression analysis (118). When the outcome is categorical (Studies 1 and 3), a logistic regression is utilised, whereas linear regression analyses are used for continuous outcomes. The literature and experience suggest which confounders influence the exposure and outcome. Possible confounders are added to the equation through regression analyses, and their effect on the outcome can be quantified and controlled for. This increases the probability of identifying any true association between the exposure and outcome. We used logistic regression analyses in Studies 1 and 3. To use regression analyses, a list of assumptions needs to be examined (118, 119). The assumptions of logistic regression, with examples from Studies 1 and 3, are listed in Table 5.

Table 5, Assumptions of Logistic Regression (118, 119)

Assumptions	Examples from Study 1 and 3
Independence of observations	Observations need to be independent. As we excluded bilateral THA cases, every THA case represented a unique independent participant.
No important variables must be left out of the model	We used DAGs to prepare the analyses.
The absence of multicollinearity	Multicollinearity occurs when two or more variables correlate strongly with each other, making it difficult to assess the independent influence of each variable. Multicollinearity may be checked by the variance inflation factor (VIF). A VIF > 10 may indicate a correlation. In Study 1, age and BMI correlate with a VIF > 10. Similarly, in Study 3, the exposure (Physical activity level) and age correlate. The removal of the correlation did not alter the results in either study, and the variables were retained due to the interpretation of the association in both studies.
Consideration of Interactions	Interaction means that one variable's effect on the outcome depends on the value of another variable. In study 3, physical activity level showed an interaction with surgical approach on the risk of revision due to aseptic loosening. Suggesting that patients operated through the anterior approach had a higher risk of aseptic loosening when performing high levels of physical activity. However, this was based on only a few observations and could not be interpreted as an actual effect.
Linear effect on the log odds scale	Linear effect on the log odds scale was checked and confirmed in Study 3. Furthermore, the model fit of the logistic regression was compared with that of a cubic spline model; however, the model fit of the spline model was found to be weaker.

Analysing RCT data with more than one follow-up measurement

In RCTs, participants are randomised. Thus, if we had an infinite number of participants in the intervention and control groups, the baseline values would have been equal. In such a study, we could have analysed the outcome with a simple t-test. However, including participants is time-consuming and expensive, and is usually restricted to the necessary estimated sample size, thus, baseline values are seldom 100% equal between groups. For example, in Study 2, the number of participants was 48 in the intervention group vs. 50 in

the control group. Thus, due to the limited number of participants, gait speed at baseline differed by 0.21 m/s in the intervention group compared to 0.29 m/s in the control group. Moreover, due to the phenomenon known as “regression to the mean,” high values tend to decrease, and low values of the measured variable tend to increase (120). In Study 2, we expect an increase in gait speed following the intervention. Thus, it is easier to achieve a higher gait speed in the intervention group due to the lower baseline value and the regression to the mean effect. Nevertheless, if participants drop out of the study, the baseline values of the participants could be skewed even more. Therefore, we needed a test that handles differences in baseline values and values measured at different time points. Such a test is the linear mixed model (LMM) (87). In Study 2, we used the LMM, including the variability of repeated measurements within each participant. Thus, in the LMM, we adjusted for the difference in gait speed between the intervention and control groups by accounting for baseline values of gait speed, time, and the interaction between time and group, as the intervention could affect measurements at different time points.

Missing data and imputation of data

Missing data occurs when the study participants lack observations. For example, if a participant fails to appear at a measurement point, the measurement remains unknown. Data may be missing due to various mechanisms, which is important to consider before treating the missing values (121).

Missing completely at random (MCAR) means that there is no systematic difference between missing and observed data. For example, in Study 2, the lockdown due to the COVID-19 pandemic could have prevented participants from participating independently of their age, sex, or group allocation, etc.

Missing at random (MAR) means that there is a systematic difference between missing and observed data that can be explained by observed data. For example, in Study 1, missing data on physical activity were more likely in certain patient groups (women and the elderly).

Missing not at random (MNAR) means that the observed data cannot explain a systematic difference between the missing and observed data, but this difference may still be assumed.

For example, in Study 1, we could speculate that participants with a high activity level were more likely to report their data than participants with a low activity level and perhaps little interest in physical activity. Thus, we would miss data from low activity participants, and the results would be skewed towards higher activity.

In MCAR and MAR, also known as ignorable missing data, imputation techniques on missing data may and should be performed to increase power in the analyses. Multiple imputation (MI) is a recommended technique which creates values for the missing data based on observed data. Thus, with MNAR, nonignorable data, imputation must be performed with caution (88).

Methodological considerations by study

Study 1

Design

In Study 1, we compared the physical activity level after THA with that of a population similar to the general population, as measured in the HUNT study. Since we compared a group of subjects with a defined condition, THA, and compared them to a corresponding group without this condition, a case-control design was proper. However, since the outcome, physical activity level, was measured at a specific current time point, the design could be reminiscent of a cross-sectional design. Nevertheless, as two different populations were compared, the design was assessed as a matched case-control.

Prospectively collected physical activity levels before THA and after would have strengthened the causal relationship. In such a situation, a cohort study could have been performed, telling us whether the physically active population in Study 1 was a selected population, more active than the general population from the beginning (Table 4). However, we did not possess such data and considered a case-control design to be the most appropriate. However, if we had waited for the results of HUNT4 (2017-2019), it would have been possible to match those participating in both HUNT3 and 4 with the NAR, identifying participants who underwent THA between HUNT3 and 4. Thus, baseline levels of physical activity before THA (HUNT3) and follow-up measures of physical activity after THA (HUNT4)

could have been compared with those of HUNT participants without THA, providing an opportunity for more extensive regression analyses. A similar study on physical activity and the risk of having a THA was done in 2016 (122). However, by this design, we would have sacrificed the national sample from the NAR.

Materials

In Study 1, we had a group of 429 unrevised THAs and needed a control group similar to the general population. Thus, we chose the HUNT population as the control group. At the time of HUNT3, Nord-Trøndelag was one of 19 counties in Norway, with a population of 128,694. Of the 93,860 individuals aged 20 and older who were invited, 50,807 (54%) participated. Despite the absence of large cities in the county, the study population is considered representative of Norway's general population. Apart from matching on age, we made no selection from the HUNT3 cohort. HUNT consultants advised this decision due to the risk of introducing unnecessary bias. However, some participants in HUNT3 possessed THA despite being in the control group. In a study from the NAR, the prevalence of THA was 140 per 100,000 inhabitants in Norway during the HUNT3 period (2006-2008), which would estimate 71 THA cases among the 50,807 HUNT participants (123). However, the HUNT3 population included in the study was 50–90 years old (n = 29,272), thus probably with a higher prevalence of THA due to age. According to Johnsen et al. (2016), 1,636 participants from HUNT2 (n = 64,978) and HUNT3 (n = 41,196) underwent a THA from 1987 to 2011. Dec 2013. Thus, eliminating participants from HUNT2 and those with THA after 2008, the number of participants with THA in our control group is probably somewhere < 1000 (<3,4%), considered too small to influence the result.

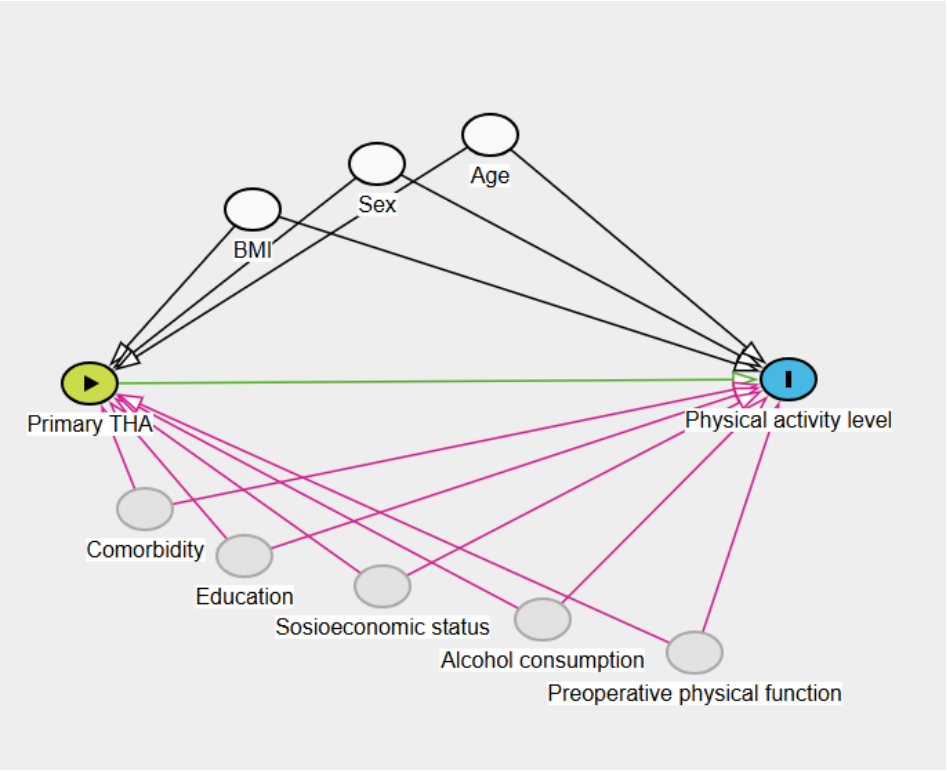
The outcome of Study 1 was the HUNT LPA questionnaire, which was calculated into a dichotomous variable indicating whether participants met or did not meet the general recommendations for physical activity. Although the HUNT LPA questionnaire is validated as an index (73), it is calculated into categories of physical activity by several authors (6, 122, 124). Garnvik et al. transformed these categories into their ability to meet general physical activity recommendations, which was an applicable method for communicating physical activity levels (125). In our opinion, this approach is more communicative than an index. However, as self-reported physical activity levels are known to be overestimated (126), we

could have considered an objective method, such as an accelerometer. Nevertheless, such measurement was considered beyond the budget and time frame for this study, besides having its own weaknesses, including the selection of a smaller sample size and the possibility of underestimating activity levels (127).

Statistics

The primary outcome of physical activity levels between THA cases and HUNT3 controls was analysed by a logistic regression analysis. In the planning phase, we created a DAG to address confounders. Figure 7 shows the DAG including confounders/predictors on physical activity after THA published by Buirs et al. (40).

Figure 7, DAG with confounders of Study 1



Green: exposure, Blue: outcome, White: adjusted variable, Grey: unobserved variable

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The DAG of Study 1 illustrates that several confounders were unobserved. The possession of these variables would have strengthened the causal interpretation of the regression analysis, and the lack of these represents a limitation to the study. However, as Study 1 was part of a

larger project including Study 3, we avoided including too many questions. Furthermore, HUNT3 did not possess a comorbidity scale.

In addition to the confounding bias, Study 1 suffered from selection bias. THA respondents were younger and healthier according to the ASA class. However, as we possessed NAR data on THA non-respondents, we were able to evaluate the selection bias.

Considering missing data, both multiple and single imputation methods were employed in Study 1. Initially, only multiple imputation was performed on the missing values of physical activity levels among cases (10%) and controls (5%). Thus, we assumed that the data were MAR. However, there was a chance that missing data was MNAR. Thus, the reviewer asked us to perform a worst-case scenario (missing data = not meeting physical activity recommendations) and a best-case scenario (missing data = meeting physical activity recommendations) single imputation, including all eligible cases and controls. The conclusion following the imputation did not differ from that of the initial regression analyses.

The sample size consisted of 856 eligible primary THA cases and 45,448 eligible participants from HUNT3. One could argue that the HUNT3 control group was too large because it did not provide a correspondingly increased power (as discussed later in the sample size of Study 3). However, the HUNT3 data were already collected, and we chose not to reduce the number of participants to emphasise that the data were provided from a large population.

Study 2

Design

In Study 2, we questioned the effect of prehabilitation on gait speed after THA. This question was suitable for an intervention study and an RCT, allowing for a causal relationship to be established. Other possible, even stronger, designs not mentioned above are the collection of data from earlier performed studies. In our case, we could have compared results from previous RCTs (Systematic Review) or pooled analysis of data from multiple RCTs (Meta-Analysis). Prehabilitation studies on patients awaiting THA in the literature are heterogeneous, considering the type of intervention and outcome measures. Thus, performing a meta-analysis was difficult. Several systematic reviews have been done on the

topic (53, 128). However, most previous studies have been performed in younger patients (< 70 years) with shorter intervention periods, yielding various results. Thus, an RCT was established for older patients (> 70 years) with an intervention lasting up to 12 weeks.

RCTs are criticised for being expensive and hard to accomplish. Furthermore, RCTs are at risk of selecting patients into the study and performing an intervention, which is not generalisable to a "real world" setting (129). By including the oldest patients with severe hip osteoarthritis (Harris Hip score < 60 points), we aimed to provide data on patients who are often excluded from similar studies. Furthermore, the use of "local physiotherapists" performing the established "AktivA" as the intervention made the intervention both feasible, inexpensive, and generalisable. However, participation in the study was affected by the COVID-19 pandemic, which is explained in more detail below in the "Statistics" section.

Lastly, register-based multicentre randomised controlled trials, combining the strengths of systematic data collection and randomisation, are a more recent design gaining popularity, e.g., the ALBA trial (130). As patients are entered into the NAR at the date of surgery, a randomisation 12 weeks before surgery, performed by the register, would not have been possible. Nevertheless, it would have been unethical to keep patients in prehabilitation > 6 weeks, in hospitals with a routine < 6 weeks from inclusion to surgery.

Materials

Recruitment of participants was planned at several hospitals in the Oslo area. Finally, the three hospitals that managed to recruit participants (Ahus, MHH, and Diakohjemmet) did so because of a latency of more than 6 weeks to surgery, which was decisive for an intervention period of 6-12 weeks. Unfortunately, we were unable to collect data on the excluded eligible THAs. Therefore, we collected descriptive characteristics of eligible patients during the recruitment period at the three hospitals provided by the NAR (Appendix Table 7). The participants included in Study 2 were similar to the eligible patients in terms of age, sex, and ASA class. However, although eligible patients were similar in age and sex between hospitals, they were somewhat healthier, as indicated by the ASA class at MHH. Patients seeking treatment at MHH are selected based on their ability to choose treatment at a hospital far from home, as well as their suitability for treatment in a restricted intensive care unit. As

Ahus and Diakonhjemmet are responsible for the inhabitants of their respective regions, their patient populations are expected to be older and more fragile compared to the selected population at MHH. However, patients were randomised independently of their treating hospital. Thus, this difference in patient population should not influence the result.

The intervention period was reduced from the planned 8-12 weeks to 6-12 weeks due to the short waiting time to surgery in the hospitals. However, the median duration of the intervention in the study was 11 weeks. There was no difference in rehabilitation after surgery, with both groups reporting the use of physiotherapy.

To evaluate physical function in patients with hip and knee osteoarthritis, the OARSI has recommended a set of five tests that assess typical activities (131). Three of these tests, the 30-chair-stand test, 40m fast-paced walk test, and a stair-climb test, were recommended as a minimum. The timed-up-and-go test and 6-minute walk test were recommended as additional tests because of the overlap between activities in the timed-up-and-go test and practical feasibility issues with the 6-minute walk test. We selected all five tests and chose the 40m fast-paced walk test as the primary outcome due to its ability to predict disability in older adults. Perera et al. conclude *that in older adults, gait speed predicts the 3-year incidence of bathing or dressing dependence, mobility difficulty, and a composite outcome of disability and mortality* (86). Furthermore, in a recent epidemiological study of elderly individuals from Poland, gait speed was highly associated with frailty (132). The limited size of an RCT enables the use of performance-based outcomes. A performance-based outcome is associated with measuring the ability to perform physical activity, while a self-reported measure is associated with the experience of performing the activity (133). Thus, the performance-based and self-reported outcomes complement each other. In our study, HOOS and EQVAS were used as complementary PROMS.

Statistics

Data were analysed according to the intention-to-treat (ITT) principle to avoid selection bias (129). When performing ITT analysis, participants' outcomes are analysed based on the treatment they were randomised into, independently of how they behaved. The opposite is the per-protocol (PP) analysis, where participants' outcomes are compared based on their

compliance with the provided treatment. For example, in Study 2, the PP analysis compared participants who completed ≥ 80% of the provided exercises with the controls. In contrast, the ITT analysis compared participants randomised to the intervention and control groups, regardless of the amount of prehabilitation they performed. The ITT analysis risks underestimating the treatment effect, while the risk of overestimation lies with the PP analysis. In study 2, the ITT analysis showed no effect of prehabilitation on the primary outcome. Thus, we performed a PP analysis to see if the participants' compliance with the prehabilitation program had an effect, but it did not.

Unfortunately, we experienced a high drop-out rate in the study. 26 participants (27%) at 3 months post-surgery, 34 (34%) at 6 months, and 40 (40%) at 12 months. The recalculation of our sample size, due to slowed recruitment due to COVID-19, ensured 80% statistical power with the inclusion of 98 participants. As these 98 participants were reduced to 72 at the measurement of the primary end point, the subsequent analysis became underpowered. Insufficient statistical power may have influenced the result, as we may not have been able to demonstrate a difference in gait speed between the intervention and control groups. Such a bias is referred to as a type 2 error (129). Thus, we performed sensitivity analyses on the missing data. Missing data at the primary endpoint, 3 months post-surgery, was considered as missing at random, and multiple imputation was performed. Analyses of the imputed dataset confirmed the results of the initially performed ITT and PP analyses, providing sufficient statistical power to support the conclusion. Furthermore, because participants in the intervention group were somewhat taller than those in the control group, we performed a sensitivity analysis adjusting for body height and sex. The sensitivity analyses showed the same result as the primary LMM analysis.

Study 3

Design

In Study 3, the traditional case-control design was employed. The study question of study 3 was “Is physical activity a risk factor for aseptic loosening of a THA?”. Thus, physical activity level was measured retrospectively as an exposure for the risk of revision due to aseptic loosening, the predefined outcome. A limitation of our study is the recall bias. Cases reoperated due to aseptic loosening are at risk of only remembering their painful hip and

forgetting their physical activity levels before their THA loosened, in contrast to controls without experiencing complications. Prospectively collected physical activity levels could have solved this problem before and after THA. In such a situation, a cohort study could have censored patients who underwent reoperation due to aseptic loosening and compared their physical activity levels with the rest. Sadly, we did not possess such prospectively collected data. However, the NAR began collecting PROMS at baseline and at 1, 6, and 10 years post-THA in 2017, which makes it possible to study the risk of aseptic loosening in relation to prospectively collected physical activity levels in the future.

In theory, an experimental design could have been performed in study 3. However, as aseptic loosening is rare, and wear is a time-consuming process, it is not feasible. Besides, it may not be possible and certainly unethical to randomise patients to high and low levels of physical activity as a lifestyle.

Materials

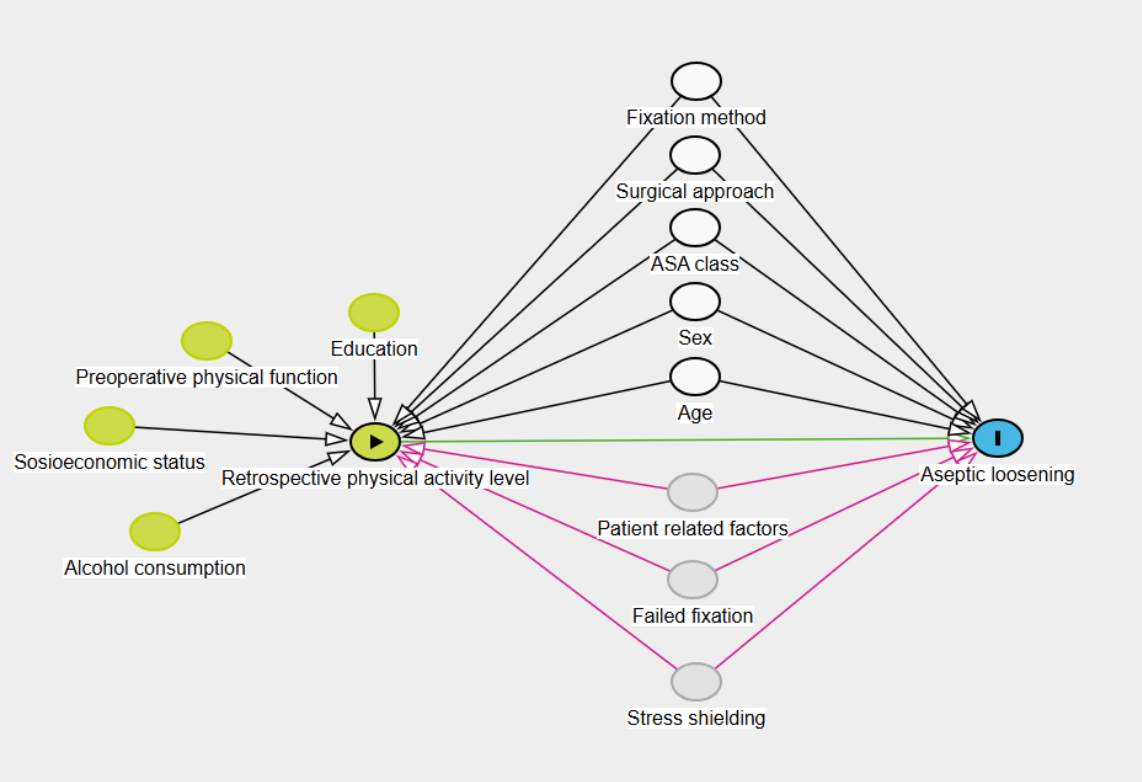
Cases and controls were identified from the same population with THA from 2005 to 12, which was important due to the causal inference of the association between physical activity and aseptic loosening. The retrospective physical activity levels were collected with the UCLA activity score. As mentioned, the UCLA score is the most commonly used one-item score for assessing physical activity levels after THA, also utilised by the NAR since 2017 (23). Thus, it was considered proper for study 3. Objectively measured physical activity was not possible due to the need for retrospective measures. A limitation of the UCLA score is that it is not validated in Norwegian. Heiberg et al. discussed the possibility that it may be problematic that few Norwegians are bowling (UCLA score 8), while “Norwegian” hiking in the forest is not accurately captured by the American-validated scale (134). As there are several versions of both the English version and several translations into Norwegian, we chose a Norwegian version as close to the original scale validated by Zahiri et al (76). However, we included the hikers into the UCLA score 8, as hiking is considered to have a higher impact on the hip than bicycling (UCLA score 7), and less than jogging (UCLA score 9-10). The UCLA score was validated in Danish in 2021 (135), and we aim to validate a Norwegian version after completing this thesis.

Statistics

As participants in Study 3 were selected from the NAR, we had relevant confounders that were included in the logistic regression analyses. For example, the NAR uses the ASA class as a surrogate considering comorbidity. However, several variables that could affect aseptic loosening were beyond our control. Patient-related factors, such as specific diseases like osteoporosis, radiotherapy for metastatic bone disease, or the use of different medications, may influence the integration of uncemented implants (136). Furthermore, genetic susceptibility may be a prognostic factor regarding implant survival (137, 138). Regarding implant-related confounders, Huiskes listed failure scenarios in 1993. Although particle reaction due to wear, as well as physical activity level, is mentioned by Huiskes, other explanations, such as accumulated damage of the cement mantle, failed perioperative bonding of uncemented implants, or stress shielding of the cortical femoral bone around the stem, are also proposed (139). Finally, confounders related to the surgery affecting the positioning and fixation of the implant were not available for analysis. The surgeon's experience is associated with improved implant survival in both primary and revision arthroplasty (140, 141). Thus, the data were analysed adequately; however, according to the DAG, several confounders were not available, and a conclusion on causality was not possible (Figure 8).

As in Study 1, NAR provided data on non-respondents in Study 3. Both cases and controls included in Study 3 were younger and had fewer women than non-respondents. However, despite this selection bias, it is less likely that the older non-respondents were more physically active than respondents. Thus, it is more likely that the most physically active individuals with THA participated in the study among both cases and controls. As the study aimed to assess high physical activity levels on the risk of aseptic loosening, it is less likely that the inclusion of non-respondents would change the result.

Figure 8, DAG with confounders of Study 3



Green: exposure and ancestors of exposure, Blue: outcome, White: adjusted variable, Grey: unobserved variable

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Considering missing data, imputation was considered unnecessary due to only 5% missing values. Missing data below approximately 5% is known as a lower limit to which MI gain little value (142).

The sample size estimation concluded that a total sample of 148 participants was large enough. We aimed to study a large enough THA-HXLPE population with as long a follow-up period as possible to investigate the potential association between physical activity level and aseptic loosening. Since the number of cases revised due to aseptic loosening was the restricted one, we used this number as the target for the sample size. We chose a control group of primary THAs 5 times larger to increase power in the study. Although more than 3 controls per case yield little power (143), we chose 5 controls per case since this group also represented the cases in Study 1. With 77 cases and 429 controls included, the sample size

was sufficient to reject the null hypothesis correctly. Thus, making us able to pick up a difference in physical activity level between cases and controls, if it existed.

Ethical considerations

In Norway, medical and health research is regulated by "the Health Research Act" (144), besides the worldwide "Declaration of Helsinki" developed by the World Medical Association (145). According to the Health Research Act § § 4 and 9, health research conducted to generate new medical or health-related knowledge requires approval from the regional committee for medical and health research ethics (REC) before it can commence. Thus, the studies performed in the present thesis were approved by the REC.

Table 6, Approvals from the regional ethical committee and the local data protection officer by study

Study	Ref.no.	Approval	Date
Study 1 and 3	44572	REC -project application	16.12.19
		REC-change 1	29.05.20
		REC-change 2	26.06.20
		REC-change 3	14.12.22
	2019/159	DPO - project application	18.08.20
		DPO-change 1	27.06.22
Study 2	2018/503	REC -project application	30.04.18
		REC-change 1	10.12.18
		REC-change 2	03.02.19
		REC-change 3	03.07.20
	2019/82	DPO - project application	28.03.19
		DPO-change 1	21.05.22

REC; The Regional committee for medical and health research ethics. DPO; Data protection officer at Akershus University Hospital

The REC approval takes into account several ethical considerations rooted in the ethical principles outlined in the Declaration of Helsinki. Participation in the studies was voluntary and performed through informed and written consent. A sample size calculation was performed to reduce the number of eligible patients to the necessary numbers. The collected data were anonymised and stored in secure data zones, such as the University of Oslo's service "TSD" and the secure zone at Akershus University Hospital. Data remains

secured after study completion and is deleted at a fixed time, 5 years after study completion.

The purpose of interventional studies involving human participants needs to be transparent; thus, Study 2 was published in the publicly accessible database clinicaltrials.gov before the recruitment of the first participant.

The REC approval also included a cost-benefit consideration of study participation. As Studies 1 and 3 were observational, participation did not constitute any risk. However, participation was not associated with benefits for the participants, as they had lived with their THA for a minimum of 7 years without having the opportunity to apply the study's conclusions. On the contrary, the knowledge provided to future THA patients about the possibilities of physical activity after THA was crucial for these studies to be performed. As Study 2 was an interventional study, participants risked being randomised to exercises of physical activity. We had to consider if participants had severe comorbidity, e.g. cardiovascular disease, risking deterioration or even mortality if they participated in the intervention exercises. However, patients eligible for the study were already eligible for surgery; thus, patients with unresolved comorbidities were excluded. According to guidelines, patients with known cardiovascular disease are encouraged to engage in moderate to high-intensity physical activity, just as healthy individuals are (146). Furthermore, the physiotherapists coached participants through the exercise program, reducing the exercise load if the participant experienced too much pain. Thus, participants in the intervention group were not considered to be at any unfavourable risk, but rather to receive the hypothesised improvement in physical activity behaviour.

According to the Declaration of Helsinki § 3, patients included in research cannot suffer as a result of their participation; thus, the health and well-being of the patient are a priority (145). In Study 2, the 6–12-week prehabilitation intervention period challenged the eligibility of patients in hospitals with short latencies to surgery. These patients could not be included. Similarly, participants who were offered surgery earlier than intended could not refuse this possibility due to their study participation. Thus, some participants had intervention periods < 6 weeks.

Conclusions and clinical Implications

The purpose of this thesis was to enhance our understanding of the physical activity levels that patients attain after THA, to determine whether these levels can be improved through prehabilitation, and to assess whether such physical activity levels pose a risk for aseptic loosening of the implant. Individuals with THA aged 50 to 90 years reported physical activity levels that exceeded those of an age-matched control group, similar to those of the general population. Furthermore, nearly two-thirds of the respondents with THA engaged in physical activity meeting health-enhancing guidelines. Old individuals with THA showed improved pre- and postoperative physical performance compared to a reference population. A 6- to 12-week prehabilitation program of education and tailored hip exercises did not improve postoperative physical activity levels until 12 months of follow-up. However, prehabilitation improved preoperative gait speed compared to usual care. Peak physical activity levels after primary THA were not higher in individuals who required revision due to aseptic loosening compared to unrevised control patients at an average follow-up of 9.1 years. Both groups reported moderate levels of physical activity after THA, consistent with mean levels documented in the literature. Thus, physical activity was not a risk factor for aseptic loosening of the THA. However, due to the retrospective study design, our conclusion needs to be confirmed on prospectively collected data.

Individuals with hip osteoarthritis can anticipate a physical activity level that meets health-enhancing guidelines after THA. Young individuals should be encouraged to embrace the health benefits of physical activity rather than facing restrictions due to concerns about implant wear and loosening. Given that physical activity is closely associated with independence among older adults, and that THA can increase physical activity even in elderly patients, age should not be a barrier to undergoing THA. Instead, THA should be viewed as essential for enhancing the quality of life. While routine prehabilitation should not be prescribed for all individuals awaiting THA, it may be beneficial in preventing deterioration for those facing prolonged delays before surgery.

This thesis provides valuable insights into physical activity following total hip arthroplasty. Given that surgery inherently carries risks, it is essential to inform patients about the

potential benefits, thereby helping them make informed decisions. As physical activity is not only vital for enhancing health but also crucial for managing daily living activities, the ability to engage in physical activity is essential at every stage of life.

Future perspectives

Based on current knowledge, physical activity is not a risk factor for aseptic loosening of the THA after the introduction of HXLPE. However, the longest published follow-up of HXLPE is 15 to 20 years. Given the low wear rate, HXLPE needs to be analysed due to wear in the coming decades. In 2017, the NAR began prospectively collecting PROMS. This enables evaluation of UCLA activity scores before, and 1, 6, and 10 years after THA in the years to come. These activity scores should be analysed for all-cause revision surgery, not only aseptic loosening, but also dislocations and periprosthetic fractures, as physical activity may both prevent and constitute a risk to such complications (147).

As engagement in physical activities differs between countries, the UCLA activity score needs to be validated for a Norwegian population. Sports like golf and bowling are not that common in Norway, while regular hiking is. This may not be adequately covered in the present UCLA questionnaire.

There is a sparse literature on individuals with THA regularly engaging in high-impact physical activities. Such studies are more commonly performed after Hip Resurfacing Arthroplasty (HRA), an arthroplasty that imitates the native hip (35). HRA is not offered in Norway due to an unacceptably high revision rate (148, 149). However, individuals with THA also participate in sports such as regular running. Future literature should involve such individuals, providing more knowledge about the safety and durability of implants. Such studies should consider using technology to measure physical activity objectively, as done in the NorEx study (The Norwegian Trial of Physical Exercise After Myocardial Infarction) (150).

As THA surgery is an accessible procedure in Norway, with the possibility of a short waiting time, we do not recommend or consider it meaningful to do further prehabilitation studies on patients awaiting THA in the country.

Finally, aseptic loosening of hip implants is reduced after the introduction of HXLPE but is still one of the most frequent causes of revision surgery. Although considerable attention is devoted to improving implants, less is known about other causes of implant loosening. Correctly performed surgery is maybe the most important factor, which relies on the responsible institution. However, less is known about the host's vulnerability. There are genetic variations associated with osteolysis and aseptic loosening, but the causal association remains unknown (151). A greater understanding of the host's biological susceptibility to aseptic loosening may be an area where diagnostic tools or drugs can be developed to prevent implant loosening (152).

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Appendix table 7

Descriptive characteristics of patients eligible for the study and their primary Total hip arthroplasty (THA) by the recruiting hospitals. Values are counted (%) unless otherwise specified.

Characteristic	Ahus (n = 434)	MHH (n = 840)	Diakonhjemmet (n=294)
Patient*			
Mean age** (SD)	77.7 (4.9)	76.5 (4.8)	78.3 (5.2)
Female sex	294 (67.7)	580 (69.1)	203 (69.1))
ASA class			
ASA 1	9 (2)	70 (8)	7 (2)
ASA 2	259 (60)	615 (73)	194 (66)
ASA 3	163 (38)	153 (18)	91 (31)
ASA 4	2 (0)	1 (0)	0
Not reported	1 (0)	1 (0)	2 (1)
THA			
Surgical approach			
Anterior (Smith-Petersen)	0	2 (0)	0
Lateral	3 (1)	2 (0)	4 (1)
Posterior	425 (98)	807 (96)	285 (97)
Other	2 (0)	20 (2)	0
Not reported	4 (1)	9 (1)	5 (2)
Fixation method			
Cemented	154 (35)	281 (34)	141 (48)
Uncemented	11 (3)	36 (4)	33 (11)
Hybrid	265 (61)	522 (62)	101 (34)
Reversed hybrid	4 (1)	1 (0)	19 (7)

* The patients were all aged ≥ 70 years, with osteoarthritis as the reason for surgery. The surgeons registered them to the National Arthroplasty Register (NAR). We identified them from the NAR as having a THA during the study period from 01.09.2019 to 31.12.2022.

**Age at time of surgery.

ASA class, American Society of Anesthesiologists classification

Articles 1 - 3 with appendix

Article 1

OPEN ACCESS

Acta Orthopaedica 2024; 95: 268–274

Patients with total hip arthroplasty were more physically active 9.6 years after surgery: a case-control study of 429 hip arthroplasty cases and 29,272 participants from a population-based health study

Jakob Vangen NORDBØ [1], Truls M STRAUME-NÆSHEIM [1], Geir HALLAN [2,3], Anne Marie FENSTAD [3], Einar Andreas SIVERTSEN [4], and Asbjørn ÅRØEN [1]

[1] Department of Orthopedic Surgery, Akershus University Hospital, Lørenskog; Institute of Clinical Medicine, Campus Ahus, University of Oslo, Oslo; [2] Department of Orthopedic Surgery, Haukeland University Hospital, Bergen; Department of Clinical Medicine (K1), University of Bergen, Bergen; [3] The Norwegian Arthroplasty Register, Department of Orthopedic Surgery, Haukeland University Hospital, Bergen; [4] Department of Orthopedic Surgery, Lovisenberg Diaconal Hospital, Norway
Correspondence: jakob.nordbo@gmail.com
Submitted 2024-01-05. Accepted 2024-04-08.

Background and purpose — Few studies report on long-term levels of physical activity after THA compared with a control population. This case-control study aimed to find the long-term habitual level of leisure-time physical activity after THA and compare it with a large control group.

Patients and methods — A randomized sample of 856 patients, treated with primary THA, were identified from the Norwegian Arthroplasty Register. 429 (50%) responded to a questionnaire with a mean follow-up time of 9.6 years. We compared them with a control group of 29,272 (64%) from a population-based health study. Physical activity was measured with a questionnaire and categorized into groups according to the general recommendations for physical activity.

Results — 245 (63%) of the THA cases reported a level of leisure-time physical activity meeting the general recommendations, compared with 10,803 (39%) in the control group. The difference persisted at all ages (50–90 years). In sex, age, and BMI-adjusted regression models the chance of meeting the physical activity recommendations was higher in the THA group than in the control group (OR 2.9, 95% confidence interval 2.4–3.6).

Conclusion — The majority of the patients with THA reported a level of leisure-time physical activity meeting the general recommendations for physical activity. THA patients were more physically active in their leisure time than a control group representing a normal population.

Regular physical activity is associated with improved quality of life and a wide range of health benefits [1]. It is recommended for adults of all ages to do at least 150–300 minutes a week of moderate-intensity or 75–150 minutes a week of vigorous-intensity aerobic physical activity to reduce all-cause mortality and morbidity [2]. Patients with osteoarthritis (OA) experience pain as the most disabling symptom leading to reduced physical activity levels [3]. According to a WHO citation from 2015, globally, 80% of individuals with OA will have limitations in movement [4].

While it is known that total hip arthroplasty (THA) relieves pain and increases physical function in patients with end-stage OA, there is only a small to moderate improvement in observed physical activity in the first 6–12 months after THA [5]. After THA, patients are more likely to return to low-intensity activities such as walking and cycling than high-intensity activities such as running and tennis [6]. Physical activity levels in the years following THA seem to be low, with less than half of subjects meeting health-enhancing guidelines [7]. Few studies report on long-term levels of physical activity after THA compared with a control population [8]. Considering the benefits of physical activity and the increasing numbers of THA in younger and more physically active patients (< 65 years old) [9], it is important to know the long-term physical activity level in THA patients.

The purpose of this study was to explore the achievable long-term level of physical activity after THA and to compare it with a control group representing a normal population.

DOI 10.2340/17453674.2024.40815

The HUNT LPA questionnaire:
By exercise we mean, for example, going for walks, skiing, swimming or training/sport

How frequently do you exercise? (*Give an average*)

○ Never	(0)
○ Less than once a week	(0.5)
○ Once a week	(1)
○ 2–3 times per week	(2.5)
○ Almost every day	(5)

If you do such exercise as frequently as once or more times a week: How hard do you push yourself? (*Give an average*)
○ I take it easy without breaking into a sweat or losing my breath
○ I push myself so hard that I lose my breath and break into a sweat
○ I push myself to near-exhaustion

How long does each session last? (*Give an average*)

○ Less than 15 minutes	(7.5)
○ 15–29 minutes	(22.5)
○ 30 minutes to 1 hour	(45)
○ More than 1 hour	(60)

Figure 1. The HUNT LPA questionnaire. Numbers in parentheses indicate the score used for each response when calculating the LPA categories. LPA = leisure-time physical activity.

Methods

Study design and data sources

This is a case-control study based on data from the Norwegian Arthroplasty Register (NAR), patient-reported outcomes (PROMS) and the Trøndelag Health Study (HUNT) reported according to the STROBE guidelines [10]. Norwegian surgeons register data on primary THAs in NAR with a completeness of 97% [11]. The collected data includes information on the patient's age, sex, date of the operation, American Society of Anesthesiologists classification (ASA class), indication for surgery, type of surgical procedure, surgical approach, fixation method, and time spent on surgery. The HUNT Study is a large population-based health study conducted in a region in the middle of Norway. It collects questionnaire data, clinical measurements and biological samples. All residents above 18 years of age are invited. In this study, we use data from the third wave of HUNT [12].

Study population

Patients eligible for the study had unilateral primary THAs with articulations made of a metal or ceramic femoral head on a highly cross-linked polyethylene counter surface (HXLPE). HXLPE was introduced in Norway in 2005. To study patients with reasonably high physical activity at a long-term follow up we selected patients aged 40–75 years at the time of surgery, registered in 2005–2012 [13]. Patients revised before the end of the study were excluded. Identified patients were asked to fill out a questionnaire sent by mail in December 2020. Non-responders received a reminder by mail in February 2021. A second reminder was sent as a text message by phone in July 2021.

Table 1. Categories of leisure-time physical activity (LPA) according to the general PA recommendations

Item	Minutes of LPA per week Moderate intensity	 Vigorous intensity
Not meeting the recommendations		
Inactive	None	None
Low	< 150	< 75
Meeting the recommendations		
Moderate	150–299	75–149
High	≥ 300	≥ 150

To match the THA population at the age of data collection we selected a control population of participants from the HUNT3 Survey aged 50–90 years. The HUNT3 Survey was carried out in 2006–2008. The HUNT3 cohort is previously described in more detail elsewhere [12].

Outcome

Participants reported their leisure-time physical activity levels by answering the previously validated HUNT LPA questionnaire [14], which contains questions on the frequency, intensity, and duration of exercise (Figure 1). The answer option "I take it easy without breaking into a sweat or losing my breath" was considered as moderate intensity and the options "I push myself so hard that I lose my breath and break into a sweat" or "I push myself to near-exhaustion" were considered as high intensity. We multiplied weighted scores of frequencies and duration of physical activity and categorized it into moderate or high-intensity physical activity. From this we made the 4 categories inactive, low, moderate, and high leisure-time physical activity. To perform the statistical analysis, a dichotomous variable, meeting or not meeting the general recommendations for physical activity, was constructed according to the recommendations from the European Society of Cardiology (ESC) [2,15] (Table 1).

Statistics

Descriptive data is presented as means with standard deviations (SD), compared using the independent samples t-test, for continuous variables and numbers with percentages (%), compared using the chi-squared test, for categorical variables. We investigated the coherence of leisure-time physical activity between the study groups at increasing age, with 95% confidence intervals (CI). We performed logistic regression analyses to study the association between the 2 study groups and the chance of meeting the leisure-time physical activity level adjusted for age, sex, and BMI. All statistical analyses were performed using Stata 17.0 SE standard edition (StataCorp LLP, College Station, TX, USA). All tests were 2-sided and a P value < 0.05 was considered statistically significant.

Sensitivity analyses

To verify the robustness of the measured categories of lei-

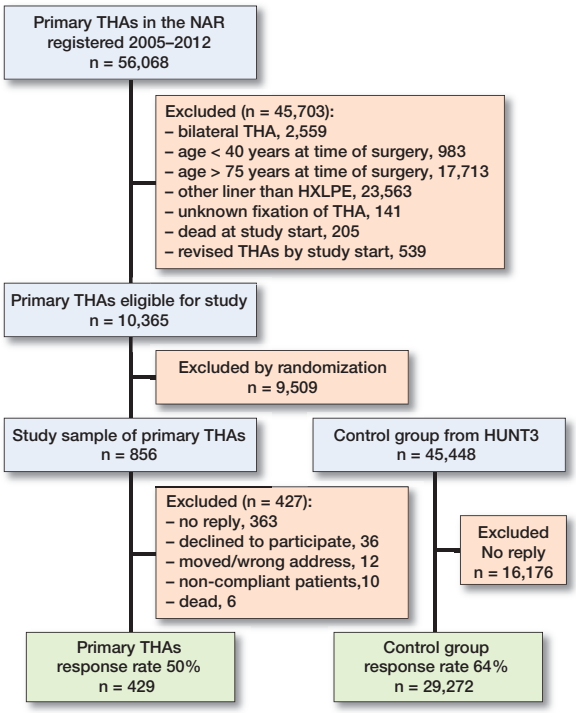

Figure 2. Flowchart of the selection of eligible patients from the Norwegian Arthroplasty Register (NAR), the inclusion process of the sample of patients with primary total hip arthroplasty (THA), and the inclusion process of the control group from the Trøndelag Health Study, a population health study in Norway (HUNT). HXLPE = highly cross-linked polyethylene.

sure-time physical activity we performed a linear regression between the study groups on the previously validated LPA index, which is a continuous variable formed by the product of frequency, duration, and intensity of leisure-time physical activity [14]. We performed multiple imputation analyses on the dependent variable of leisure-time physical activity to include a value for missing observations among the responders in the regression analyses. We also conducted single imputation analyses on the missing leisure-time physical activity data of the non-responders, predicting a worst- and best-case scenario. In the worst-case scenario, missing data was replaced by inactive levels and in best-case scenario by high levels of leisure-time physical activity.

Ethics, funding, and disclosures

The regional committee for medical and health research ethics approved the study (2019/44572/REK sør-øst A). All participants in the NAR and the HUNT study gave informed written consent before participating. Based on this consent the NAR has permission from the Norwegian Data Inspectorate to collect patient data (ref 24.1.2017: 16/01622-3/CDG). The project received a research grant from Ortomedic AS and Eckbos legate. The authors declare no conflicts of interest for this work. Complete disclosure of interest forms according to ICMJE are available on the article page, doi: 10.2340/17453674.2024.40815

Table 3. Comparison of the descriptive characteristics by study groups

Characteristic	THA group n = 429	Control group n = 29,272	Difference between groups (CI)
Mean age (SD) [a]	71.6 (7)	64.3 (10)	7.3 (6.5 to 8.3) [b]
Female sex, n (%)	247 (58)	15,556 (53)	5% (–1 to 9) [c]
BMI (SD)	26.3 (4)	27.6 (4)	–1.3 (–1.7 to –0.8) [b]

[a] Age at data collection.
[b] Independent samples t-test.
[c] Chi-squared test.
THA = total hip arthroplasty.

Table 4. Level of leisure-time physical activity (LPA) by study groups after exclusion of incomplete questionnaires. Values are count (%) unless otherwise specified

LPA	THA group n = 388	Control group n = 29,272	Difference between groups (CI)
Index [a]	4.0 (3.1)	2.4 (2.5)	1.6 (1.3 to 1.8) [b]
In 4 categories			
Inactive	12 (3.1)	6,086 (22)	–19% (–21 to –17) [c]
Low	131 (34)	11,043 (40)	–6% (–11 to –1) [c]
Moderate	110 (28)	6,258 (22)	6% (1 to 10) [c]
High	135 (35)	4,545 (16)	19% (14 to 23) [c]
Dichotomized (meeting recommendations) [d]			
	245 (63)	10,803 (39)	24% (20 to 29) [c]

[a] LPA index, mean (SD): Validated LPA index, which is a continuous variable formed by the product of frequency, duration, and intensity of leisure-time physical activity (LPA) (14).
[b] Independent-samples t-test.
[c] Chi-squared test.
[d] Dichotomized LPA level: meeting or not meeting the general PA recommendations.

Results

429 (50%) of the sampled THA cases from the NAR and 29,701 (64%) of the HUNT participants joined the study. The selection process is illustrated in the flowchart in Figure 2.

THA responders vs. non-responders

On average, the patients who responded in the THA group were 1.5 years younger, healthier (lower ASA class), and the proportion of males was slightly higher than among the non-responders. Osteoarthritis was the dominating indication for surgery and the implants were mostly uncemented or reversed hybrid through the lateral or the posterior approach in both responders and non-responders (Table 2, see Appendix)

THAs vs. control group

Patients answered the questionnaire from 7 to 15 years after the date of surgery, with a mean follow-up time of 9.6 (SD 1.6) years. On average, the THA patients were 7.4 years older and had a slightly lower BMI than the control group. The sex distribution between the groups was equal (Table 3).

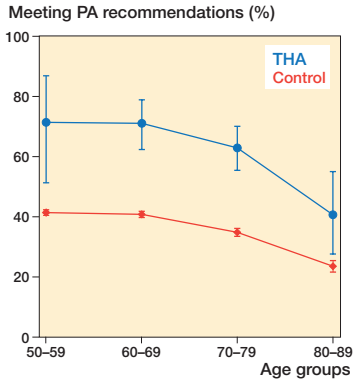

Figure 3. The line chart shows the coherence of meeting the general physical activity (PA) recommendations at increasing ages between the total hip arthroplasty (THA) group and the control group. The leisure-time physical activity levels are shown as the proportion (%) meeting the general PA recommendation with 95% confidence intervals.

Leisure-time physical activity

245 (63%) of the THA patients reported a level of leisure-time physical activity meeting the general recommendations compared with 10,803 (39%) in the control group (Table 4). The level of physical activity decreased with increasing age and the difference between groups was significant in all age groups (Figure 3). Divided into the 4 categories inactive, low, moderate, and high leisure-time physical activity, there were more inactive and low-activity participants in the control group and more moderate and high-activity participants in the THA group (Table 4). In logistic regression analyses adjusted for sex, age, and BMI the chance of meeting the recommendations for physical activity was higher in the THA group than in the control group (OR 2.9, CI 2.4–3.6). Male sex, younger age, and lower BMI were associated with higher levels of physical activity.

Sensitivity analyses

We analyzed the level of leisure-time physical activity as a continuous index [13], being 4.0 (SD 3.1) in the THA group and 2.4 (SD 2.5) in the control group (Table 4). In linear regression analyses adjusted for sex, age, and BMI, being in the THA group was associated with higher LPA index compared with the control group (β 1.7, CI 1.4–1.9).

The HUNT LPA questionnaire was incomplete for 41 participants (10%) in the THA group and 1,340 (5%) in the control group. We performed multiple imputation on the missing values of leisure-time physical activity with 10 imputations of each missing value. In logistic regression analyses of the imputed leisure-time physical activity level, adjusted for age and sex, the chance of meeting the recommendations for physical activity was still higher in the THA group than in the control group (OR 3.1, CI 2.5–3.9). In the single imputation analyses on the missing values of leisure-time physical activity from non-responders, both the worst- and best-case scenario supported the conclusion that the chance of meeting the recommendations for physical activity was higher in the THA group (Table 5, see Appendix).

Discussion

The aim of this study was to explore the long-term level of leisure-time physical activity after THA. Patients with THA showed a higher level of leisure-time physical activity 7 to 15 years after surgery, and were more likely to meet the health-enhancing recommendations for physical activity, compared with a representative control population.

Our study reports higher levels of leisure-time physical activity in the THA group than previously described [7]. This may be explained by selection. We selected a "middle-aged" population with THA, with a mean age of 63 years at the time of surgery, to be able to study long-term levels of leisure-time physical activity. The mean age for having a THA in Norway was 70 years for women and 68 years for men in 2022, making our sample a bit younger than the unselected THA population [11]. Compared with the non-responders the responding THAs had less comorbidity according to ASA class, slightly younger age, and were less likely to be females. Younger age and less comorbidity are predictors of increased physical functioning after THA [13]. This might have introduced selection bias considering the high proportion meeting the general recommendations for physical activity in the THA group and thus may have influenced the external validity of our results.

In a cross-sectional study of 273 primary THA cases compared with a normal population, Wagenmakers et al. found no significant difference in the total amount of physical activity at a mean of 3.3 years after the operation. The national guidelines were met by 51% of the participants with THA and 49% of the controls [16]. Our control group reported lower levels of physical activity than the control group from the study of Wagenmakers et al., which may be explained by the slightly higher age in our study with a mean of 64.3 years compared with 62.4 years. Unfortunately, we do not possess a comparable comorbidity scale between the studies, but the control group of Wagenmakers et al. consisted of age- and sex-matched "healthy" counterparts whereas our control group was matched only on age and unselected on comorbidities. In our study, the control group had a slightly higher BMI than the THA group, which is a known negative predictor of physical functioning [13]. Despite being 7.4 years younger than the THA group at the time of data collection, the control group was less physically active than the THA group. However, our control group was part of the HUNT3 cohort, which did not possess more comorbidity than the average in the eligible population. Published results of nonparticipants in HUNT3 show that they had even lower socioeconomic status, higher mortality, and higher prevalence of cardiovascular diseases, diabetes mellitus, and psychiatric disorders than participants did [17].

Patients at increased risk of early mortality are less likely to undergo surgery [18]. This selection can be transferable to the reduced mortality seen in the first decade after THA [19]. Combined with the exclusion of THA patients registered with revision surgery, this might have introduced a "healthy worker effect", selecting a healthier population, in our THA group. However, this study indicates that THA enables this population to maintain their level of physical activity. Nevertheless, selection bias and the low response rate of the study could affect the robustness of our results. In the sensitivity analyses, we showed a "worst-case scenario," with imputed inactive levels of physical activity on all missing data on leisure-time physical activity. The THA group was still more likely to meet the general recommendation of physical activity than the control group. Thus, we conclude that the result is reliable despite the missing values for leisure-time physical activity.

Though the HUNT LPA questionnaire is utilized for epidemiological research [14], self-reported physical activity is known to be overestimated due to recall bias [20]. In a cross-sectional study of 4,867 Americans, Troiano et al. found that less than 5% of adults met the criteria of recommendations based on accelerometer-derived results compared with 51% in self-reported questionnaires from the same national survey [21]. Accelerometers only give a snapshot of physical activity and are likely to underestimate certain activities such as cycling, swimming, or upper body movement [20]. The HUNT LPA questionnaire was not designed to estimate physical activity according to the recommendations for physical activity. The questionnaire does not include housework or occupational activity, which may have underestimated the level of physical activity in participants doing manual labor. We still chose this method because of the known importance of physical activity in improving the quality of life [1].

Strengths

One strength of our study is the large control group. The population is in most respects representative of Norway with the exception that the geographic region has no larger cities and therefore the population is slightly more rural than the average national population [22]. The THA cases, on the other hand, make up a random national sample.

Limitations

The low response rate of the THA cases is a limitation, though it was in the range of expected response rates of long-term follow-up registry studies [23]. Fortunately, the NAR possesses baseline data on the non-responders, which deduces the representativeness of our sample. In a study from the Australian Orthopedic Association National Joint Replacement Registry, Harris et al. found small differences between responders and non-responders on baseline data when they were asked to fill out PROMs electronically. An additional phone call to non-responders showed no significant difference for most outcomes compared with electronic responders, and the author concluded that electronic-only follow-up on PROMs after THA seems to provide a satisfactory representation of the population invited to participate [24].

The lack of a comparable comorbidity scale between the THA and the control group is a limitation. In addition, the THA cases were recruited from the whole country, whereas the control group was from a specific region. Though a case-control study design is fit to answer the research question of this study, a longitudinal design with access to preoperative levels of physical activity in the THA group could have described change on an individual level. Fortunately, the NAR started electronic follow-up on PROMs preoperatively in 2017, with intended follow-up at 1, 6, and 10 years post-surgery. This enables us to study the pre- and post-levels of physical activity in THA patients in more detail in the near future.

Conclusion

We found that OA patients with THA were more physically active in their leisure time, at a mean of 9.6 years after surgery, than a control group representing a normal population. Based on these findings, OA patients awaiting THA at an age of 40–75 years have a chance to achieve a long-term level of physical activity meeting the health-enhancing recommendations for physical activity. This is important knowledge for surgeons advising OA patients into having THA and for health authorities promoting general health in an aging population.

All authors participated in the conceptualization of the study. JN collected the patient reported outcome measures from the THA cases, performed the data analysis, and wrote the original draft of the manuscript. All authors interpreted the results, reviewed and edited the manuscript.

The authors thank the orthopedic surgeons of Norway for their excellent reporting of joint replacement surgeries to the national register. The Trøndelag Health Study (HUNT) is a collaboration between HUNT Research Centre (Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology NTNU), Trøndelag County Council, Central Norway Regional Health Authority, and the Norwegian Institute of Public Health. Finally, they thank Hanna Vangen for her critical appraisal and help with preparing the data. The project received a research grant from Ortomedic AS and Eckbos legate.

Handling co-editors: Keijo Mäkelä and Robin Christensen
Acta thanks Thomas Jakobsen and Klaus Kjær Petersen for help with peer review of this manuscript.

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APPENDIX

Table 2. Comparison of descriptive characteristics of responders and non-responders in the THA group, data from the NAR. Values are count (%) unless otherwise specified

Characteristic	Responders n = 429	Non-responders n = 427	Difference between groups (CI)
Mean age (SD) [a]	62.0 (7.4)	63.5 (8.5)	–1.5 (–2.6 to –0.4) [b]
Female sex	247 (58)	282 (66)	–8% (–15 to –2) [c]
ASA score			
1	154 (36)	89 (21)	15% (11 to 26) [c]
2	240 (56)	277 (65)	–9% (–16 to –3) [c]
≥ 3	29 (6.8)	56 (13)	–6% (–10 to –2) [c]
Not reported	6 (1.4)	5 (1.2)	0% (–3 to 3) [c]
Indication for surgery			
Osteoarthritis	348 (81)	331 (78)	3% (–2 to 9) [c]
Hip dysplasia	44 (10)	39 (9.1)	1% (–3 to 5) [c]
Acute femoral neck fractures	7 (1.6)	14 (3.3)	–1% (–4 to 1) [c]
Other [d]	30 (7.0)	43 (10)	–3% (–7 to 1) [c]
Surgical approach			
Anterior (Smith–Petersen)	42 (10)	37 (8.7)	1% (–3 to 5) [c]
Anterolateral	59 (14)	40 (9.4)	5% (1 to 9) [c]
Lateral	195 (45)	201 (47)	–2% (–8 to 5) [c]
Posterior	121 (28)	144 (34)	–6% (–12 to 1) [c]
Not reported	12 (2.8)	5 (1.2)	2% (–1 to 3) [c]
Fixation method			
Cemented	66 (15)	92 (21)	–6% (–11 to –1) [c]
Uncemented	152 (35)	145 (34)	1% (–5 to 8) [c]
Hybrid	13 (3.0)	3 (0.7)	2% (1 to 4) [c]
Reversed hybrid	198 (46)	187 (44)	2% (–4 to 9) [c]
Duration of surgery in minutes (SD)	81.8 (24.5)	84.8 (27.7)	–3.2 (–6.6 to 0.5) [b]

[a] Age at time of surgery.
[b] Independent-samples t-test.
[c] Chi-squared test.
[d] Other indications includes, rheumatoid arthritis, Bechterew's disease, Calve–Legg–Perthes disease, proximal epiphysiolysis of the femur, and other indications.
ASA = American Society of Anesthesiologists; also see Table 3 for abbreviations.

Table 5. Sensitivity analysis: level of leisure-time physical activity (LPA) by study groups after multiple and single imputation of missing values on LPA in the groups

	LPA dichotomized: Meeting PA recommendations					
	THA group		Control group			
	total n	n (%)	total n	n (%)	OR (CI) [a]	Difference between groups (CI) [b]
Observed data	388	245 (63)	27,932	10,803 (39)		24% (20–29)
Multiple imputation [c]	429	N/A	29,272	N/A	2.7 (2.1–3.3)	N/A
Single imputation,						
Worst case [d]	856	245 (29)	45,448	10,803 (24)		5% (2–8)
Best case [e]	856	713 (83)	45,448	28,319 (62)		21% (18–24)

[a] Logistic regression analyses: crude model with OR of the multiple imputed LPA level between the THA group and the control group.
[b] Chi-squared test.
[c] 10 imputations of each missing LPA value among responders with incomplete questionnaires, 41 participants in the THA group and 1,340 in the control group.
[d] Single imputation where missing data is replaced by inactive LPA levels among all participants eligible for the study in both groups.
[e] Single imputation where missing data is replaced by high LPA levels among all participants eligible for the study in both groups.
N/A, not applicable; also see Table 3 for abbreviations.

Article 2

Svinøy et al. BMC Musculoskeletal Disorders (2025) 26:227
https://doi.org/10.1186/s12891-025-08468-4

BMC Musculoskeletal Disorders

RESEARCH Open Access

The effect of prehabilitation for older patients awaiting total hip replacement. A randomized controlled trial with long-term follow up

Odd-Einar Svinøy[1*], Jakob Vangen Nordbø[2,3], Are Hugo Pripp[1,4], May Arna Risberg[5,6], Astrid Bergland[1], Pål Oliver Borgen[7] and Gunvor Hilde[1]

Abstract

Background Prehabilitation involving a planned exercise program before surgery is proposed to improve rehabilitation and postoperative outcomes. However, the current evidence on the efficacy of prehabilitation for patients awaiting total hip replacement is conflicting. The aim of this study was to evaluate efficacy of preoperative exercises and education (AktivA®) for adults 70 years or older awaiting total hip replacement.

Methods In a two-armed randomized controlled trial we recruited 98 participants aged 70 years or older with a Harris Hip Score less than 60 awaiting elective primary total hip replacement. Participants were recruited at three hospitals in Norway between 2019 and 2022. Participants were randomly assigned to prehabilitation or usual care. The prehabilitation group received a tailored exercise program for 6–12 weeks in addition to patient education. Gait speed, the primary outcome, was measured by the 40 m Fast-Paced Walk Test. Secondary outcomes included performance-based tests (Chair Stand Test, Timed Up & Go Test, 6-Minute Walk Test, Stair Climb Test) and patient-reported outcomes (Hip Disability and Osteoarthritis Outcome Score (HOOS) and EQ-5D). Outcomes were assessed at baseline, post intervention, and further 6 weeks, 3-, 6-, and 12 months post-surgery.

Results For the primary outcome gait speed at the primary endpoint (3 months post-surgery), no significant between-group differences were observed. However, post-intervention (before surgery), we found a significant improvement in favor of prehabilitation for both gait speed (0.15 m/s, 95% CI 0.02–0.28) and the HOOS quality of life subscale (11.93, 95% CI 3.38–20.48). No other significant differences were found at any post-surgery follow-up for these outcomes. For other secondary outcomes, there were no between-group differences at any point of assessment. Both groups showed improvement across all outcomes 3–12 months after surgery.

Conclusions The AktivA®program, used as a prehabilitation intervention during a period of 6–12 weeks before total hip replacement did not improve gait speed or any other post-operative outcomes compared to usual care. Both groups demonstrated significant improvement in gait speed and performed well relative to Western reference values 12 months post-surgery. Thus, replacing painful hip joints through total joint replacement seems to outweigh the efficacy of prehabilitation.

*Correspondence:
Odd-Einar Svinøy
odd-einar.svinoy@oslomet.no
Full list of author information is available at the end of the article

Trial registration ClinicalTrials.gov Identifier: NCT03602105—initial release: 06/06/2018.
Keywords Hip arthritis, Prehabilitation, Gait speed, Elderly, Total hip replacement, Quality of life

Introduction

Osteoarthritis (OA) is one of the leading global causes of years lived with disability, with its prevalence increasing with age, and affecting approximately one in three adults above 70 years old [1]. Among weight bearing joints, hip OA is the second most prevalent after knee OA [1]. According to a meta-analysis by Fan et al. [2] the global pooled prevalence of hip OA, based on a Kellgren-Lawrence grade of ≥ 2, is estimated to 8.55% (95% CI 4.85 −13.18). Europe has the highest prevalence of hip OA with 12.59% (95% CI 7.17–19.25) [2]. Data from six European countries indicate that OA is strongly associated with frailty and prefrailty in the community dwelling individuals over the age of 65 [3]. OA is linked to poorer physical health and increased utilization of health care services [4, 5].

First-line treatment for hip OA consists of management programs that include exercise, patient education and weight reduction; key strategies for reducing pain and improving function [4–7]. However, when first-line treatment proves insufficient and the condition severely impacts the patient's quality of life, total hip replacement (THR) should be considered [7]. Worldwide, more than 1.4 million THRs are performed annually [8], with 10,812 recorded in Norway in 2023 [9]. Patients' expectations for THR are high [10], and long-term expectations are often fulfilled [11–13], but not always [14]. Prospective studies indicate that 7–23% of the patients experience persistent long-term pain after having THR [14]. Pre-surgery factors such as reduced muscle strength, gait speed and balance are possible predictors of delayed recovery after total hip replacement [15]. A recent cross-sectional study using computed tomography found that the preoperative ratio of lean muscle mass / total muscle area may be negatively correlated with gait speed 6 months after THR [16].

Prehabilitation in terms of a planned exercise program before surgery is proposed to improve the rehabilitation process and postoperative outcomes [17]. Several systematic reviews have summarized the evidence on efficacy of exercise or exercise combined with patient education before THR, but they differ in their conclusions. Among the most recent reviews, Punnoose et al. [18] state moderate certainty evidence for improved muscle strength and improved quality of life after surgery in favor of prehabilitation prior to THR, whereas others find inconclusive evidence [19–21]. Some issues highlighted on efficacy of prehabilitation prior to THR include the use of low-to-moderate intensity exercise intervention and inclusion of participants who were not at high risk for delayed recovery [22–25].

The decline in physical performance with age is well documented [26, 27], with population studies showing a notable decrease after the age of 65 years [28, 29]. This decline is even more pronounced in individuals with OA [28, 30]. To focus on participants likely to benefit from prehabilitation, we chose to include patients aged 70 years or older with a Harris Hip Score less than 60, a score considered as poor [31] and often used by orthopedic surgeons as a criterion for severe hip OA, indicating eligibility for THR [32]. While there is no definitive conclusion regarding the effectiveness of prehabilitation for patients awaiting THR, further high-quality research with robust methodology and interventions is needed [22, 23, 33]. Additionally, more studies are required to specifically address older adults at higher risk for suboptimal surgical outcomes [25, 34].

The primary aim of this study was to assess the efficacy of a prehabilitation program consisting of exercises and education (AktivA®) [35] on postoperative gait speed for patients 70 years or older with Harris Hip Score < 60 awaiting THR. Secondary aims were to assess the efficacy of prehabilitation on additional outcomes including pain, symptoms, activity of daily living (ADL), physical activity, and quality of life (QoL). Performance-based tests such as walking long distances, getting in and out of a chair, ambulatory transitions and walking up and down stairs [36] were also assessed as secondary outcomes. The exercise intervention was designed to meet the guidelines set by the American College of Sports Medicine [37].

Methods

Design and setting of the study

This study was a two-armed randomized controlled trial, comparing the efficacy of a prehabilitation program (AktivA®) against usual care on performance-based physical outcomes and patient reported outcome measures. The study protocol has been previously published [38]. The study was conducted in South-Eastern Norway, and participants were included from Akershus University Hospital, Martina Hansens Hospital and Diakonhjemmet Hospital between November 2019 and December 2022. The orthopedic surgeons at the collaborating hospitals screened for eligible participants meeting the study's inclusion criteria and assessed the patient's severity of

hip pain and functional limitations using the Harris Hip Score. Physiotherapists delivered the prehabilitation before surgery in a real-world clinical setting in the primary health care sector. All physiotherapists delivering the intervention had attended an 8-h AktivA course, as part of a national model for implementation of evidence-based guidelines for patients with OA [35].

The completed study had some deviations from the published study protocol [38]. While we initially planned to include 150 participants, slow recruitment rates and challenges posed by the Covid-19 pandemic resulted in the inclusion of 98 participants. For participants whose surgery dates were rescheduled and delayed beyond 12 weeks, the intervention period was continued until surgery. The primary endpoint of interest was set to 3 months post-surgery [38]. After obtaining additional funding for long-term follow-ups, we have also included follow-up assessment at 6- and 12-months post-surgery to the current study.

All physiotherapists delivering the prehabilitation intervention had access to appropriate exercise facilities at their respective clinics. The study adheres to the CONSORT checklist for randomized controlled trials [39] and the CHAMP statement [40].

Study population

We included community-dwelling participants aged 70 years or older with residential addresses in the county of Oslo or Akershus scheduled for elective primary THR due to end-stage osteoarthritis. Additional inclusion criteria included a Harris Hip Score of less than 60 [31, 41], mental capability to follow the preoperative program, and being able to read and fill out questionnaires independently. Participants were excluded if they had known rheumatoid arthritis, medical contraindications for physical activity, neurological disease affecting gait or were unable to speak and understand the Norwegian language. Furthermore, we excluded participants already enrolled in an AktivA® program.

Randomization and blinding

Participants were randomly allocated to the intervention or control group with a 1:1 ratio. A computer-generated random number sequence with randomly permuted block sizes and opaque sealed envelopes was used for group allocation. The randomization to groups was performed by the researcher coordinating the study. This person was not involved in the recruitment of study participants and did not perform outcome assessments at any point in time throughout the study. Participants were stratified by the hospital performing the surgery. Outcome assessors and research personnel entering data into the data files were blinded to group allocation.

Intervention

The exercise intervention was described following the Consensus on Exercise Reporting Template (CERT) [42] (Appendix File 1). The prehabilitation program included exercises and patient education [35] lasting 6 to 12 weeks. Participants completed 3 to 4 weekly training sessions, each lasting 45 to 60 min. Two of the weekly sessions were supervised by an experienced physiotherapist individually, or in a group. The remaining session(s) were performed at home following a prescribed exercise program provided by the supervising physiotherapist. The exercise program included both progressive resistance training and neuromuscular training, tailored to each participant's specific needs, with a focus on large muscle groups. Key exercises included leg presses, leg extensions, gluteal bridges, and functional movements such as squats, lunges, and balance exercises [38].

General recommendations for exercise dosage and progression were followed [37, 43], with resistance exercises targeting 40–60% of one repetition maximum, allowing for 8–12 repetitions in 1–3 sets. Resistance equipment, including bands, dumbbells, and machines, was used to tailor and adjust the resistance level for each individual. Load and progression were adjusted based on pain levels; if participants rated their pain as 5 or higher on a 0–10 Numeric Rating Scale after exercise, modifications to the exercise program and dosage were made. The physiotherapist tracked adherence to the supervised sessions, while participants self-recorded their adherence to home-based training using exercise diaries. Overall adherence was defined as completing 80% or more of both the supervised and home-based training sessions. The education component of the intervention provided patients with information on arthritis management, the importance of physical activity, and when applicable, recommendations for weight loss. Education was delivered by the physiotherapist either through group sessions or personalized guidance.

Participants in the control group received standard care without supervised prehabilitation before surgery. Regardless of group, all participants received standard preoperative information and preparation from the recruiting hospital.

Assessment and outcome measures

Outcome assessments were performed at baseline (before randomization), post intervention (within a week after ended intervention), and 6 weeks and further 3-, 6- and 12 months after THR surgery. Gait speed measured

by the 40 m Fast Paced Walk Test [36] was the primary outcome, and the primary endpoint set to 3 months post-surgery. Secondary performance-based outcomes included Chair Stand Test [44], Timed Up & Go Test [45], 6 Minute Walk Test (6 MWT) [46], and Stair Climb Test [47]. Additional self-reported secondary outcomes were the Hip Disability and Osteoarthritis Outcome Score (HOOS) with subscales for pain, symptoms, activity of daily living (ADL), physical activity, and quality of life [48] and the and the EQ visual analogue scale (EQ VAS) rating general health [49]. Sociodemographic data and use of health care services were collected through questionnaires. Testing was administered by the researcher coordinating the study in collaboration with outcome assessors blinded to group allocation. The outcome assessors were all experienced physiotherapists employed as research assistants in the project or they worked at the collaborating hospital paid by the hour. Before project start, they were trained in the testing procedures for all the performance-based outcomes in our study, using the standardized procedures outlined by the Osteoarthritis Research Society International [36], except for the 6 MWT. Due to practical reasons, the 6 MWT was performed by walking back and forth along a 15-m straight line covering as much ground as possible over 6 min. Performing the 6 MWT by walking back and forth has shown acceptable reliability and construct validity [50].

Sample size

Sample size estimation was based on a clinically meaningful between-group difference in gait speed at the primary end point 3 months post-surgery. As described in our protocol paper [38], a substantial meaningful mean difference between groups at 3 months post-surgery in habitual gait speed was set at 0.1 m/s with an expected standard deviation (SD) of 0.2 m/s. This estimate was based on findings by Perera et al. [51]. The sample size calculation was performed using an analysis of covariance (ANCOVA) model to assess the mean difference between the randomized groups. Based on this calculation a sample size of 120 participants was sufficient to obtain 80% statistical power. The recruitment rate was substantially slowed down due to the Covid-19 pandemic and a recalculation of the sample size was performed to potentially reduce the required study sample size. Based on the recalculation, we included 98 participants instead of 120, which reduced the statistical power by less than 10%. However, by using the Stata command sampsi, the recalculation still ensured 80% statistical power with an ANCOVA model, assuming a correlation of 0.5 between the baseline and follow-up measurement.

Statistical methods

Our statistical analysis plan outlining the analytical approach for data gathered in this study was published at ClinicalTrials.gov [52] before we revealed the group allocation variable to our data files ready to be analyzed. Demographic and baseline characteristics in the two study groups were presented as number (n) and percentage (%) for categorical data, and for continuous data by mean and standard deviation (SD) or median with minimum and maximum values (min–max) as appropriate depending on the distribution of the variable. Within group analyses were explored using the Paired-samples t-test if data were normally distributed, if not the Wilcoxon Signed Rank test was used.

Linear mixed models for repeated measurements were our primary analysis of differences between randomized groups for continuous outcome variables. We assessed mean differences in primary outcome between randomized groups at each follow-up time with 95% CI and p-value using estimated marginal means from the maximum likelihood estimated models. The model included a random intercept to account for the within subject correlation of repeated measurements and the following independent fixed effects: the respective outcome variable at baseline, the follow-up times, the randomized groups, the interaction term between randomized groups and follow up times. Secondary outcomes were assessed using statistical procedures similar to the primary outcome. Intention to treat (ITT) was the principal analysis assessing effect of the intervention. We also performed a 'per-protocol analysis' including those completing the trial with an overall exercise adherence $\geq 80\%$.

All calculated p-values were two-sided and set to a 5% significance level. StataSE 18.0 for Windows (StataCorp LLC, 4905 Lakeway Drive, College Station, TX, 77,845, USA) were used to conduct statistical analysis.

To assess the impact of missing data during follow-up, we explored the missing data mechanism by comparing participants with or without missing data at any point of follow-up assessment against their respective baseline values. We assumed the missing data to be either completely at random (MCAR) or missing at random (MAR) and applied multiple imputation (MI) to assess the robustness of our dataset in terms of precision or variance, accuracy, and power [53]. In case the missing data were not at random (MNAR), we also used MI as a sensitivity analysis to explore the robustness of our analysis [53]. In building our model for imputation we conducted 25 multiple imputations using chained equations and linear regressions models. These were based on data from baseline to end of follow-up for the respective outcome, and baseline data on age, sex, TUG, and HOOS quality of life. For imputation of TUG

and HOOS quality of life, we used baseline data of the gait speed measured with the 40 m Fast Paced Walk Test. We examined the distribution of the imputed data for the outcome measure to ensure the values that were realistic. Any values outside the lower or upper range of observed values were replaced with the observed minimum or maximum value respectively.

Ethical considerations

All participants signed an informed consent before the baseline assessment. The Regional Ethical Committee in the Health Region South-East in Norway approved the study protocol (ref no. 2018/503), and the Data Inspectorate at the collaborating hospitals approved the study.

Results

We ceased participant enrollment at 98 individuals, assigning 48 to the intervention group and 50 to the control group through randomization. At the primary endpoint, 3 months post-surgery, 26 participants (27%) had withdrawn their consent. This withdrawal rate increased to 34% at 6 months, and further to 40% at

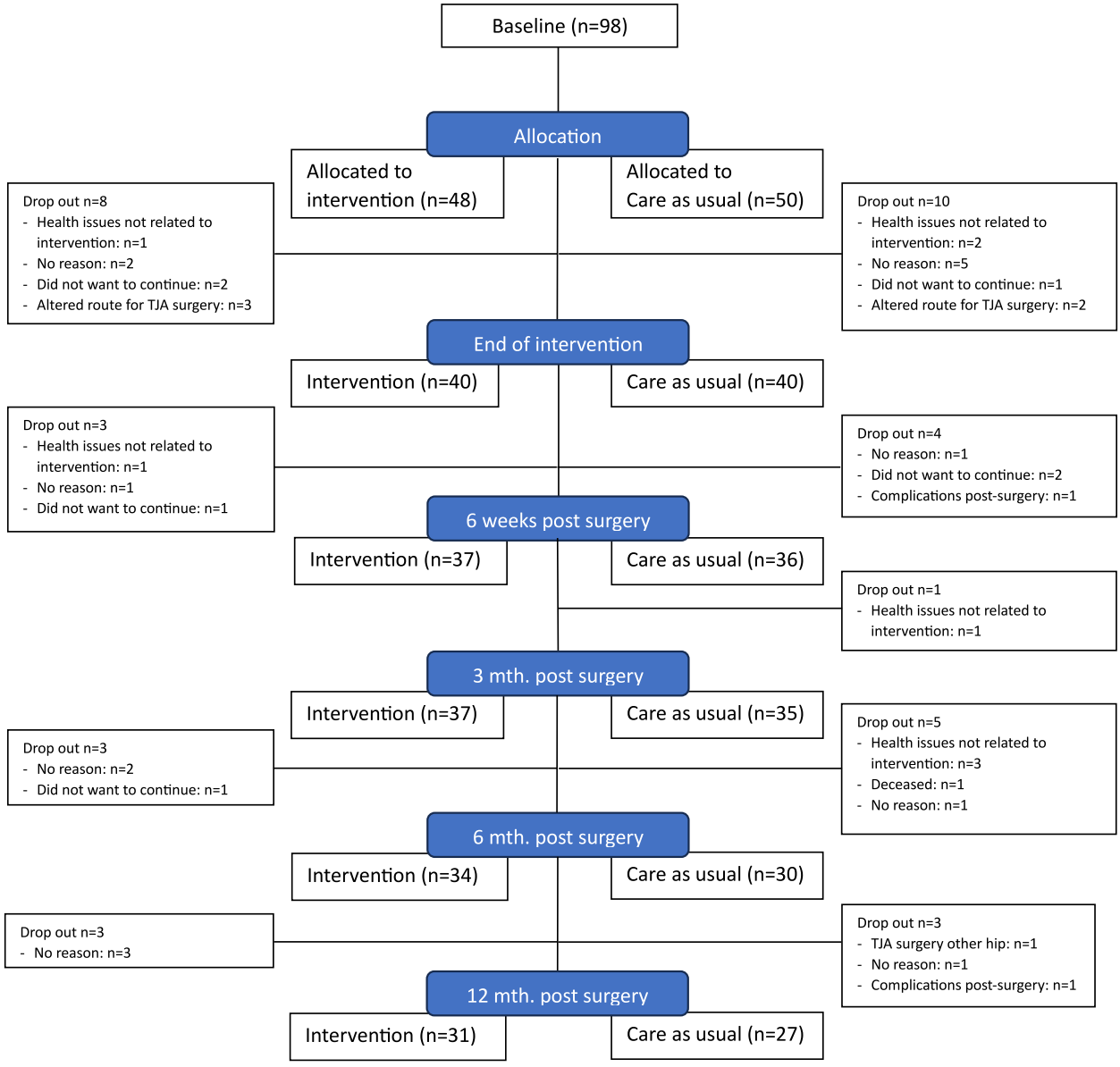

Fig. 1 Participant flow-chart

12 months post-surgery. The dropout rates were comparable between the intervention and control groups. The flow-chart (Fig. 1) provides information on participant dropout and reasons for withdrawal. Additionally, we encountered missing data primarily due to the Covid-19 pandemic, during which outpatient clinics at the hospitals were closed for periods, and many participants were hesitant to attend in-person testing after reopening. Also with reopened outpatient clinics, some participants did not attend scheduled follow-ups despite repeated reminders. We analyzed the missing data and determined that the missing mechanism was mostly missing completely at random or missing at random for follow-ups until 3 months, but not missing at random at 6- and 12-months post-surgery. Notably, control group participants with poor baseline gait speed performance were more likely to be lost to follow-up at six and twelve months compared to those in the intervention group.

The mean age was 76.8 ± 4.4 years in the intervention group and 76.3 ± 4.7 years in the control group. For Harris Hip Score, the intervention group had an average score of 48.02 ± 9.73 and the control group 47.64 ± 7.37. There were no significant differences between the groups in baseline characteristics, except for body height, where participants in the intervention group were somewhat taller than those in the control group. Baseline

Table 1 Baseline characteristics of study participants

Characteristics	Intervention ($n = 48$)	Control ($n = 50$)
Age (years)	76.84 ± 4.40	76.30 ± 4.73
Female (%)	27 (56%)	37 (74%)
Weight (kg)	79.62 ± 17.21	79.02 ± 14.19
Height (cm)*	169.54 ± 11.22	167.80 ± 8.39
BMI (kg/m^2)	27.56 ± 4.60	28.10 ± 4.95
Level of education		
- Primary	18 (37.5%)	13 (26.5%)
- Secondary	12 (25.0%)	20 (40%)
- Tertiary	17 (35.4%)	17 (34%)
- Missing	1 (2.1%)	-
Harris Hip Score (0–100)	48.02 ± 9.73	47.64 ± 7.37
ASA-score: n (%)		
- ASA 1	-	2 (4%)
- ASA 2	34 (71%)	31 (62%)
- ASA 3	14 (29%)	15 (30%)
- Missing ASA	-	2 (4%)
FCI (numbers of comorbidities)	1.40 ± 1.29	1.44 ± 1.48
EQ-VAS (0–100)	56.55 ± 21.64	54.00 ± 17.52
Physical outcome measures		
- 40 m Fast-Paced Walk Test (m/s)	1.21 ± 0.38	1.29 ± 0.37
- 30 s Sit-to-Stand Test (no. of repetitions)	10.33 ± 3.71	10.02 ± 3.64
- Timed Up and Go Test (s)	11.13 ± 3.41	11.13 ± 3.63
- 6 min Walk Test (m)	353.04 ± 104.98	353.23 ± 104.12
- Stair Climb Test (s)	18.51 ± 8.41	19.99 ± 11.78
HOOS (0–100)		
- Pain	41.33 ± 12.05	41.65 ± 12.57
- Symptoms	41.41 ± 16.72	39.08 ± 14.67
- ADL	42.08 ± 13.41	44.53 ± 14.71
- Sports/recreation	26.85 ± 19.46	27.00 ± 17.74
- QOL	27.13 ± 13.74	26.5 ± 13.86

Continuous variables given as means (± standard deviation, SD), categorical variables as numbers (percentages, %)

Tests of statistical significance were done with independent samples t-tests for continuous variables and chi-squared tests for categorical variables

HOOS Hip Disability and Osteoarthritis Outcome Score, *ADL* activities of daily living, *QOL* quality of life, *ASA-score* American Society of Anesthesiologists Physical Status Classification System, *FCI* Functional comorbidity index, *EQ-VAS* EuroQol visual analogue scale; part of the EuroQol 5-dimensional quality of life questionnaire

* Statistically significant difference between groups ($p < 0.05$)

characteristics of the participants are provided in Table 1. The median length of the intervention was 11 weeks (range 4 to 20 weeks). Two prehabilitation participants had an intervention period of 20 weeks, as their THR surgery was rescheduled by several weeks. Apart from the prehabilitation, the comparison groups did not differ in their use of healthcare services during the intervention period. Additionally, there were no differences between the groups in their use of physiotherapy or other healthcare services during the postoperative period. Three months post-surgery, the intervention group reported an average of 8.26 physiotherapy sessions, while the control group reported 6.34 sessions over the previous 12 weeks.

Between-group differences for primary outcome

For the primary outcome gait speed, no significant between-groups differences were found at the primary endpoint 3 months post-surgery (mean diff 0.08 m/s; 95% CI: −0.06 to 0.21) or at any other points of assessment post-surgery. However, post-intervention (before surgery), we observed a significant between-group difference in favor of prehabilitation for gait speed (mean diff 0.15 m/s; 95% CI: 0.02 to 0.28). After applying multiple imputation for missing participant data, the between-group difference for gait speed remained consistent, indicating no effect of the prehabilitation intervention neither at 3 months after surgery nor at any other post-surgery follow ups (Table 2). We also performed a sensitivity analysis for gait speed where we adjusted for differences in body height and sex at baseline, the analysis yielded similar results as the primary analysis. The per-protocol analysis also yields results similar to the primary findings (Appendix Table 3).

Between-group differences for secondary outcomes

Post-intervention, the mean difference between groups for the HOOS quality of life subscale was 11.93 in favor of the intervention group (95% CI: 3.38 to 20.48). However, there were no significant between-group differences for this outcome at the primary endpoint 3 months post-surgery or any other follow ups. For other secondary outcomes we found no between-group differences at any point of assessment. Analysis after imputation for missing data yielded consistent results (Table 2). The per protocol analysis of secondary outcomes produced similar findings, except from the 30 s Sit-to-Stand test. The mean differences in number of repetitions in Sit-to-Stand were 1.81 repetitions (95% CI: 0.01 to 3.60) in favor of the intervention group 3 months post-surgery and 1.89 repetitions (95% CI: 0.14 to 3.69) 12 months post-surgery (Appendix Table 3).

Within group differences between baseline and follow-up

Both groups demonstrated improvement across all outcomes 3–12 months after surgery. For the primary outcome, gait speed, the mean change in score between baseline and 3 months after surgery was 0.31 m/s ($p < 0.05$) and 0.19 m/s ($p < 0.05$) within the intervention and control group respectively. At 12 months post-surgery, the improvement relative to baseline was 0.36 m/s ($p < 0.05$) within the intervention group and 0.22 m/s ($p < 0.05$) within the control group. The improvements in gait speed within the groups throughout the study period are also displayed in Fig. 2 (ITT-analysis). Appendix Table 4 shows descriptive values and number of observations of all outcome measures within each group at all assessment points. Physical performance scores, stratified by sex, are presented in Appendix Table 5.

Adherence

Among the prehabilitation participants who did not drop out but completed their intervention period, 34 out of 40 (85%) were adherent to the supervised exercise protocol, whereas 31 out of 40 (77%) were adherent to the unsupervised exercise protocol.

Use of aids during physical testing

At the post-intervention assessment, the control group showed significantly higher use of walking aids when performing the TUG test ($p < 0.05$). No other significant between-group differences were observed in the using any aid at any time point. Frequencies of aid usage during physical performance testing are presented in Appendix Table 6.

Adverse events

No preoperative adverse events linked to the study intervention, or the clinical assessments, were recorded throughout the study period. However, one participant in the control group experienced a post-surgical complication involving a neurological disorder of the foot and subsequently withdrew from the study 6 months after surgery.

Discussion

No significant between-group differences in gait speed were observed at the primary endpoint 3-month post-surgery or any other post-surgery assessments. This indicates that the prehabilitation program did not affect gait speed postoperatively in community-dwelling participants aged 70 years or older who were scheduled for elective primary THR due to end-stage osteoarthritis. Similarly, no significant differences were found for any secondary outcomes at any post-surgery time point.

Table 2 Mean differences between the intervention and control group (95% CI)

Outcome	Intention to treat: Intervention vs. control		Multiple imputation for MPD: Intervention vs. control	
	Mean difference	**95% CI**	**Mean difference**	**95% CI**
40 m Fast-Paced Walk Test (m/s)				
Post-intervention	0.15*	0.02, 0.28	0.20*	0.02, 0.36
6 weeks post-surgery	−0.01	−0.16, 0.13	−0.01	−0.29, 0.28
3 months post-surgery	0.08	−0.06, 0.21	0.07	−0.09, 0.24
6 months post-surgery	0.01	−0.13, 0.14	0.02	−0.14, 0.18
12 months post-surgery	0.11	−0.03, 0.25	0.14	−0.03, 0.32
30 s Sit-To-Stand Test (no. of rep.)				
Post-intervention	1.16	−0.19, 2.52	1.57	−0.32, 3.46
6 weeks post-surgery	−0.11	−1.69, 1.48	−0.32	−2.68, 2.04
3 months post-surgery	0.80	−0.56, 2.16	0.95	−0.90, 2.79
6 months post-surgery	0.81	−0.56, 2.19	0.40	−1.58, 2.38
12 months post-surgery	1.37	−0.04, 2.78	1.48	−0.82, 3.77
Timed Up and Go Test (s)				
Post-intervention	−0.76	−1.54, 0.01	−0.59	−1.73, 0.55
6 weeks post-surgery	0.70	−1.12, 1.71	0.76	−0.96, 2.48
3 months post-surgery	−0.14	−0.92, 0.63	−0.14	−1.11, 0.83
6 months post-surgery	0.12	−0.66, 0.91	0.38	−0.66, 1.42
12 months post-surgery	−0.23	−1.05, 0.57	0.04	−0.88, 0.97
6 min Walk Test (m)				
Post-intervention	18.98	−15.02, 52.99	31.94	−14.63, 78.52
6 weeks post-surgery	26.77	−10.56, 64.10	35.51	−26.44, 97.47
3 months post-surgery	13.52	−20.44, 47.48	11.13	−33.04, 55.30
6 months post-surgery	27.84	−5.50, 62.08	32.23	−10.65, 75.11
12 months post-surgery	19.21	−15.67, 54.09	15.95	−28.68, 60.59
Stair Climb Test (s)				
Post-intervention	−0.86	−3.36, 1.63	−0.92	−4.60, 2.75
6 weeks post-surgery	−0.38	−3.23, 2.47	1.00	−5.69, 7.70
3 months post-surgery	−0.26	−2.71, 2.18	−0.34	−3.45, 2.76
6 months post-surgery	0.77	−1.75, 3.29	2.15	−0.62, 4.93
12 months post-surgery	−0.53	−3.16, 2.10	−0.18	−3.24, 2.88
HOOS Pain (0–100)				
Post-intervention	2.06	−5.20, 9.32	1.90	−5.37, 9.18
6 weeks post-surgery	0.29	−7.32, 7.92	0.91	−13.22, 15.05
3 months post-surgery	−1.20	−7.92, 5.40	−1.34	−8.36, 5.68
6 months post-surgery	−2.65	−9.72, 4.42	−3.09	−11.03, 4.86
12 months post-surgery	−3.03	−10.35, 4.29	−4.07	−12.99, 4.83
HOOS Symptoms (0–100)				
Post-intervention	4.69	−2.59, 11.98	3.06	−6.37, 12.49
6 weeks post-surgery	−1.94	−9.51, 5.62	−2.37	−11.60, 6.86
3 months post-surgery	−2.39	−9.15, 4.41	−3.56	−11.85, 4.74
6 months post-surgery	−3.13	−10.16, 3.90	−1.86	−9.49, 5.67
12 months post-surgery	−3.84	−11.34, 3.66	−6.10	−13.96, 1.75
HOOS ADL (0–100)				
Post-intervention	8.66	−1.84, 19.16	2.51	−6.38, 11.40
6 weeks post-surgery	4.20	−7.69, 16.10	−0.83	−9.66, 8.00
3 months post-surgery	−2.40	−12.45, 7.63	−2.61	−9.80, 4.58
6 months post-surgery	1.95	−8.43, 12.33	−1.34	−9.20, 6.52

Table 2 (continued)

Outcome	Intention to treat: Intervention vs. control		Multiple imputation for MPD: Intervention vs. control	
	Mean difference	**95% CI**	**Mean difference**	**95% CI**
12 months post-surgery	−7.15	−18.09, 3.78	−3.92	−11.29, 3.44
HOOS Sports/recreation (0–100)				
Post-intervention	8.66	−1.84, 19.16	5.26	−5.60, 16.14
6 weeks post-surgery	4.20	−7.69, 16.10	1.51	−24.29, 21.28
3 months post-surgery	−2.40	−12.45, 7.63	−0.30	−12.74, 12.14
6 months post-surgery	1.95	−8.43, 12.33	6.01	−7.16, 19.20
12 months post-surgery	−7.15	−18.09, 3.78	−3.80	−17.90, 10.30
HOOS QoL (0–100)				
Post-intervention	11.93*	3.38, 20.48	9.89*	0.77, 19.01
6 weeks post-surgery	4.79	−4.27, 13.85	1.32	−13.04, 15.67
3 months post-surgery	−4.86	−12.85, 3.12	−2.94	−13.28, 7.40
6 months post-surgery	−1.29	−9.63, 7.05	−2.93	−11.30, 5.45
12 months post-surgery	−5.03	−13.80, 3.74	−6.66	−15.84, 5.52
EQ-VAS (0–100)				
Post-intervention	7.19	−0.34, 14.73	6.68	−3.00, 16.36
6 weeks post-surgery	−7.61	−15.52, 0.28	−8.17	−19.02, 2.69
3 months post-surgery	−2.64	−9.63, 4.35	−3.28	−11.87, 5.31
6 months post-surgery	1.21	−6.04, 8.46	2.12	−7.07, 11.32
12 months post-surgery	2.30	−5.44, 10.05	1.27	−8.56, 11.11

Differences between randomized groups for continuous outcome variables analyzed by linear mixed models for repeated measurements, p-values were two-sided and set to a 5% significance level but not presented in the table, *statistical significance between groups $p < 0.05$

CI Confidence interval, *MPD* missing participant data, *HOOS* Hip Disability and Osteoarthritis Outcome Score, *ADL* activities of daily living, *QOL* quality of life, *EQ-VAS* EuroQol visual analogue scale; part of the EuroQol 5-dimensional quality of life questionnaire

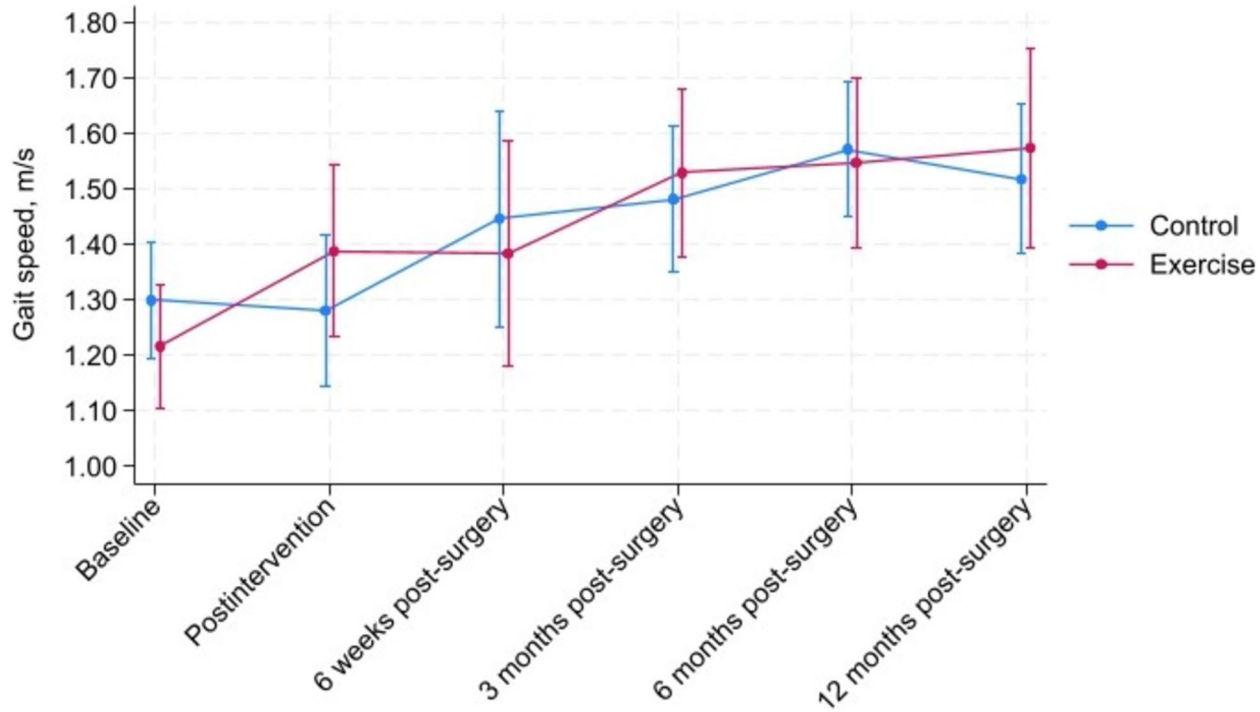

Fig. 2 Intention to treat analyses with point estimates on the primary outcome measure gait speed at all points of measurement within the prehabilitation group and control croup respectively

As the exercise intervention duration in our study ranged from 4–20 weeks (median 11 weeks), most participants met our study protocol outlining an intervention period of 6 to 12 weeks [38]. An exercise program exceeding 12 weeks could potentially enhance the efficacy of our exercise program. However, ethical requirements to avoid delaying surgery, extending the intervention period was not feasible in our study. Progression of exercise dosage through the training period is crucial for musculoskeletal and cardiovascular adaptations [54]. Prior studies have shown that patients awaiting THR can tolerate progressive resistance training without adverse effects [33], and that moderate- [55] to high-intensity [56] training is feasible. Although our prehabilitation intervention intended to follow current exercise recommendations for dose and progression [37, 43], the physiotherapists delivering the intervention reported through verbal communication that progression was particularly challenging for our study participants as they experienced significant pain during and after exercise. The supervising physiotherapists had to balance intensity with participant willingness to continue exercising throughout the intervention period, sometimes resulting in a lower exercise intensity than prescribed in the study protocol [38]. This may explain the limited post-surgery efficacy of prehabilitation in our study. Another factor that could influence the limited effect on gait speed is the lack of focus on gait-training exercises in our prehabilitation program.

The effectiveness of an exercise program relies heavily on adherence to the exercise protocol, making it a crucial predictor of outcomes [57]. In our study, satisfactory adherence was defined as attending at least 80% of the scheduled sessions, a common threshold in trials [58]. Eighty-five percent of the prehabilitation participants attended 80% or more of the planned supervised sessions. Given the age of the study sample, the use of outreach-supervised training at home could potentially have improved adherence even more [59]. However, while outreach visits by physiotherapists delivering the intervention were an option in our study, none of the participants opted for outreach visits. For the unsupervised home sessions, 77% completed at least 80% of the sessions, which was lower than expected, though not uncommon. A systematic review by Smith et al. [60] reported an average adherence rate of 67.9% for unsupervised exercise, which is based on data from 72 trials examining exercise interventions for patients with osteoarthritis.

To our knowledge, only three previous RCTs have evaluated gait speed (m/s) for prehabilitation before THR [61–63]. Unlike our findings, Wang et al. [62] reported no prehabilitation effect before surgery but a significant effect post-surgery at 3 weeks, 3 months, and 6 months. In line with our study, Villadsen et al. [61] found no difference between groups at 6 weeks or 3 months post-surgery, whereas Holsgaard-Larsen et al. [63] found an effect at 3 months post-surgery with a mean difference of 1.5 m/s (95% CI: 0.2 to 2.7), though the difference was not significant at 12 months.

Four previous RCTs on prehabilitation before THR assessed gait capacity using the 6 MWT [55, 59, 62, 64]. Two studies [59, 64] found significant improvements in the 6 MWT before surgery, while our results showed no effect. Post-surgery, former studies report in line with our findings no significant differences between comparison groups neither at short term [55, 59] nor when assessed 3- and 6 months post-surgery [62].

Six former RCT publications report findings on mobility measured by the TUG test [55, 59, 61, 64–66]. Apart from Zeng et al. [64] who reported improved TUG scores before surgery, no other studies found significant differences between comparison groups either before or after surgery [55, 59, 65]. These findings are consistent with our study.

Eight previous RCTs [55, 56, 59, 61, 63, 65, 67, 68] have assessed lower extremity strength. Three of these studies [55, 59, 61] reported no significant differences between comparison groups neither before nor after surgery. Contrary to our findings, four studies [56, 65, 67, 68] reported enhanced muscular strength favoring prehabilitation before surgery and two studies [63, 67] demonstrated an effect of prehabilitation program on postoperative function.

We found a significant effect of the prehabilitation program on the HOOS quality of life subscale post-intervention. This aligns with Hermann et al. [56] but contrasts with other RCTs [55, 59, 61]. However, we found no significant between-group differences for any of the other patient-reported outcomes, consistent with five other RCTs [55, 59, 61, 68, 69]. Holsgaard-Larsen et al. [63] found significant effects on the HOOS sport/recreation subscale at 3 months post-surgery but not at later follow-ups.

Heterogeneity

The descriptive comparison of study results above is complicated by heterogeneity across studies. Gilbey et al. [67] concluded that customized prehabilitation exercises before THR were effective in enhancing functional recovery after surgery. This conclusion is based on their significant findings favoring the intervention group both at short term and long term (6 months). However, the participants in their intervention group also engaged in supervised and homebased exercise from 3–12 weeks post-surgery making it difficult to isolate the effect of

prehabilitation during post-surgery follow ups. This limitation also applies to Wang et al. [62], as this study is a sub study of the RCT presented by Gilbey et al. Moreover, previous studies differ in participants characteristics. The mean age in our study was 76 and 77 years in the intervention- and control group respectively, comparable to the study samples included by Hoogeboom et al. [55] and Oosting et al. [59]. In contrast, the other studies referred to above included younger participants. Additionally, some of these studies have small sample sizes [55, 59, 62, 68], making them vulnerable for type II error [70]. However, two of these studies were designed as pilot RCTs [55, 59] and were not specifically aimed at detecting possible differences between groups. Furthermore, the studies varied in the testing modalities used to assess outcomes, complicating direct comparisons. An example is gait speed, measured as habitual gait speed in the study by Wang et al. [62], while Villadsen et al. [61] and Holsgaard-Larsen et al. [63] reported both habitual and fast paced gait speed. Similarly, lower extremity strength was measured using different methods, such as 1-repetition maximum testing [56, 63, 65, 67], functional testing [55, 59, 61] and subjective grading [68].

Strengths and limitations

A strength of this study is that the physiotherapists delivering the intervention were experienced in working with this specific patient population. All physiotherapists had completed an 8-h AktivA®-course, part of a national model designed to implement evidence-based practice for patients with OA [35]. This study was conducted in a real-world clinical setting, utilizing outcome measures that are manageable in practice, which enhance the external validity of the findings. Additionally, the study population was comparable to the age-matched THR population at the participating hospitals during the recruitment period based on age, sex, and ASA-score [71, 72], highlighting the high external validity of the study. We followed the participants for 12 months after surgery, addressing a common shortcoming in many RCTs including short-term follow-up assessments [73]. An added strength of the study is that the outcome assessors were kept blinded to group allocation, and utilization of valid and reliable performance-based outcome measures relevant to the intervention's end users [36].

The study has several limitations. The high dropout rate and missing participant data limits the interpretation of the results. In line with several ongoing RCTs during the Covid-19 pandemic we had considerable challenges in including participants. During the early stages of the pandemic, participant testing was not possible due to the closure of outpatient facilities. When these facilities reopened, many participants hesitated to meet in crowded areas, such as public hospitals, contributing to continued missing data. Before all testing appointments, participants received phone calls and text messages to confirm their attendance. For those who did not show up for testing, the project coordinator and physiotherapists called and sent them text messages to reschedule the appointment. Unfortunately, many did not respond or chose not to attend the testing appointment.

Missing participant data may affect the precision of the between-group differences and increase the risk of type II error due to lack of statistical power [53]. The MNAR missing mechanism for missing data at 6- and 12-months post-surgery may also lead to type II error, as control participants with poor baseline performance in gait speed were more likely to be lost to follow-up, potentially underestimating a possibly treatment effect. Nevertheless, after applying MI to address the missing data, the between-group difference in gait speed remained consistent with our primary analyses without MI, thus lending credibility to our findings, despite the high rate of missing data. We chose to replace missing data through MI, as simulation studies have shown that MI performs well even when the missing mechanism is assumed to be MNAR [53].

Measures to avoid missing participant data are important in clinical trials. In our study, the project coordinator was employed in an academic position at the university and not in a clinical position at the recruiting hospitals, and the General Data Protection Regulation (GDPR) privacy restrictions limited the project coordinator contacting participants until they gave informed consent. Consequently, the initial contact between the study participant and the project coordinator was made through a phone call rather than an in-person meeting. Earlier closer contact between the project coordinator and the participants might have increased willingness to attend testing and reduced drop-out rates throughout the study. Another limitation of the study is the absence of complete exercise diaries from intervention participants. While some training diaries were thoroughly completed, providing valuable data on intensity and progression, many were incomplete, which limited our ability to draw definitive conclusions about the dose–response relationship.

The postoperative course

Improvements were observed in both groups across all outcomes at the follow-ups after surgery. For gait speed at baseline, the men in the intervention group scored on average 1.25 m/s and the control group 1.48 m/s, and for the women scored 1.19 m/s and 1.23 m/s respectively. Reference values on maximal gait speed from Denmark [74] and the United States [75], show a score of 2.01 m/s

and 2.07 m/s respectively for men in their 70 s and 1.81 m/s and 1.74 m/s respectively for women in their 70 s. This demonstrates that our study sample had considerably lower walking speed at baseline when compared to reference values in healthy populations from Denmark and the US. However, 12 months post-surgery the mean gait speed among men in our study were 1.88 m/s and 1.73 m/s in intervention- and control-group respectively, whereas the corresponding scores for women were 1.44 m/s and 1.46 m/s, thus closing the gap to the reference values reported by Tibaek [74] and Bohannon [75].

For the secondary outcome measure, TUG, population-based reference values from Norway are available [28]. At baseline our male participants scored 10.68 s and 10.22 s in the intervention and control group respectively, a score that positioned them close to the reference value presenting the 75th percentile (10.7 s) for the male population aged 75 years. Corresponding baseline values for women were 11.49 s and 11.45 s, also representing scores close to the 75th percentile (10.9 s) for the female population aged 75 years. At 12 months post-surgery, a significant improvement was observed for both sexes. Men in the intervention- and control group scored 7.62 s and 7.35 s respectively, positioning both groups close to the 10th percentile (7.2 s), whereas women scored 8.70 s and 8.69 s respectively, thus close to the 25th percentile (8.2 s). These results highlight significant mobility gains after THR regardless of the pre-operative group allocation.

Clinical implications

The efficacy of prehabilitation was not seen in any post-surgery measurements in our study. However, having a THR had an immense effect on all measured outcomes both for intervention and control participants. Notably, both groups performed well against Western reference values on fast-paced gait speed 12 months post-surgery. Therefore, this older population should be prioritized for early surgery and rehabilitation rather than spending time in prehabilitation. Importantly, although our findings show that prehabilitation did not directly improve postoperative outcomes, there may be potential for prehabilitation to prevent functional deterioration for patients facing extended waiting times before their total hip replacement. Further investigations are warranted.

Conclusion

The AktivA® program used as a prehabilitation intervention before THR was evaluated against usual care, and did not result in improvement in the primary outcome gait speed or improvement in any of the secondary outcomes, neither at the primary endpoint of 3 months post-surgery or at any other post-surgery assessments. Both groups showed improvement across all outcomes 3–12 months after surgery and performed well against reference values for gait speed at 12 months post-surgery. This suggests that the benefits of replacing painful hip joints through TJR outweigh the impact of this prehabilitation program. The study had limitations, including dropouts, missing participant data, and challenges with exercise progression.

Abbreviations

OA	Osteoarthritis
CI	Confidence Interval
THR	Total Hip Replacement
QoL	Quality of Life
RCT	Randomized Controlled Trial
PROMs	Patient Reported Outcome Measures
CONSORT	Consolidated Standards of Reporting Trials
CHAMP	Consensus on Hip Arthroplasty Measurement Properties
MCAR	Missing Completely at Random
MAR	Missing at Random
MNAR	Missing Not at Random
MI	Multiple Imputation
HOOS	Hip Disability and Osteoarthritis Outcome Score
ADL	Activities of Daily Living
TUG	Timed Up & Go
6 MWT	6 Minute Walk Test
SD	Standard Deviation
ANCOVA	Analysis of Covariance
ITT	Intention to Treat
CERT	Consensus on Exercise Reporting Template
WMA	World Medical Association
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
GDPR	General Data Protection Regulation
ASA	American Society of Anesthesiologists
MRC	Medical Research Council

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-025-08468-4.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

Supplementary Material 5.

Supplementary Material 6.

Acknowledgements

We are grateful for clinical testing undertaken several physiotherapists affiliated with the project; James Wilson (Akershus University Hospital), Anne Vileid Gärtner and Birgitte Holt Olsen (Martina Hansens Hospital), Karianne Gåsland Bjellånes, Diana Nystuen, Katinka Koen Frøystad Webjørnsen, Hanna Birkeland and Caroline Navestad (OsloMet). We appreciate the valuable efforts from Dr. Skjalg Hov and nurse Sølvi Ristvedt Molvik (Diakonhjemmet Hospital) for participant recruitment. We are also thankful to all collaborating AktivA-physiotherapists in Oslo and Akershus for their essential contribution and expertise in delivering the preoperative intervention. Lastly, we want to thank all participants for participating in the study.

Authors' contributions
GH was responsible for grant application. OES and GH wrote the first draft of the manuscript. AHP has contributed to the statistical plan and sample size calculation in collaboration with OES and GH. AHP and OES conducted the statistical analysis, and GH, MAR, JVN and AB contributed with interpretation of the data. OES has been responsible for study administration and data collection. JVN and POB have recruited participants and gathered medical journals. All authors have critically revised and approved the final version of the manuscript.

Funding
Open access funding provided by OsloMet - Oslo Metropolitan University The Norwegian Fund for Post-Graduate Training in Physiotherapy (grant number 105467 and 124437).

Data availability
Data may be available for replication analysis in an anonymous format in accordance with GDPR. For request, contact the corresponding author.

Declarations

Ethics approval and consent to participate
The project was approved by The Regional Committee for Medical Research Ethics in South-East Norway, REK South-East (ref no. 2018/503). Informed consent was obtained from all participants included in the analyses, and the project was conducted according to the WMA Declaration of Helsinki. The consent form was approved by REK South-East.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Faculty of Health Sciences, Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University, Oslo, Norway. [2]Department of Orthopedic Surgery, Akershus University Hospital, Lørenskog, Norway. [3]Institute of Clinical Medicine, Campus Ahus, University of Oslo, Oslo, Norway. [4]Oslo Centre of Biostatistics and Epidemiology, Research Support Services, Oslo University Hospital, Oslo, Norway. [5]Department of Sports Medicine, Norwegian School of Sport Sciences, Oslo, Norway. [6]Division of Orthopaedic Surgery, Department of Research, Oslo University Hospital, Oslo, Norway. [7]Department of Orthopedics, Martina Hansens Hospital, Bærum, Norway.

Received: 25 October 2024 Accepted: 24 February 2025
Published: 6 March 2025

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Publisher's Note

Appendix Table 3 – Per protocol analysis with mean differences between the intervention and control group (95% CI) at different assessment points throughout the study period

Outcome	Mean	95% CI
40m Fast-Paced Walk Test (m/s)		
Post-intervention	0.22*	0.04, 0.39
6 weeks post-surgery	-0.30	-0.21, 0.15
3 months post-surgery	0.12	-0.55, 0.30
6 months post-surgery	0.01	-0.17, 0.18
12 months post-surgery	0.11	-0.06, 0.28
30s Sit-To-Stand Test (no. of rep.)		
Post-intervention	0.48	-1.34, 2.30
6 weeks post-surgery	-0.32	-2.21, 1.57
3 months post-surgery	1.81*	0.01, 3.60
6 months post-surgery	1.31	-0.47, 3.10
12 months post-surgery	1.89*	0.14, 3.69
Timed Up and Go Test (s)		
Post-intervention	-0.77	-1.87, 0.32
6 weeks post-surgery	0.89	-0.25, 2.03
3 months post-surgery	-0.67	-1.74, 0.40
6 months post-surgery	-0.06	-1.13, 0.99
12 months post-surgery	-0.54	-1.58, 0.50
6 min Walk Test (m)		
Post-intervention	7.79	-34.60, 50.18
6 weeks post-surgery	11.37	-31.30, 54.06
3 months post-surgery	35.16	-6.73, 77.05
6 months post-surgery	17.28	-24.41, 58.98
12 months post-surgery	19.45	-21.63, 60.53
Stair Climb Test (s)		
Post-intervention	-0.80	-4.46, 2.84
6 weeks post-surgery	0.32	-3.32, 3.97
3 months post-surgery	-0.71	-4.24, 2.80
6 months post-surgery	1.21	-2.45, 4.69
12 months post-surgery	-1.03	-4.63, 2.58
HOOS Pain (0-100)		
Post-intervention	4.02	-4.53, 12.58
6 weeks post-surgery	-0.98	-9.18, 7.22
3 months post-surgery	2.63	-4.85, 10.10
6 months post-surgery	-0.83	-8.41, 6.75
12 months post-surgery	-3.12	-10.85, 4.61
HOOS Symptoms (0-100)		
Post-intervention	4.32	-4.38, 13.03
6 weeks post-surgery	-2.63	-10.79, 5.54
3 months post-surgery	-2.39	-9.99, 5.21
6 months post-surgery	-2.80	-10.51, 4.90
12 months post-surgery	-4.06	-12.12, 4.00
HOOS ADL (0-100)		
Post-intervention	4.85	-3.90, 13.59
6 weeks post-surgery	-2.50	-10.88, 5.88
3 months post-surgery	-3.33	-11.12, 4.46
6 months post-surgery	-3.47	-11.67, 4.73
12 months post-surgery	-2.57	-10.77, 5.63
HOOS Sports/recreation (0-100)		
Post-intervention	8.61	-4.95, 22.16

6 weeks post-surgery	-1.51	-15.28, 12.27
3 months post-surgery	3.00	-9.16, 15.17
6 months post-surgery	0.86	-11.86, 13.58
12 months post-surgery	-11.79	-24.37, 0.80
HOOS QoL (0-100)		
Post-intervention	11.05*	0.45, 21.64
6 weeks post-surgery	3.77	-6.32, 13.85
3 months post-surgery	-2.42	-11.92, 7.08
6 months post-surgery	-3.09	-12.80, 6.62
12 months post-surgery	-6.89	-16.68, 2.91
EQ-VAS (0-100)		
Post-intervention	7.44	-3.32, 18.19
6 weeks post-surgery	-6.27	-16.57, 4.02
3 months post-surgery	-3.69	-13.32, 5.94
6 months post-surgery	4.39	-5.55, 14.32
12 months post-surgery	3.73	-6.25, 13.71

Differences between randomized groups for continuous outcome variables analyzed by Linear mixed models for repeated measurements, p-values were two-sided and set to a 5% significance level but not presented in the table, *statistical significance between groups $p<0.05$

CI: confidence interval, HOOS: Hip Disability and Osteoarthritis Outcome Score, ADL: activities of daily living, QOL: quality of life, EQ-VAS: EuroQol Visual Analogue Scale

Appendix Table 4 – Descriptive values within groups for primary and secondary outcomes at different assessment points throughout the study period

Outcome	Intervention		Control	
	n	Mean (SD)	n	Mean (SD)
40m Fast-Paced Walk Test (m/s)				
Baseline	48	1.21 (0.38)	50	1.29 (0.37)
Post-intervention	25	1.38 (0.37)	26	1.28 (0.34)
6 weeks post-surgery	22	1.38 (0.45)	16	1.44 (0.36)
3 months post-surgery	26	1.52 (0.37)	26	1.48 (0.32)
6 months post-surgery	28	1.54 (0.39)	23	1.57 (0.28)
12 months post-surgery	23	1.57 (0.41)	24	1.51 (0.31)
30s Sit-to-Stand Test (no. of rep.)				
Baseline	48	10.33 (3.71)	50	10.02 (3.64)
Post-intervention	25	11.56 (3.34)	26	10.23 (3.69)
6 weeks post-surgery	19	11.16 (3.40)	16	11.75 (2.35)
3 months post-surgery	26	13.81 (2.63)	26	12.42 (3.34)
6 months post-surgery	28	14.21 (4.84)	23	13.39 (3.62)
12 months post-surgery	23	14.22 (3.77)	24	12.75 (3.77)
Timed Up and Go Test (s)				
Baseline	47	11.13 (3.41)	50	11.13 (3.63)
Post-intervention	25	9.80 (3.08)	26	10.44 (2.78)
6 weeks post-surgery	20	10.51 (3.82)	16	8.99 (1.76)
3 months post-surgery	26	8.85 (1.58)	26	8.84 (2.10)
6 months post-surgery	28	8.73 (1.91)	23	8.32 (1.48)
12 months post-surgery	23	8.37 (1.78)	24	8.41 (1.43)
6 min Walk Test (m)				
Baseline	48	353.04 (104.98)	50	353.23 (104.12)
Post-intervention	25	374.48 (101.81)	26	343.50 (98.03)
6 weeks post-surgery	22	391.40 (121.64)	16	375.68 (105.70)
3 months post-surgery	26	430.30 (104.74)	26	419.07 (83.92)
6 months post-surgery	28	448.92 (105.06)	23	425.26 (109.78)
12 months post-surgery	23	449.34 (105.57)	24	437.70 (83.32)
Stair Climb Test (s)				
Baseline	47	18.51 (8.41)	48	19.99 (11.78)
Post-intervention	25	16.17 (9.89)	25	17.97 (8.60)
6 weeks post-surgery	21	15.68 (10.57)	16	14.21 (4.21)
3 months post-surgery	26	12.36 (5.70)	25	13.44 (8.21)
6 months post-surgery	28	12.79 (7.13)	22	11.19 (3.79)
12 months post-surgery	22	11.95 (5.76)	24	11.71 (4.90)
HOOS Pain (0-100)				
Baseline	45	41.33 (12.05)	47	41.65 (12.57)
Post-intervention	25	46.40 (15.58)	26	47.21 (11.18)
6 weeks post-surgery	27	78.61 (14.76)	18	80.83 (12.97)
3 months post-surgery	34	84.49 (17.79)	28	87.59 (12.16)
6 months post-surgery	31	88.39 (14.62)	23	92.50 (10.08)
12 months post-surgery	25	89.70 (12.95)	24	93.54 (10.95
HOOS Symptoms (0-100)				
Baseline	45	41.41 (16.72)	49	39.08 (14.67)
Post-intervention	25	46.60 (21.10)	26	44.04 (15.36)
6 weeks post-surgery	28	73.75 (14.94)	20	78.25 (13.79)
3 months post-surgery	34	79.12 (14.89)	28	83.04 (11.89)
6 months post-surgery	31	80.97 (15.07)	26	84.23 (12.93)

12 months post-surgery	24	85.21 (16.51)	24	91.46 (10.47)
HOOS ADL (0-100)				
Baseline	44	42.08 (13.41)	46	44.53 (14.71)
Post-intervention	24	47.73 (18.38)	27	47.49 (14.03)
6 weeks post-surgery	25	77.88 (14.40)	17	80.28 (10.21)
3 months post-surgery	34	82.09 (17.00)	26	87.10 (11.84)
6 months post-surgery	30	86.13 (15.02)	22	88.70 (12.87)
12 months post-surgery	24	88.48 (13.84)	24	92.46 (9.84)
HOOS Sports/recreation (0-100)				
Baseline	44	26.85 (19.46)	50	27.00 (17.74)
Post-intervention	24	29.17 (16.24)	23	22.23 (13.79)
6 weeks post-surgery	25	47.50 (23.38)	13	48.08 (18.81)
3 months post-surgery	33	60.98 (23.12)	23	65.22 (23.14)
6 months post-surgery	30	74.17 (23.37)	21	74.11 (27.47)
12 months post-surgery	23	77.17 (24.17)	20	85.00 (19.49)
HOOS QoL (0-100)				
Baseline	47	27.13 (13.74)	50	26.50 (13.86)
Post-intervention	25	35.00 (16.03)	27	26.16 (12.50)
6 weeks post-surgery	28	70.54 (21.16)	19	67.76 (21.67)
3 months post-surgery	33	76.70 (20.62)	29	82.33 (16.02)
6 months post-surgery	30	84.58 (16.39)	26	86.06 (14.39)
12 months post-surgery	25	84.50 (16.44)	24	91.67 (12.03)
EQ-VAS (0-100)				
Baseline	47	56.55 (21.64)	50	54.00 (17.52)
Post-intervention	25	60.00 (16.33)	27	53.41 (17.60)
6 weeks post-surgery	28	73.50 (18.41)	20	81.50 (10.65)
3 months post-surgery	34	74.35 (15.53)	29	77.38 (14.91)
6 months post-surgery	32	79.19 (13.24)	26	77.77 (18.44)
12 months post-surgery	25	77.28 (11.68)	24	77.17 (15.90)

Presented data are mean with standard deviation (SD)

HOOS: Hip Disability and Osteoarthritis Outcome Score, ADL: activities of daily living, QOL: quality of life, EQ-VAS: EuroQol Visual Analogue Scale

Appendix Table 5 – Descriptive mean scores for performance-based outcome measures at different assessment points throughout the study period, stratified by sex

Baseline		
40m Fast-Paced Walk Test (m/s)	Intervention (n=48)	Control (n=50)
- Male	- 1.25	- 1.48
- Female	- 1.19	- 1.23
30s Sit-To-Stand (reps)	Intervention (n=48)	Control (n=50)
- Male	- 10.43	- 11.92
- Female	- 10.26	- 9.35
Timed Up and Go (s)	Intervention (n=47)	Control (n=50)
- Male	- 10.68	- 10.22
- Female	- 11.49	- 11.45
6 Minute Walk Test (m)	Intervention (n=48)	Control (n=50)
- Male	- 369.02	- 375.23
- Female	- 340.11	- 344.14
Stair Climb Test (s)	Intervention (n=47)	Control (n=48)
- Male	- 16.72	- 15.57
- Female	- 19.94	- 21.73
Post-intervention		
40m Fast-Paced Walk Test (m/s)	Intervention (n=25)	Control (n=26)
- Male	- 1.44	- 1.45
- Female	- 1.32	- 1.20
30s Sit-To-Stand (reps)	Intervention (n=25)	Control (n=26)
- Male	- 12.08	- 12.38
- Female	- 11.00	- 9.28
Timed Up and Go (s)	Intervention (n=25)	Control (n=26)
- Male	- 8.96	- 9.27
- Female	- 10.71	- 10.69
6 Minute Walk Test (m)	Intervention (n=25)	Control (n=26)
- Male	- 384.30	- 368.00
- Female	- 363.83	- 332.61
Stair Climb Test (s)	Intervention (n=25)	Control (n=25)
- Male	- 13.40	- 14.30
- Female	- 19.34	- 19.69
6 weeks post-surgery		
40m Fast-Paced Walk Test (m/s)	Intervention (n=22)	Control (n=16)
- Male	- 1.57	- 1.63
- Female	- 1.22	- 1.38
30s Sit-To-Stand (reps)	Intervention (n=19)	Control (n=16)
- Male	- 12.57	- 10.75
- Female	- 10.33	- 12.08
Timed Up and Go (s)	Intervention (n=20)	Control (n=16)
- Male	- 9.29	- 8.01
- Female	- 11.32	- 9.32
6 Minute Walk Test (m)	Intervention (n=22)	Control (n=16)
- Male	- 432.70	- 427.50
- Female	- 357.00	- 358.41
Stair Climb Test (s)	Intervention (n=21)	Control (n=16)
- Male	- 10.79	- 11.00
- Female	- 19.34	- 15.28
3 months post-surgery		
40m Fast-Paced Walk Test (m/s)	Intervention (n=26)	Control (n=26)

- Male	- 1.67	- 1.75
- Female	- 1.40	- 1.38
30s Sit-To-Stand (reps)	Intervention (n=26)	Control (n=26)
- Male	- 14.08	- 13.71
- Female	- 13.57	- 12.00
Timed Up and Go (s)	Intervention (n=26)	Control (n=26)
- Male	- 8.65	- 7.72
- Female	- 9.02	- 9.41
6 Minute Walk Test (m)	Intervention (n=26)	Control (n=26)
- Male	- 450.83	- 480.42
- Female	- 412.71	- 394.47
Stair Climb Test (s)	Intervention (n=26)	Control (n=25)
- Male	- 10.92	- 9.49
- Female	- 13.59	- 14.79
6 months post-surgery		
40m Fast-Paced Walk Test (m/s)	Intervention (n=28)	Control (n=23)
- Male	- 1.79	- 1.75
- Female	- 1.38	- 1.49
30s Sit-To-Stand (reps)	Intervention (n=28)	Control (n=23)
- Male	- 15.18	- 13.71
- Female	- 13.59	- 13.25
Timed Up and Go (s)	Intervention (n=28)	Control (n=23)
- Male	- 7.85	- 7.72
- Female	- 9.29	- 8.58
6 Minute Walk Test (m)	Intervention (n=28)	Control (n=23)
- Male	- 493.09	- 480.42
- Female	- 420.35	- 401.12
Stair Climb Test (s)	Intervention (n=28)	Control (n=22)
- Male	- 9.58	- 9.49
- Female	- 14.87	- 11.99
12 months post-surgery		
40m Fast-Paced Walk Test (m/s)	Intervention (n=23)	Control (n=24)
- Male	- 1.88	- 1.73
- Female	- 1.44	- 1.46
30s Sit-To-Stand (reps)	Intervention (n=23)	Control (n=24)
- Male	- 16.29	- 11.60
- Female	- 13.31	- 13.05
Timed Up and Go (s)	Intervention (n=23)	Control (n=24)
- Male	- 7.62	- 7.35
- Female	- 8.70	- 8.69
6 Minute Walk Test (m)	Intervention (n=23)	Control (n=24)
- Male	- 508.85	- 512.80
- Female	- 423.31	- 417.94
Stair Climb Test (s)	Intervention (n=22)	Control (n=24)
- Male	- 8.76	- 9.37
- Female	- 13.15	- 12.32

Appendix Table 6. Frequencies of aid usage during physical performance testing in the intervention (I) and control (C) group at different assessment points throughout the study period, n (%)

	40m Fast-Paced Walk Test	30s Sit-to-Stand Test	Timed Up and Go Test	6 min Walk Test	Stair Climb Test
Baseline	I: 6 (12.5%) C: 11 (22%)	I: 7 (14.6%) C: 10 (20%)	I: 3 (6.3%) C: 9 (18%)	I: 7 (14.6%) C: 12 (24%)	I: 34 (70.8%) C: 35 (70%)
Post-intervention	I: 2 (4.2%) C: 6 (12%)	I: 3 (6.3%) C: 2 (4%)	I:1 (2.1%)* C: 6 (12%)	I: 4 (8.3%) C: 7 (14%)	I: 16 (33.3%) C: 19 (38%)
6 weeks post-surgery	I: 6 (12.5%) C: 2 (4%)	I: 2 (4.2%) C: 1 (2%)	I: 4 (8.3%) C: 0 (0%)	I: 8 (16.7%) C: 3 (6%)	I: 17 (35.4%) C: 12 (24%)
3 months post-surgery	I: 1 (2.1%) C: 2 (4%)	I: 0 (0%) C: 0 (0%)	I: 0 (0%) C: 1 (2%)	I: 1 (2.1%) C: 3 (6%)	I: 21 (43.8%) C: 15 (30%)
6 months post-surgery	I: 2(4.2%) C: 0 (0%)	I: 0 (0%) C: 0 (0%)	I: 0 (0%) C: 0 (0%)	I: 2(4.2%) C: 1 (2%)	I: 20 (41.7%) C: 16 32%)
12 months post-surgery	I: 2 (4.2%) C: 2 (4%)	I: 0 (0%) C: 1 (2%)	I: 0 (0%) C: 1 (2%)	I: 3 (6.3%) C: 2 (4%)	I: 20 (41.7%) C: 20 (40%)

Between-group analysis is assessed with Pearson $\chi 2$ tests, *$p<0.05$.

CERT ✓ *C*onsensus on *E*xercise *R*eporting *T*emplate

A Checklist for what to include when reporting exercise programs

Section/Topic	Item #	Checklist item	Location **	
			Primary paper (page, table, appendix)	† Other (paper or protocol, website (URL)
WHAT: materials	1	Detailed description of the type of exercise equipment (e.g. weights, exercise equipment such as machines, treadmill, bicycle ergometer etc)	Page 8	Reference 38 in paper
WHO: provider	2	Detailed description of the qualifications, teaching/supervising expertise, and/or training undertaken by the exercise instructor	Page 8	
HOW: delivery	3	Describe whether exercises are performed individually or in a group	Page 8-9	
	4	Describe whether exercises are supervised or unsupervised and how they are delivered	Page 8	
	5	Detailed description of how adherence to exercise is measured and reported	Page 8	
	6	Detailed description of motivation strategies	Page 8-9	
	7a	Detailed description of the decision rule(s) for determining exercise progression	Page 8-9	
	7b	Detailed description of how the exercise program was progressed	Page 8-9	
	8	Detailed description of each exercise to enable replication (e.g. photographs, illustrations , video etc)	N/A	
	9	Detailed description of any home program component (e.g. other exercises, stretching etc)	Page 8-9	
	10	Describe whether there are any non-exercise components (e.g. education, cognitive behavioural therapy, massage etc)	Page 8	
	11	Describe the type and number of adverse events that occurred during exercise	Page 16	

WHERE: location	12	Describe the setting in which the exercises are performed	Page 8-9	Ref 38 in paper
WHEN, HOW MUCH: dosage	13	Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/sessions, session duration, intervention/program duration etc	Page 8	
TAILORING: what, how	14a	Describe whether the exercises are generic (one size fits all) or tailored whether tailored to the individual	Page 8	
	14b	Detailed description of how exercises are tailored to the individual	Page 8	
	15	Describe the decision rule for determining the starting level at which people commence an exercise program (such as beginner, intermediate, advanced etc)	N/A	
HOW WELL: planned, actual	16a	Describe how adherence or fidelity to the exercise intervention is assessed/measured	Page 8	
	16b	Describe the extent to which the intervention was delivered as planned	Page 16 & 21	

***It is recommended that this checklist is used in conjunction with the Explanation and Elaboration Statement which is a guide each item in the CERT Checklist**

The CERT Checklist is designed for reporting details of an exercise intervention. The CERT Checklist should be used in conjunction with a reporting checklist appropriate for the study type e.g. the CONSORT Statement (www.consort-statement.org) for randomised controlled trials, the SPIRIT Statement (www.spirit-statement.org) for a clinical trial protocol. For further guidance regarding reporting guidelines please consult the EQUATOR network (www.equator-network.org)

****** Authors – please use N/A if an item is not applicable Reviewers – please use "?" if information is not provided or not/insufficiently reported

† If the information is not provided in the primary paper that is under consideration, please provide details of where this information is available e.g. in a published protocol, published papers (provide citation details) or on a website (provide the URL).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Pages 4-6
	2b	Specific objectives or hypotheses	Page 5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Page 7
	4b	Page 6	Page 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Page 10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			Page 7
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Page 7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Pages 10-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Pages10-12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 12
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 6
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Tables 3-6
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Tables 3-6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 16
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pages 20-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Pages 17-23
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pages 17-23
Other information			
Registration	23	Registration number and name of trial registry	Page 1
Protocol	24	Where the full trial protocol can be accessed, if available	Page 6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 26

Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8:18.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

Article 3

BMC Musculoskeletal Disorders

RESEARCH

Open Access

Physical activity and the risk of aseptic loosening after total hip arthroplasty: a case–control study from the Norwegian Arthroplasty Register

J. V. Nordbø[1,2*], T. M. Straume-Næsheim[1,2], G. Hallan[3,4], A. M. Fenstad[5], E. A. Sivertsen[6] and A. Årøen[1,2,7]

Abstract

Introduction Previous studies have shown increased wear rate and aseptic loosening of total hip arthroplasty (THA) in patients with high physical activity levels. However, highly cross-linked polyethylene (HXLPE) has a reduced wear rate compared to conventional polyethylene. Thus, studies on the amount of physical activity in THA with HXLPE are needed. We aimed to determine if the level of physical activity in patients with THA containing HXLPE was associated with the risk of aseptic loosening of this implant.

Methods In this retrospective case–control study, we identified patients aged 40–75 years with a primary THA containing HXLPE registered in the Norwegian Arthroplasty Register (NAR) from 2005–2012 ($n=10,904$). With a mean follow-up of 9.1 years, 176 patients were revised for aseptic loosening of their THA and invited into the study together with a sample of 856 patients with unrevised THA. Participants reported their physical activity level by answering the University of California, Los Angeles (UCLA) activity score at their best-remembered condition after the primary surgery. The peak physical activity levels were compared to the risk of being revised due to aseptic loosening in a multivariate logistic regression analysis.

Results Patients treated with revision surgery for aseptic loosening ($n=77$ (44%)) had a lower retrospective peak level of physical activity before revision surgery compared to unrevised control patients ($n=429$ (50%)); UCLA score median (IQR) 7 (5–8) vs. 8 (6–8). Adjusted logistic regression analyses of these UCLA scores on the risk of revision surgery due to aseptic loosening of the THA, showed that a higher level of physical activity was associated with a decreasing risk of revision surgery (OR 0.8, 95% CI 0.7–0.9, $P=0.001$).

Conclusion A retrospectively self-reported level of physical activity at the patient`s best-remembered condition after primary THA was not associated with a higher risk of revision surgery due to aseptic loosening of the THA. Patients with THA should be encouraged to gain the health benefits of regular physical activity rather than restricting their activity level because of fear of implant wear and loosening.

Keywords Osteoarthritis, Total hip arthroplasty, Highly cross-linked polyethylene, Physical activity, Aseptic loosening, Wear

*Correspondence:
J. V. Nordbø
jakob.nordbo@gmail.com
Full list of author information is available at the end of the article

Introduction

Physical activity is essential not only to improve quality of life, but a moderate to vigorous level of physical activity can reduce morbidity like cardiovascular disease [1]. Patients with end-stage osteoarthritis (OA) in the hip experience pain and joint stiffness, which can be successfully treated by total hip arthroplasty (THA) [2, 3]. In a recent study, we showed that middle-aged people with THA were more physically active than a control group representing a normal population [4]. Low-impact sports like walking or cycling are the most common activity after THA [5]. Due to an expected increase in younger patients undergoing THA in the years to come and the known health-enhancing benefits of physical activity, it is essential for patients with THA to perform physical activity as they want [6–8].

Known barriers for patients to engage in high-level physical activity after THA are patients` fear of damaging their THA and caution from health care professionals [9, 10]. The most cited risk caused by the return to sport after THA is the aseptic loosening of the implant [10, 11]. The theory is that particle debris made from the articulation of the THA introduces an inflammatory process that leads to osteolysis and loosening of the implant [12]. According to this theory, increased use of the artificial joint will lead to more particle debris and, subsequently, a higher risk of loosening the implant. With the introduction of highly cross-linked polyethylene (HXLPE) in THA, the wear rate is reduced [13], but there is a lack of studies that show how it interferes with high levels of physical activity and the risk of aseptic loosening [10]. This study aimed to determine if patients revised for aseptic loosening of the THA had higher levels of physical activity before revision surgery than unrevised control patients.

Methods

Study design and data collection

In this retrospective case–control study, the cases constitute patients with THA revised for aseptic loosening, and the controls constitute patients with an unrevised primary THA. We identified patients in the Norwegian Arthroplasty Register (NAR) who had a unilateral primary THA with articulations made of metal or ceramic femoral head on an HXLPE counter-surface from 2005 to 2012. HXLPE was introduced in Norway in 2005, and we chose an inclusion period of seven years to obtain a sufficient sample size of THAs containing HXLPE. We selected patients aged 40–75 years at the time of surgery due to their expected higher physical activity levels than older patients [14]. All hospitals in Norway report primary THA to the NAR with a completeness of 97% and revision surgery with a completeness of 91% [15].

By 31 December 2019, with a mean follow-up of 9.1 years (7.0 to 14.3 years), we identified 10,541 THAs eligible for the study. In this sample, 176 patients were revised for aseptic loosening of their THA, constituting the study`s cases. From the same sample, we randomly selected a control group ($n=856$) of the unrevised THAs that was five times larger than the cases to increase statistical power. The study coordinator invited the cases and controls to participate through a questionnaire sent by mail in December 2020, followed by two reminders. A secretary plotted the answers to a digital database, and the study coordinator controlled the data. The study is reported according to the STROBE guidelines [16].

Variables

Participants reported their physical activity levels by answering the previously validated University of California, Los Angeles (UCLA) activity score (Appendix) [17]. The UCLA score is a 10-level scale ranging from wholly inactive (level 1) to highly physically active (level 10). Due to the lack of prospectively collected physical activity levels after the primary THA, all patients were asked to report their physical activity levels retrospectively at their best condition after primary surgery (Fig. 1). This level of physical activity constituted the primary exposure for the identified outcome, revision surgery due to aseptic loosening of the THA.

Secondary exposure measures, EQ-5D-5L, EQ VAS, and Hip Disability and Osteoarthritis Outcome Score (HOOS), were collected similarly retrospectively at the patients best condition after primary surgery (Appendix). The EQ-5D-5L is an extensively validated generic 5 item questionnaire (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) concerning general health [18], which is calculated into a -0.59 (worst) to 1.0 (best) index. To calculate the EQ-5D index values from EQ-5D-5L, we used scores from the EQ-5D-3L-UK value set through a crosswalk algorithm [19, 20]. The EQ VAS is a vertical visual analogue scale ranging from 0 (worst health) to 100 (best health), where patients rate their general health. The HOOS is a validated hip-specific questionnaire with the subgroups` symptoms, pain, activities of daily living, sports and quality of life [21]. To calculate the mean values of the HOOS subgroups, we used the transformation to a 0 (worst) to 100 (best) scale presented by Roos et al. [22]. Missing values were substituted with the average value for the subgroup unless more than two values of a subgroup were omitted.

The NAR collects baseline characteristics of all primary THAs at the time of surgery, which includes information on the patient`s age, sex, date of the operation, American

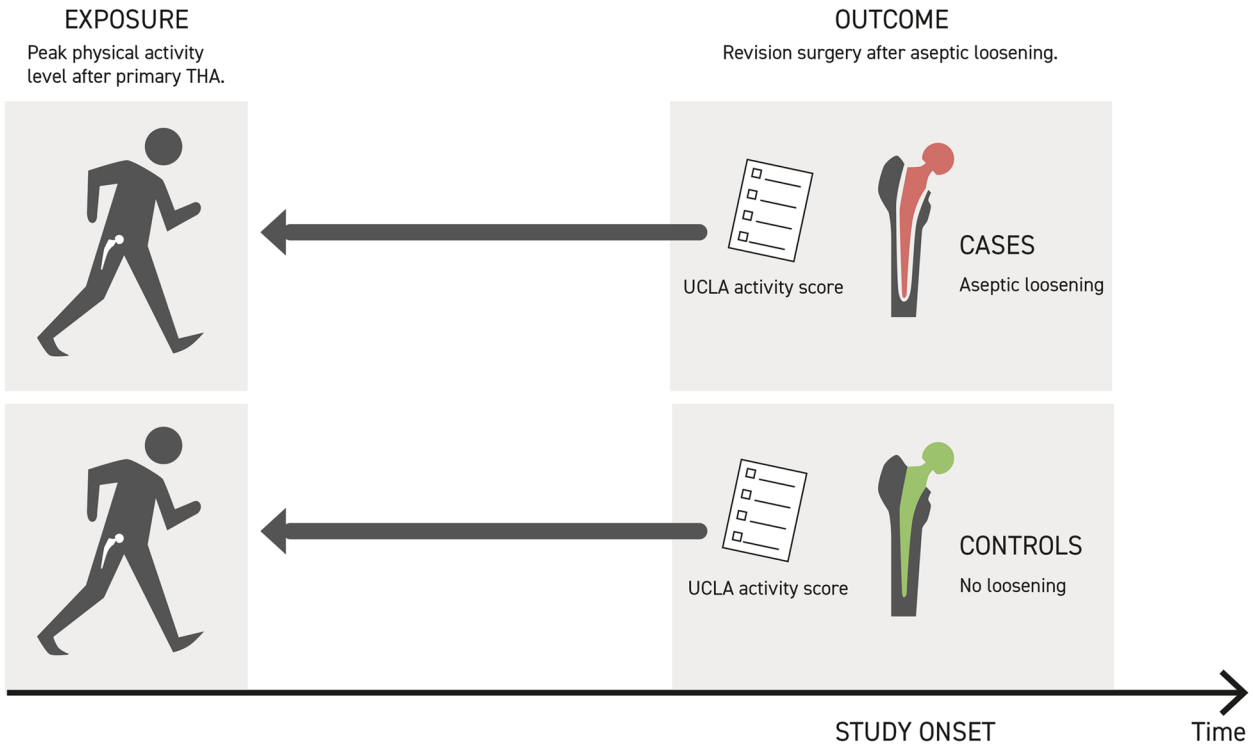

Fig. 1 The figure illustrates the case–control study design. Both cases and controls reported their physical activity levels by answering the UCLA activity score retrospectively at their best condition after the primary surgery. This level of physical activity constituted the exposure for the identified outcome, revision surgery for aseptic loosening of THA (Illustration by Hellevik studio)

Society of Anesthesiologists (ASA) classification, indication for surgery, type of surgical procedure, surgical approach, and fixation method.

Sample size

The cohort`s sample size is based on a meaningful difference in the UCLA score. SooHoo [23] defined the minimal clinically important difference in UCLA score as 0.92, and Lubbeke [24] defined the standard deviation (SD) as 2.0. This estimate requires 148 patients, 74 in each group, to obtain 80% statistical power with a 5% significance level for an independent samples t-test.

Statistical analysis

Descriptive statistics were presented for cases and controls, and respondents and non-respondents, as means and standard deviations for continuous variables, compared with independent-samples t-test, and numbers and percentages for categorical variables, compared with chi-squared test.

The UCLA score, EQ-5D index, and HOOS scores were not expected to be normally distributed; thus, we presented data with medians and interquartile range and analyzed between-group differences with the non-parametric Mann–Whitney U test. However, means and standard deviations were calculated to consider the variance in the scores and compare them with the current literature.

We used a logistic regression model to analyze the association of physical activity in the best condition after primary THA with the chance of revision surgery due to aseptic loosening. The association was adjusted for possible confounders such as age, sex, ASA class, surgical approach, and fixation method. The assumptions of the regression model were checked for linear effects and interactions on the log-odds scale. The model fit was considered according to the Akaike information criterion (AIC) and the Bayesian information criteria (BIC).

The correlation between physical activity levels after primary THA and time to revision due to aseptic implant loosening was visualized in a scatterplot and analyzed by a linear regression model.

Missing values on the primary exposure were checked among responders. With missing values > 10%, we would check if the values were missing completely at random (MCAR) or missing at random (MAR), and if so, conduct multiple imputation (MI) on the missing values. Missing values < 10% were considered not to influence the result significantly; in this case, MI was deemed unnecessary.

Results

77 (44%) of the revised THA cases and 429 (50%) of the unrevised THA controls responded the questionnaire and were included into the study. The flowchart of Fig. 2 shows the selection process.

Respondents vs. non-respondents

Both cases and controls were slightly younger and had fewer women than the non-respondents. In addition, the responding controls were healthier according to the ASA class, while the cases had a similar ASA class between the respondents and non-respondents. Regarding the hip-specific characteristics, both groups were similar regarding indication for surgery, surgical approach and fixation method between respondents and non-respondents (Appendix Tables 4 and 5).

Cases vs. controls

The cases and controls were similar in age, sex, ASA class, indication for surgery and surgical approach. However, the cases had more cemented fixations (Table 1).

Primary exposure measure

The distribution of the peak UCLA scores is shown in Fig. 3. The retrospectively measured peak UCLA score after primary THA was lower in the cases ($n=73$), median (IQR) 7 (5–8), compared to the unrevised controls ($n=408$), median (IQR) 8 (6–8) ($p=0.001$).

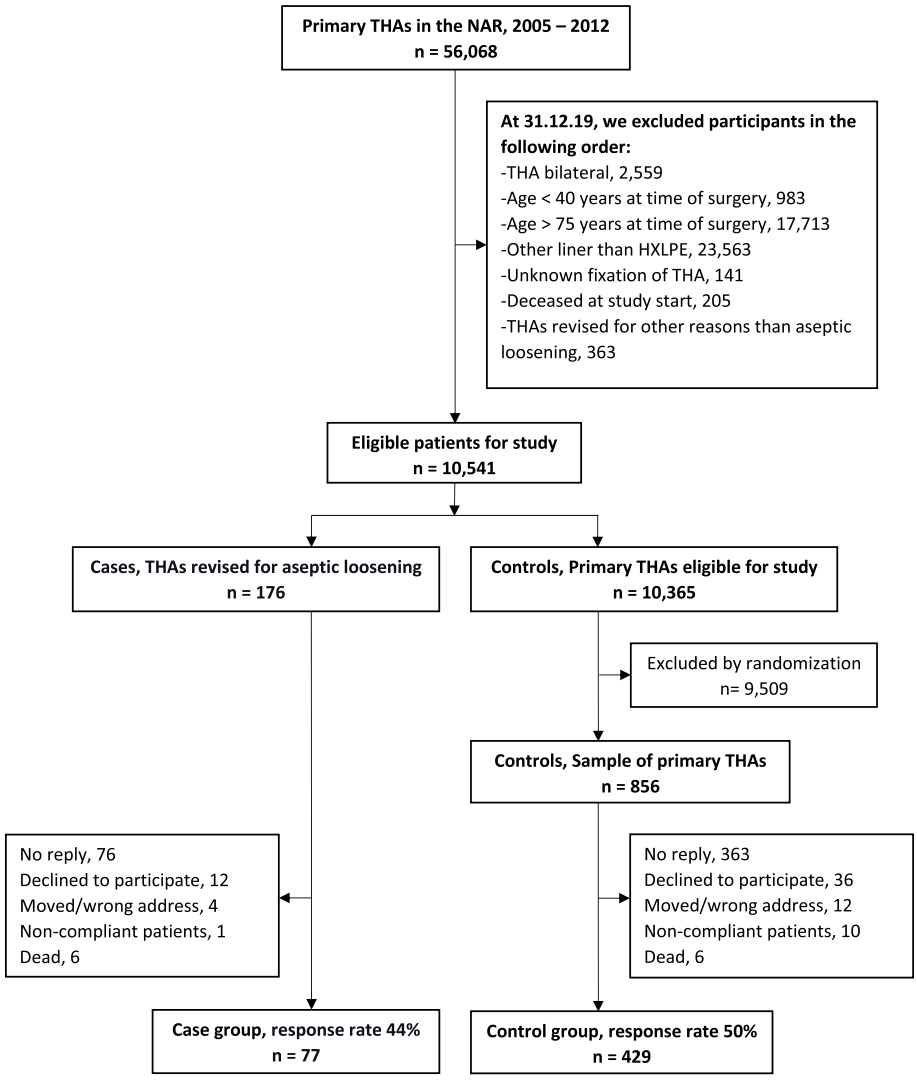

Fig. 2 Flowchart of the selection of eligible patients from the Norwegian Arthroplasty Register (NAR) and the inclusion process. THA = Total hip arthroplasty, HXLPE = Highly cross-linked polyethylene

Table 1 Comparison of patient characteristics by cases, THAs revised for aseptic loosening, and controls, primary THAs. Values are counted (%) unless otherwise specified

Characteristic	Cases *n*=77	Controls *n*=429	Difference between groups (95% CI)	p
Mean age[a] (SD)	61.0 (8)	62.0 (7)	-1.0 (-2.8 to 0.8)	0.27[b]
Female sex	41 (53)	247 (58)	-5% (-16 to 8)	0.48[c]
ASA-score				
ASA 1	21 (27)	154 (36)	-9% (-20 to 23)	0.14[c]
ASA 2	46 (60)	240 (56)	4% (-8 to 16)	0.54[c]
ASA 3+	8 (10)	29 (7)	3% (-4 to 11)	0.26[c]
Not reported	2 (3)	6 (1)	1% (-3 to 5)	0.44[c]
Indication for surgery				
Osteoarthritis	61 (79)	348 (81)	-2% (-12 to 8)	0.70[c]
Surg. approach				
Anterior (Smith-Petersen)	9 (12)	42 (10)	2% (-6 to 10)	0.61[c]
Anterolateral	11 (14)	59 (14)	0 (-8 to 9)	0.90[c]
Lateral	37 (48)	195 (45)	3% (-10 to 15)	0.67[c]
Posterior	19 (25)	121 (28)	-3% (-14 to 7)	0.52[c]
Not reported	1 (1)	12 (3)	-2% (-5 to 1)	0.39[c]
Fixation method				
Cemented	21 (27)	66 (15)	12% (1 to 22)	0.01[c]
Uncemented	19 (25)	152 (36)	-11% (-21 to 0)	0.07[c]
Hybrid	1 (1)	13 (3)	-2% (-5 to 1)	0.39[c]
Reversed hybrid	36 (47)	198 (46)	1% (-12 to 13)	0.92[c]

THA Total hip arthroplasty, *CI* Confidence interval, *ASA* American Society of Anesthesiologists

[a] Age at time of surgery

[b] Independent-samples t-test

[c] Chi-squared test

Secondary exposure measures

The peak EQ-5D index, EQ VAS, and all subdomains of HOOS were lower in the cases compared to controls, measured retrospectively after the primary THA (Table 2, Fig. 4).

Physical activity and time to revision for aseptic loosening

The time from primary THA to revision surgery for aseptic loosening ranged from 50 days to 12 years, with a mean of 4.5 years. We compared the measured physical activity levels after primary THA with time to revision and found a linear increase in physical activity at a longer time to revision (Fig. 5). Because of this finding, we ranged the cases based on time to revision and stratified them into quartiles. We did separate analyses on the first, early, and last, late quartile $n=19$ (25%), constituting cases from 50 days to 1.2 years and 7.3 to 12 years from primary to revision surgery. The early quartile had a retrospective UCLA score of median (IQR) 6 (3–8), and the late quartile had 7 (6–8).

Physical activity and the risk of aseptic loosening after THA

Logistic regression analyses of the retrospective physical activity levels on the risk of revision surgery due to aseptic loosening of the THA showed that higher physical activity was associated with a decreasing risk of revision surgery (OR 0.8, 95% CI 0.7–0.9. $P<0.001$). The result did not change after adjustment for possible confounders, though cemented fixation was associated with a higher risk of revision surgery. We found a similar result when analyzing the early revision quartile. In logistic regression

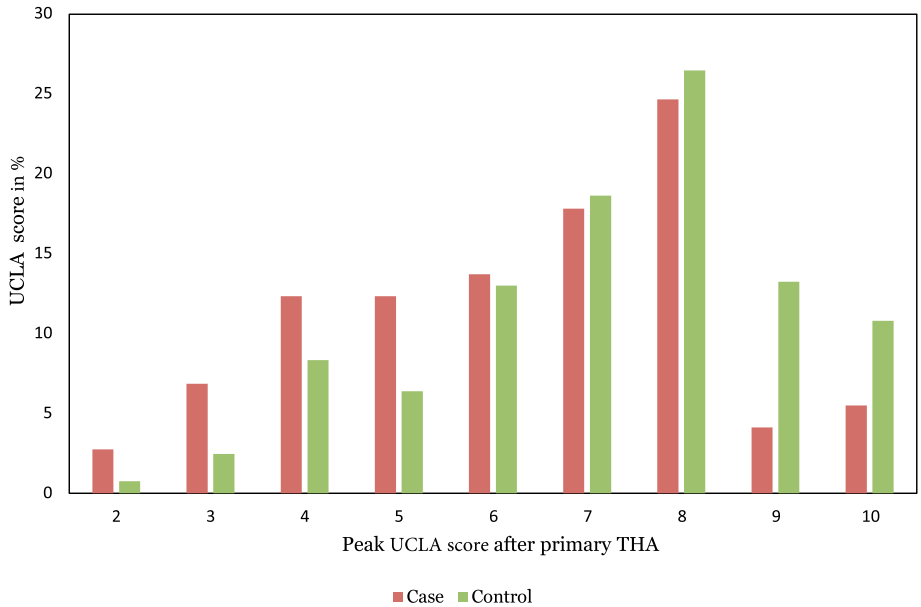

Fig. 3 Distribution of retrospective peak UCLA scores after primary THA in % by cases and controls

Table 2 Retrospective peak primary and secondary exposure measures by cases and controls

Peak exposure measure	Cases			Controls			Cases vs Controls
	n	Median (IQR)	Mean (SD)	n	Median (IQR)	Mean (SD)	p[a]
UCLA score	73	7 (5–8)	6.3 (2.0)	408	8 (6–8)	7.2 (1.9)	0.001
EQ-5D index	66	0.8 (0.6–0.9)	0.7 (0.3)	404	1.0 (0.8–1.0)	0.9 (0.2)	<0.001
EQ-VAS	68	71 (50–88)	68 (23)	397	90 (78–91)	83 (15)	<0.001
HOOS symptoms	66	70 (50–85)	64.2 (24.5)	411	90 (75–100)	84.4 (16.4)	<0.001
HOOS pain	62	71 (50–89)	67.2 (24.8)	396	95 (83–100)	87.4 (17.6)	<0.001
HOOS activities of daily living	62	75 (56–92)	69.1 (25.8)	395	94 (81–100)	87.0 (17.4)	<0.001
HOOS sport	67	50 (31–75)	53.0 (27.5)	397	81 (56–94)	73.8 (23.2)	<0.001
HOOS quality of life	67	69 (38–81)	60.9 (28.2)	406	88 (75–100)	82.8 (19.9)	<0.001

Cases THAs revised for aseptic loosening, *Controls* unrevised THAs, *UCLA score* The University of California, Los Angeles activity score, *VAS* Visual analogue scale, *HOOS* Hip disability and Osteoarthritis Outcome Score with five subscores

[a] Mann-Whitney U test

analyses of the retrospectively physical activity level in the late revision quartile compared to the unrevised controls, physical activity had no association with the aseptic loosening of the implant. The logistic regression analyses are presented in Table 3.

Sensitivity analysis

With only 5% missing values on the retrospectively reported physical activity levels in both cases (4/77) and controls (21/429), MI on missing values was considered unnecessary.

Considering the assumptions of the logistic regression model, our observations were independent patients with unilateral THA from a national sample. The OR from the regression analyses was linear on the log odds scale. A cubic spline model with four knots had a lower model fit according to AIC and BIC. There was no significant interaction between the measured physical activity level and age, sex, or ASA class, except for physical activity and surgical approach. This interaction did not change the results from the primary analysis. Additionally, the model fit according to AIC and BIC was weaker after introducing this interaction.

Discussion

Main results

Patients revised for aseptic loosening of their THA reported a lower peak physical activity level before the revision surgery than patients still having their primary THA. The peak physical activity level before revision surgery was higher the longer these patients lived with their primary THA. However, neither the cases with extended time to revision (7.3 – 12 years) reported higher physical activity levels than controls with unrevised THA. Except for cemented THA fixation, the baseline data did not reveal any predictors for aseptic loosening. We found no association between a high level of physical activity and the risk of revision surgery due to aseptic loosening of the THA.

Context within current literature

In a systematic review by Mooiweer on physical activity from one year and forward after THA, most articles reported mean UCLA scores between 5.5 and 7, which is comparable to our results [5]. The UCLA score is validated to be a useful measure of physical activity on a group level. Still, it has shown substantial variability on an individual level, with patients often overestimating their scores compared to investigators [17, 25]. This highlights a potential limitation in the data, as self-reported physical activity is generally known to be overestimated compared to objectively measured physical activity [26]. However, the simplicity of the scale measuring the amount of physical activity, and not only what the patient can do, makes it suitable for studies exploring physical activity in large groups.

We found no association between a high physical activity level and the risk of aseptic loosening of THAs containing HXLPE, with a minimum follow-up of 7 years. This is in line with the current literature. Streck et al. found no higher revision rates in THA patients with a high level of physical activity compared to a low level at a minimum of 2 years of follow-up [27]. Ennis et al. showed a similar result at a minimum 5-year follow-up [28]. Although these results seem uncontroversial based on the reduced wear rate provided by HXLPE, they contrast the known association between high physical activity levels and the aseptic loosening of THAs using conventional polyethylene. Thus, our results add knowledge to the recommendations on the amount of physical activity

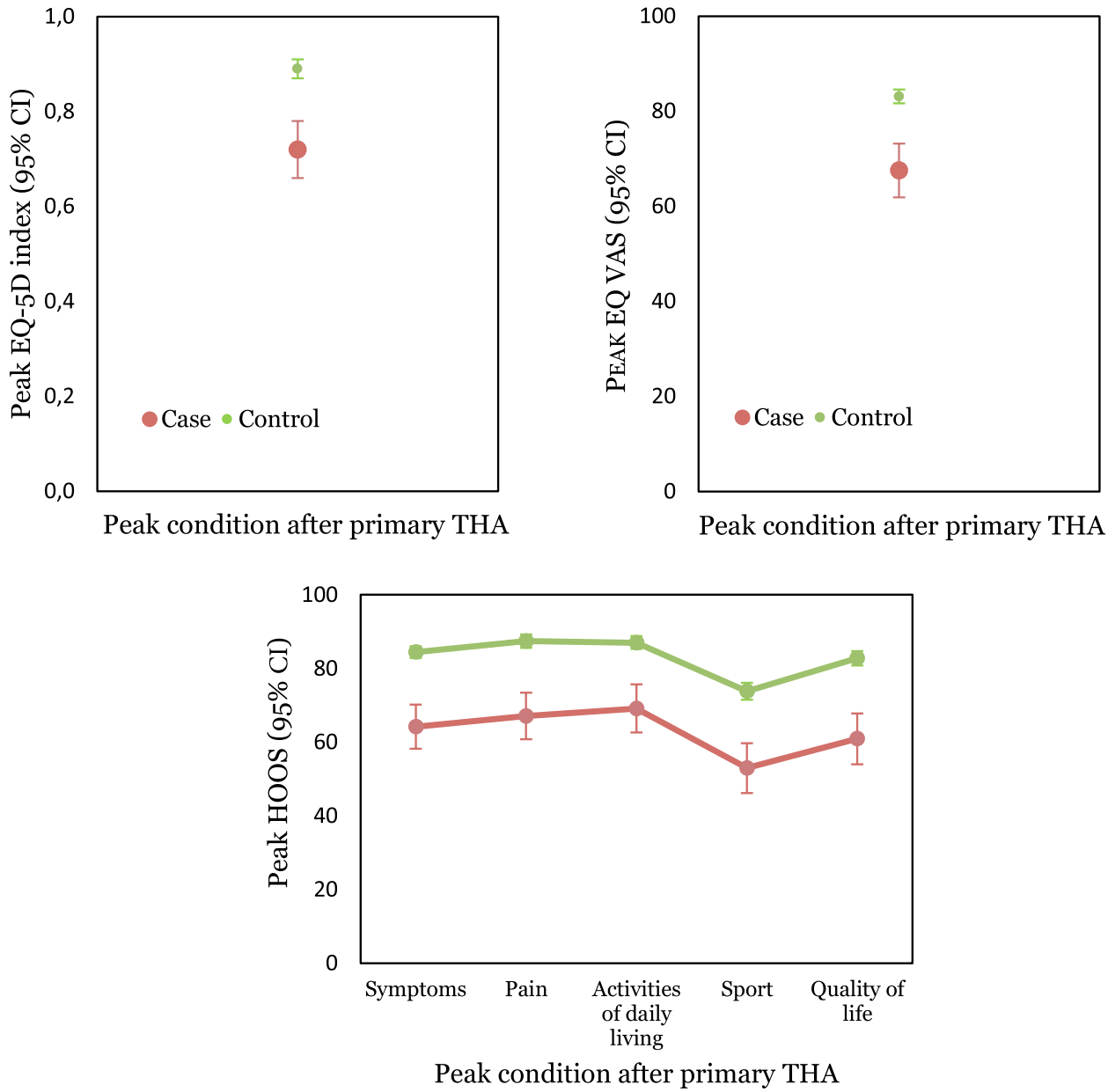

Fig. 4 The distribution of retrospective peak EQ VAS, EQ-5D index, and all subdomains of HOOS after primary THA by cases and controls, reported with means and 95% CI

after THA [29]. An even more offensive interpretation would be to argue that physical activity prevents implants from aseptic loosening due to improved peri-prosthetic bone quality [30]. However, the retrospective observational design of this study cannot draw such conclusions; instead, it supports the hypothesis for future research.

Besides the lower peak physical activity levels before revision surgery, peak HOOS subscores, EQ-5D index, and EQ-VAS were low in the revised group compared to the unrevised and below previously published patient acceptable symptom state (PASS) values after THA [31, 32]. Thus, some cases did not seem to reach a sufficient reduction in pain or improvement in hip function after the index surgery. This might help us understand the low peak physical activity levels in cases that occur quickly from primary to revision surgery. It is unlikely that a well-fixed implant will fail in the early recovery phase, and these cases were more likely a result of failed primary fixation [33]. Additionally, confounders like sex, age, ASA class, surgical approach or fixation method did not

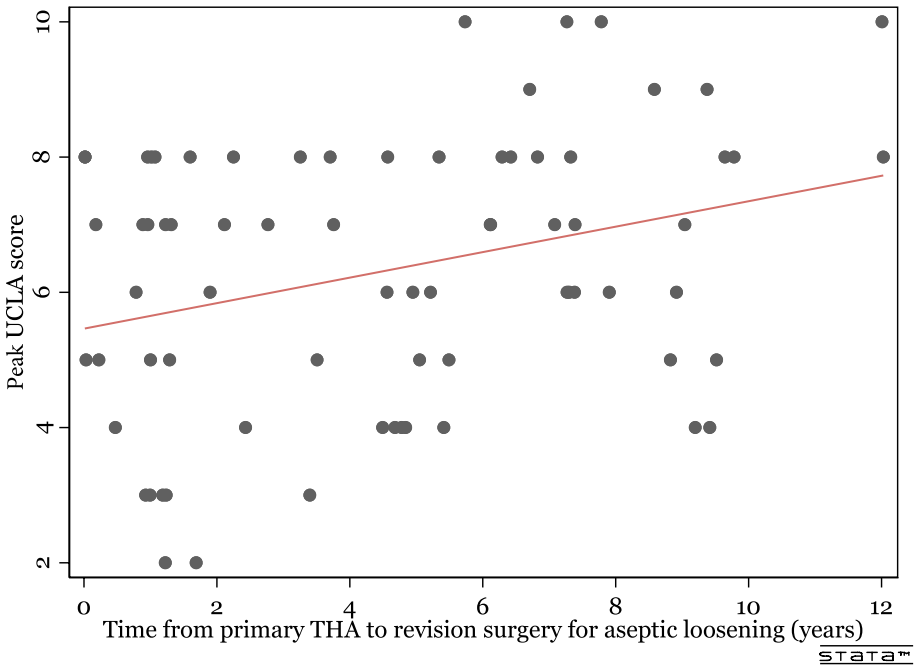

Fig. 5 Patients treated with revision surgery for aseptic loosening of their THA had a linear increase of peak physical activity level before revision surgery at an extended time from primary surgery. The linear regression line shows a linear effect with an increase of 0.2 points of UCLA score for every year to revision, $p = 0.01$. The result did not change after adjusting for age, sex, ASA class**,** surgical approach, and fixation method

Table 3 Association of physical activity and the risk of aseptic loosening after Total Hip Arthroplasty

	Controls	Cases			
		Unadjusted		Adjusted[a]	
	OR (95% CI)	OR (95% CI)	p[b]	OR (95% CI)	p[b]
Model 1	1	0.8 (0.7 to 0.9)	0.00	0.8 (0.7 to 0.9)	0.00
Model 2	1	0.7 (0.5 to 0.8)	0.00	0.7 (0.5 to 0.9)	0.01
Model 3	1	0.9 (0.7 to 1.2)	0.55	1.0 (0.8 to 1.3)	0.97

[a] Adjusted for age, sex, ASA class**,** surgical approach, fixation method

[b] Logistic regression analyses

Model 1: All cases ($n = 73$) vs controls ($n = 408$)

Model 2: Early quartile (the first 19 THAs revised from aseptic loosening, from 50 days to 1.2 years after primary THA) vs controls ($n = 408$)

Model 3: Late quartile (the last 19 THAs revised from aseptic loosening, from 7.3 to 12 years after primary THA) vs controls ($n = 408$)

OR odds ratio. Also, see Table 1 for abbreviations

influence the association between physical activity and time to revision.

We found a higher rate of all-cemented THA in the revision cases compared to controls. This association is seen in patients < 70 years, where cemented femoral stems are more associated with aseptic loosening than uncemented [34]. However, in a systematic review, Prock-Gibbs et al. found similar rates of osteolysis in cemented and uncemented THAs [13]. Though cemented THA were associated with a higher risk of aseptic loosening in our study, it did not influence the result. The direct anterior approach (DAA) showed an interaction with physical activity on increased risk of aseptic loosening. However, only 9 cases were operated through the DAA in our study. Due to the few observations, it isn't possible to conclude the causal relationship between DAA and physical activity on the risk of aseptic loosening. Additionally, bringing this interaction into the logistic regression model of physical activity on the risk of aseptic loosening made the model less balanced, according to AIC and BIC [35]. Thus, omitting the interaction of DAA and physical activity from the model described our data better.

Strengths and clinical applicability

We identified the study participants in the NAR, which makes our study sample representative of the average THA patient in Norway. The relatively low response rate was disappointing. However, we did have baseline data on the non-respondents from the NAR; this helped us to understand the respondents' representativeness. Additionally, only 5% of the observations of physical activity levels were missing among the responding cases and controls. We, therefore, considered the regression analyses

of the results robust, with no need for further sensitivity analyses with imputation methods.

The average follow-up time of 9.1 years for THA patients with HXLPE was the longest possible in Norway at the study onset. HXLPE was introduced in Norway in 2005, and an inclusion period until 2012 was necessary to achieve a sufficient sample size. The long follow-up time of THA cases with HXLPE on physical activity and the risk of aseptic loosening of the implant is also unique in the international literature, with only a few publications available [27, 28].

Though this is a retrospective case–control study that is not fit for conclusions on causal relationships, the result of no association between physical activity and aseptic loosening of THA is intuitive due to reduced wear of HXLPE liners [13]. According to reduced wear in HXLPE liners, the use of UCLA score in the recent literature evaluates THA surgery rather than questioning the wear rate [25]. Thus, considering the benefits of physical activity [1], patients with THA should be recommended to perform physical activity rather than being restricted [8].

Limitations and future perspectives

Since our study sample missed PROMs before revision surgery of the THA, a case–control design was the only option. Recall bias is a known challenge in this design, where the cases might have a "bad" experience of the revision surgery, not shared by the controls, which might influence their memory. To minimize the recall bias, we tried to simplify the question by asking about their peak physical activity level. By this phrasing, we asked of a state, hopefully, more accessible to remember than a specific time point.

We aimed to find a possible association between patients with high levels of physical activity and aseptic loosening of the THA. Since the characteristics of the respondents (cases and controls) were similar in age, gender, and ASA class, the selection bias made by the low response rate probably had a minor influence on the association between physical activity and aseptic loosening. However, the non-respondents were older and had a higher percentage of females. According to the ASA class, the non-respondents in the control group had more comorbidity than the respondents. Thus, it is reasonable to believe that patients who responded (both cases and controls) were more physically active than non-respondents. Additionally, we selected patients aged 40–75 years at the time of surgery, making the study sample younger than the average patient with a primary THA [36].

The observational study design is susceptible to confounding bias. Although regression analyses and examinations of interactions between variables are utilized, combinations of variables may constitute a potential confounding factor. Additionally, unmeasured confounding variables could influence the result.

The undefined criteria of aseptic loosening of the components is a source of bias. In the NAR, surgeons report the reason for revision surgery based on preoperative measures and intraoperative findings. Early cases of aseptic loosening were more likely failed fixations rather than true aseptic loosening. This is not possible to confirm in the present data. Additionally, we measured physical activity with a PROM. Though the scale is validated to report the patients' current physical activity level, we used it retrospectively despite the risk of recall bias. As mentioned, these measures are probably overestimated but suitable for studies in large groups [26].

The retrospective case–control design of this study is suitable for emphasizing our hypothesis. However, the results must be confirmed on prospectively collected physical activity levels in patients with THA. Such full-scale data collection was introduced in 2017 in the NAR, with pre-and post-THA measures of the UCLA activity score [36]. This enables longitudinally designed studies on physical activity levels in THA patients on the risk of revision surgery. Given the low wear rate of HXLPE, the association of physical activity with the aseptic loosening of THAs should be analyzed in the future with a longer follow-up time.

Conclusions

At a mean follow-up of 9.1 years, patients revised for aseptic loosening of their THA did not remember to have a higher level of physical activity before the revision surgery, compared to patients still having their primary THA. Physical activity was not associated with an increased risk of revision surgery due to aseptic loosening of the THA. This finding supports the hypothesis that reduced wear rate in THAs with HXLPE makes the THA more resistant to a high level of physical activity. This result should be confirmed with prospectively collected physical activity levels in patients with THA at a longer follow-up. Our study implies that patients with THA should be encouraged to gain the health benefits of regular physical activity rather than restricting their activity level because of fear of implant wear and loosening.

Appendix

Table 4 Comparison of patient characteristics by respondents and non-respondents in the case group, THAs revised for aseptic loosening. Values are counted (%) unless otherwise specified

Characteristic	Respondents *n*=77	Non – respondents *n*=99	Difference between groups (95% CI)	p
Mean age[a] (SD)	61.0 (8)	64.1 (8)	-3.1 (-5.5 to -0.8)	0.01[c]
Female sex	41 (53)	68 (69)	-16% (-30 to -1)	0.04[d]
ASA-score				
ASA 1	21 (27)	27 (27)	0% (-13 to 13)	1.00[d]
ASA 2	46 (60)	54 (55)	5% (-10 to 20)	0.49[d]
ASA 3+	8 (10)	15 (15)	-5% (-15 to 5)	0.35[d]
Not reported	2 (3)	3 (3)	0% (-5 to 5)	0.86[d]
Indication for surgery				
Osteoarthritis	61 (79)	80 (81)	-2% (-14 to 10)	0.79[d]
Hip dysplasia	6 (8)	7 (7)	1% (-7 to 9)	0.86[d]
Acute femoral neck fractures	1 (1)	3 (3)	-2% (-6 to 2)	0.45[d]
Other[b]	9 (12)	9 (9)	3% (-7 to 12)	0.57[d]
Surg. approach				
Anterior (Smith-Petersen)	9 (12)	12 (12)	0% (-10 to 9)	0.93[d]
Anterolateral	11 (14)	18 (18)	-4% (-15 to 7)	0.49[d]
Lateral	37 (48)	50 (51)	-3% (-17 to 12)	0.75[d]
Posterior	19 (25)	17 (17)	8% (-5 to 20)	0.22[d]
Not reported	1 (1)	2 (2)	-1% (-4 to 30)	0.71[d]
Fixation method				
Cemented	21 (27)	22 (22)	5% (-8 to 18)	0.44[d]
Uncemented	19 (25)	36 (36)	-11% (-25 to 2)	0.10[d]
Hybrid	1 (1)	1 (1)	0% (-3 to 3)	0.86[d]
Reversed hybrid	36 (47)	40 (41)	6% (-9 to 21)	0.40[d]

[a] Age at time of surgery

[b] Other indications includes femoral neck fracture, Rheumatoid arthritis, Bechterew`s disease, Calve-Legg-Perthes disease, proximal epiphysiolysis of the femur and other indications

[c] Independent-samples t-test

[d] Chi-squared test

See Table 1 for abbreviations

Table 5 Comparison of patient characteristics by respondents and non-respondents in the control group, THAs revised for aseptic loosening. Values are counted (%) unless otherwise specified

Characteristic	Respondents *n*=429	Non – respondents *n*=427	Difference between groups (95% CI)	p
Mean age[a] (SD)	62.0 (7.4)	63.5 (8.5)	−1.5 (−2.6 to −0.4)[b]	0.01[c]
Female sex	247 (58)	282 (66)	−8% (−15 to −2)[c]	0.01[d]
ASA-score				
ASA 1	154 (36)	89 (21)	15% (11 to 26)[c]	0.00[d]
ASA 2	240 (56)	277 (65)	−9% (−16 to −3)[c]	0.01[d]
ASA 3+	29 (7)	56 (13)	−6% (−10 to −2)[c]	0.00[d]
Not reported	6 (1)	5 (1)	0% (−3 to 3)[c]	0.77[d]
Indication for surgery				
Osteoarthritis	348 (81)	331 (78)	3% (−2 to 9)[c]	0.19[d]
Hip dysplasia	44 (10)	39 (9)	1% (−3 to 5)[c]	0.58[d]
Acute femoral neck fractures	7 (2)	14 (3)	−1% (−4 to 1)[c]	0.12[d]
Other[b]	30 (7)	43 (10)	−3% (−7 to 1)[c]	0.11[d]
Surg. Approach				
Anterior (Smith-Petersen)	42 (10)	37 (9)	1% (−3 to 5)[c]	0.57[d]
Anterolateral	59 (14)	40 (9)	5% (1 to 9)[c]	0.05[d]
Lateral	195 (45)	201 (47)	−2% (−8 to 5)[c]	0.64[d]
Posterior	121 (28)	144 (34)	−6% (−12 to 1)[c]	0.08[d]
Not reported	12 (3)	5 (1)	2% (−1 to 3)[c]	0.09[d]
Fixation method				
Cemented	66 (15)	92 (21)	−6% (−11 to −1)[c]	0.02[d]
Uncemented	152 (35)	145 (34)	1% (−5 to 8)[c]	0.65[d]
Hybrid	13 (3)	3 (1)	2% (1 to 4)[c]	0.01[d]
Reversed hybrid	198 (46)	187 (44)	2% (−4 to 9)[c]	0.49[d]

[a] Age at time of surgery

[b] Other indications includes femoral neck fracture, Rheumatoid arthritis, Bechterew`s disease, Calve-Legg-Perthes disease, proximal epiphysiolysis of the femur and other indications

[c] Independent-samples t-test

[d] Chi-squared test

See Table 1 for abbreviations

Abbreviations

AIC	Akaike information criterion
ASA class	American Society of Anesthesiologists classification
BIC	Bayesian information criteria
CI	Confidence interval
DAA	Direct anterior approach
EQ-5D-5L	Five-level-Euro-Qol five-dimension
EQ-VAS	EQ-5D visual analog scale
HOOS	Hip Disability and Osteoarthritis Outcome Score
HXLPE	Highly cross-linked polyethylene
IQR	Interquartile range
MAR	Missing at random
MCAR	Missing completely at random
MI	Multiple imputation
NAR	Norwegian Arthroplasty Register
OA	Osteoarthritis

OR	Odds ratio
PASS	Patient acceptable symptom state
PROM	Patient reported outcome measure
SD	Standard deviation
THA	Total hip arthroplasty
UCLA score	University of California, Los Angeles activity score

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-025-08865-9.

Supplementary Material 1.

Acknowledgements
The authors thank the orthopedic surgeons of Norway for their excellent reporting of joint replacement surgeries to the national register.

Authors' contributions
AÅ had the original idea for the study and supervised its progression. All authors participated in the conceptualization of the study. AMF prepared the data from the NAR. JN collected the patient-reported outcome measures, performed the data analysis, and wrote the original draft of the manuscript. All authors interpreted the results and reviewed and edited the manuscript.

Funding
Open access funding provided by Akershus University Hospital (AHUS) The project received a research grant from Ortomedic AS and Eckbos legate.

Data availability
The datasets used in this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the local data protection officer (project approval 2019/159) and the Regional Committee for Medical and Health Research Ethics (2019/44572/REK sør-øst A). Patients were included in the study by informed written consent. Additionally, data from the NAR is collected after informed written consent from the patients, which gives the NAR permission from the Norwegian Data Inspectorate to collect patient data (ref 24.1.2017: 16/01622–3/CDG).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Department of Orthopedic Surgery, Akershus University Hospital, Lørenskog, Norway. [2]Institute of Clinical Medicine, Campus Ahus, University of Oslo, Oslo, Norway. [3]Department of Orthopedic Surgery, Haukeland University Hospital, Bergen, Norway. [4]Department of Clinical Medicine (K1), University of Bergen, Bergen, Norway. [5]Department of Orthopedic Surgery, Haukeland University Hospital, Bergen, Norway. [6]Department of Orthopedic Surgery, Lovisenberg Diaconal Hospital, Oslo, Norway. [7]Oslo Sports Trauma Research Center, The Norwegian School of Sport Sciences, Oslo, Norway.

Received: 21 June 2024 Accepted: 6 June 2025
Published online: 04 July 2025

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Publisher's Note

Questionnaire

PHYSICAL ACTIVITY – RETROSPECTIVE UCLA ACTIVITY SCALE

What was your physical activity level AT YOUR BEST CONDITION after the primary surgery? The 10 categories of physical activity load your hip increasingly from level 1 to 10. Consider your physical activity level when you were IN YOUR BEST CONDITION after the primary surgery. Please mark only one option
○ 1. Wholly inactive: dependent on others, cannot leave residence
○ 2. Mostly inactive: restricted to minimal activities of daily living
○ 3. Sometimes participate in mild activities, such as walking, limited housework, and limited shopping
○ 4. Regularly participate in mild activities, such as walking, limited housework, and limited shopping
○ 5. Sometimes participate in moderate activities, such as swimming and unlimited housework or shopping
○ 6. Regularly participate in moderate activities, such as swimming and unlimited housework or shopping
○ 7. Regularly participate in active events, such as bicycling
○ 8. Regularly participate in very active events, such as hiking, bowling or golf
○ 9. Sometimes participate in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor, or backpacking
○ 10. Regularly participate in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor, or backpacking

HIP FUNCTIONING AND HEALTH RELATED QUALITY OF LIFE – RETROSPECTIVE HIP DISABILITY AND OSTEOARTHRITIS OUTCOME SCORE (HOOS)

Hip functionality AT YOUR BEST CONDITION after the primary surgery:
This survey asks for your view about your hip. This information will help us keep track of how you feel about your hip and how well you are able to do your usual activities. Answer every question by ticking the appropriate box, only one box for each question. If you are uncertain about how to answer a question, please give the best answer you can.

Symptoms
These questions should be answered thinking of your hip symptoms and difficulties when you were IN YOUR BEST CONDITION after the primary surgery

S1. Do you feel grinding, hear clicking or any other type of noise from your hip?
○ Never ○ Rarely ○ Sometimes ○ Often ○ Always

S2. Difficulties spreading legs wide apart?
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

S3. Difficulties to stride out when walking?
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

Stiffness
The following questions concern the amount of joint stiffness you have experienced when you were IN YOUR BEST CONDITION after the primary surgery. Stiffness is a sensation of restriction or slowness in the ease with which you move your hip joint.

S4. How severe is your hip joint stiffness after first wakening in the morning?
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

S5. How severe is your hip stiffness after sitting, lying or resting **later in the day?**
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

Pain
P1. How often is your hip painful?
○ Never ○ Monthly ○ Weekly ○ Daily ○ Always

What amount of hip pain did you experience when you were IN YOUR BEST CONDITION after the primary surgery during the following activities?

P2. Straightening your hip fully
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P3. Bending your hip fully
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P4. Walking on a flat surface
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P5. Going up or down stairs
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P6. At night while in bed
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P7. Sitting or lying
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P8. Standing upright
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P9. Walking on a hard surface (asphalt, concrete, etc.)
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

P10. Walking on an uneven surface
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you experienced due to your hip when you were IN YOUR BEST CONDITION after the primary surgery

A1. Descending stairs
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A2. Ascending stairs
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A3. Rising from sitting
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A4. Standing
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A5. Bending to floor/pick up an object
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A6. Walking on flat surface
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A7. Getting in/out of car
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A8. Going shopping
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A9. Putting on socks/stockings
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A10. Rising from bed
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A11. Taking off socks/stockings
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A12. Lying in bed (turning over, maintaining hip position)
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A13. Getting in/out of bath
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A14. Sitting
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A15 Getting on/off toilet
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

A17. Light domestic duties (cooking, dusting, etc)
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

Function, sports and recreational activities
The following questions concern your physical function. The questions should be answered thinking of what degree of difficulty you experienced due to your hip when you were IN YOUR BEST CONDITION after the primary surgery

SP1. Squatting
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

SP2. Running
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

SP3. Twisting/pivoting on your injured hip
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

SP4. Walking on uneven surface
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

Quality of life
Q1. How often are you aware of your hip problem?
○ Never ○ Monthly ○ Weekly ○ Daily ○ Always

Q2. Have you modified your life style to avoid potentially damaging activities to your hip?
○ Not at all ○ Mildly ○ Moderately ○Severly ○ Extremely

Q3. How much are you troubled with lack of confidence in your hip?
○ Not at all ○ Mildly ○ Moderately ○Severly ○ Extremely

Q4. In general, how much difficulty do you have with your hip?
○ None ○ Mild ○ Moderate ○ Severe ○ Extreme

HEALTH RELATED QUALITY OF LIFE – RETROSPECTIVE FIVE-LEVEL-EURO-QOL FIVE-DIMENSION QUESTIONNAIRE (EQ-5D-5L)

Health related quality of life AT YOUR BEST CONDITION after the primary surgery:
This survey asks for your view about your health. Under each heading, please tick the ONE box that best describes how your health was when you were IN YOUR BEST CONDITION after the primary surgery.

Mobility
- ○ I have no problems in walking about
- ○ I have slight problems in walking about
- ○ I have moderate problems in walking about
- ○ I have severe problems in walking about
- ○ I am unable to walk about

Self-care
- ○ I have no problems washing or dressing myself
- ○ I have slight problems washing or dressing myself
- ○ I have moderate problems washing or dressing myself
- ○ I have severe problems washing or dressing myself
- ○ I am unable to wash or dress myself

Usual activities (e.g. work, study, housework, family or leisure activities)
- ○ I have no problems doing my usual activities
- ○ I have slight problems doing my usual activities
- ○ I have moderate problems doing my usual activities
- ○ I have severe problems doing my usual activities
- ○ I am unable to do my usual activities

Pain / discomfort
- ○ I have no pain or discomfort
- ○ I have slight pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have severe pain or discomfort
- ○ I have extreme pain or discomfort

Anxiety / depression
- ○ I am not anxious or depressed
- ○ I am slightly anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am severely anxious or depressed
- ○ I am extremely anxious or depressed

We would like to know how good or bad your health was. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Mark an X on the scale to indicate how your health was when you were IN YOUR BEST CONDITION after the primary surgery.