A multidisciplinary intervention tailored to knee osteoarthritis patients at risk of chronic pain after total knee arthroplasty.

Turid Rognsvåg

Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
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UNIVERSITY OF BERGEN

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SCIENTIFIC ENVIRONMENT

When I began work on this thesis in 2018, I was employed at Haukeland University Hospital, Costal Hospital in Hagevik, where I served as the head of the physiotherapy department. The work commenced through collaboration with the MultiKnee research group at Lovisenberg Diaconal Hospital in Oslo, focusing on research concerning patients with knee osteoarthritis. The collaboration eventually expanded to include Martina Hansens Hospital in Bærum. I was admitted as a PhD candidate at the University of Bergen, Faculty of Medicine, Clinical Institute 1. My supervisors there had extensive experience in knee osteoarthritis treatment and research.

In the latest article, I also collaborated with the National Arthroplasty Registry at Haukeland University Hospital.

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I extend profound gratitude to the MultiKnee team, led by Maren Falch Lindberg, Anners Lerdal and Arild Aamodt, for orchestrating the entire study and welcoming me into their group. Their meticulous guidance throughout the PhD journey, along with their invaluable insights, has been instrumental. I am deeply thankful for their hospitality and the provision of accommodation during study visits at Lovisenberg Diaconal Hospital. I also appreciate the enriching discussions, encouragement, and support from my colleagues at "Villa Viten" at Lovisenberg during study stays there. My supervisors have been indispensable throughout the process.

First and foremost, I extend heartfelt thanks to my primary supervisor, Mona Badawy (MD, PhD), orthopaedic surgeon at Haukeland University Hospital, Coastal Hospital in Hagevik, for her unwavering commitment and encouragement throughout my PhD studies. She generously shared her expertise, inspired, and supported me when needed, demonstrating immense patience. I also want to thank my co-supervisors Maren Falch Lindberg (PhD) Senior Researcher at Lovisenberg Diaconal Hospital and Associate Professor at University of Oslo, Professor Ove Furnes (MD, PhD), orthopaedic surgeon at Helse Bergen, Norwegian Arthroplasty Register and Professor at University of Bergen, and Søren T Skou (PT, MSc, PhD) professor at the Department of Sports Science and Clinical Biomechanics at the University of Southern Denmark and The Research and Implementation Unit PROgrez, Region Zealand, Denmark, for their valuable contributions to my scientific development and insightful input into manuscripts. Many thanks also to all other co-authors who contributed to the three articles included in this dissertation.

Thanks to Kari Indrekvam, Chief Surgeon, and clinical Director of the Coastal Hospital in Hagevik and Associate Professor at University of Bergen, for facilitating my ability to conduct research alongside my role as head of the physiotherapy department at the hospital. I also want to express gratitude to my colleagues in the physiotherapy department for their encouragement and support, as well as their patience when research activities took precedence. Thanks to the rest of the staff at the hospital for their contributions that enabled us to include patients in this study.
I must also thank my family, my husband, my children, my in-laws, and grandchildren, who have encouraged and supported me throughout my studies. As this project comes to a close, I promise to be more available to you all.

SUMMARY IN ENGLISH

Background: The MultiKnee study is a randomized controlled trial (RCT) aiming to test the effectiveness of an intervention combining education, exercise therapy, and internet-based cognitive behavioral therapy (iCBT), either as an alternative to or in addition to knee arthroplasty surgery for knee osteoarthritis patients.

Aim: The aim of this study was to: 1) assess the digital health literacy (eHL) among patients who underwent total hip arthroplasty (THA) or total knee arthroplasty (TKA) and examine the relationship between eHL and health-related quality of life (HRQoL), 2) develop an internet-based cognitive behavioral therapy (iCBT) program tailored to patients with knee osteoarthritis (OA), and 3) test the feasibility of the MultiKnee intervention and trial.

Methods: The UK Medical Research Council's framework for developing and evaluating complex interventions was used to develop the iCBT program and test it on patients and physiotherapists. A cross-sectional study was conducted to assess eHL among TKA and THA patients and examine the relationship between eHL and HRQoL. A feasibility RCT was conducted to test the feasibility of a full-scale RCT.

Results: Norm data for eHL were described. Older patients with lower education had the lowest eHL. Patients with higher engagement with digital services and who are feeling safe and in control reported better HRQoL. An iCBT program tailored for OA patients was developed, along with a physiotherapy manual to guide physiotherapists in patient follow-up. The feasibility study indicated the need for changes in the inclusion criteria during the study to recruit enough patients for a full-scale RCT and further adaptation of the iCBT program before starting the RCT.

Conclusion: eHL norm data can be used to tailor digital health services for THA and TKA patients to ensure equal healthcare access. The iCBT program is tailored for OA and TKA and feasible to be tested in a full-scale RCT. The feasibility study showed that a full-scale RCT is feasible to evaluate the combined intervention's effectiveness, either as an alternative to or in addition to surgery.

SUMMARY IN NORWEGIAN

Bakgrunn: MultiKnee studien er en randomisert kontrollert studie (RCT) som har som mål å teste effekten av en intervensjon som kombinerer undervisning, treningsterapi og kognitiv adferdsterapi, når den gis i stedet for eller i tillegg til kneproteseoperasjon hos artrosepasienter.

Mål: Målet med denne studien var å: 1) kartlegge den digitale helsekompetansen hos pasienter operert med totalprotese i hofte eller kne og undersøke sammenhengen mellom digital helsekompetanse og helserelatert livskvalitet, 2) utvikle et internettbasert kognitivt adferdsterapi (iCBT) program tilpasset pasienter med artrose i kne, og 3) teste gjennomførbarheten av MultiKnee programmet og studien.

Metode: En tverrsnitts-studie ble brukt for å kartlegge digital helsekompetanse hos pasienter med hofte- eller kneprotese, og undersøke sammenhengen mellom digital helsekompetanse og helserelatert livskvalitet. UK Medical Research Counsil's rammeverk for utvikling og testing av komplekse intervensjoner ble brukt i utviklingen av iCBT programmet og testingen på pasienter og fysioterapeuter. En feasibility RCT ble utført for å teste gjennomførbarheten av en full- skala RCT.

Resultat: Eldre pasienter med lav utdanning, hadde lavest digital helsekompetanse. Pasienter med mer engasjement og kontroll rapporterte høyere helserelatert livskvalitet. Et iCBT program ble utviklet og tilpasset artrose pasienter i tillegg til en fysioterapimanual for å veilede fysioterapeutene i oppfølgingen av pasientene. Normdata for digital helsekompetanse ble beskrevet. Feasibility studien viste at det var nødvendig med noen endringer i inklusjonskriteriene underveis i studien for å kunne rekruttere nok pasienter til en full skala RCT, og at det var nødvendig å tilpasse iCBT programmet ytterligere før oppstart av RCT studien.

Konklusjon: Norm data for digital helsekompetanse kan brukes for å tilpasse digitale helsetjenester til hofte- og kneprotesepasienter for å gi et likt helsetilbud til alle. iCBT programmet er tilpasset artrosepasienter og pasienter med totalprotese i kne. Feasibility studien viste at en full skala RCT er mulig å gjennomføre for å teste effekten av den kombinerte intervensjonen når den gis enten i tillegg til eller i stedet for operasjon med totalprotese i kne.

LIST OF PUBLICATIONS

This thesis is based on the following papers:

I. Digital Health Literacy in Norwegian Patients Undergone Hip and Knee Arthroplasty Surgery – Normative data from a cross-sectional study. *Rognsvåg T, Nordmo IK, Bergvad IB, Fenstad AM, Furnes O, Lerdal A, Lindberg MF, Skou ST, Badawy M.* (in review)

II. Development of an internet-delivered cognitive behavioural therapy program for use in combination with exercise therapy and education by patients at increased risk of chronic pain following total knee arthroplasty. *Rognsvåg T, Lindberg MF, Lerdal A, Stubberud J, Furnes O, Holm I, Indrekvam K, Lau B, Rudsengen D, Skou ST, Badawy M. BMC Health Services Research 2021* BMC Health Serv Res. 2021;21(1):1151.

III. Exercise therapy, education, and cognitive behavioural therapy alone, or in combination with total knee arthroplasty, in patients with knee osteoarthritis: A randomized feasibility study. *Rognsvåg T, Bergvad IB, Furnes O, Indrekvam K, Lerdal A, Lindberg MF, Skou ST, Stubberud J, Badawy M. BMC Pilot and Feasibility studies 2024* Pilot and feasibility studies. 2024;10(1):43.

ABBREVIATIONS

CBT:	Cognitive Behavioural Therapy
CONSORT:	The Consolidated Standards of Reporting Trials
eHL	Digital Health Literacy
eHLQ:	Digital Health Literacy Questionnaire
EQ-5D-5L	EuroQual – 5 Dimensions – 5 Levels
ExE:	Exercise Therapy and Education
GUIDED:	Guidance to reporting intervention development.
HL:	Health Literacy
HRQoL:	Health-related Quality of Life
iCBT:	Internet-delivered Cognitive Behavioural Therapy
IQR:	Inter-Quartile Range
ISCED:	International standard Classification of Education
MI:	Motivational Interviewing
MRC:	Medical Research Council
NSAID:	Non-Steroidal Anti-Inflammatory Drugs
OA:	Osteoarthritis
OARSI:	Osteoarthritis Research Society International
PROM:	Patient Reported Outcome Measures
RCT:	Randomized Controlled Trial
ROM:	Range of Motion
SPSS:	Statistical Package for Social Science

SRH:	Self-Reported Health
TIDieR:	Template for Intervention Description and Replication
TKA:	Total Knee Arthroplasty
THA:	Total Hip Arthroplasty
VAS:	Visual Analog Scale

INTRODUCTION

A significant portion of my professional career has been dedicated to elective orthopaedic patients. There have been significant evolutions in this field from 1983, when I started my career as a physiotherapist, to the present day. Initially, very few patients underwent knee arthroplasty surgery. As implants, surgical techniques, and anaesthesia methods have advanced, the number of surgeries for hip and knee osteoarthritis has increased dramatically. The proportion of old and obese individuals are increasing, resulting in an increase in knee arthroplasty surgery, along with this the desire of a physically active life is prominent, resulting in younger and more active patients undergoing knee arthroplasty surgery (1). Moreover, I have registered a trend over the years that patients have higher expectations that the surgery will result in a pain-free knee and enabling them to return to their desired level of activity. This was also confirmed in a study by Mannion et al (2009) who found that patients were overly optimistic about the likelihood of being pain-free and of not being limited in usual activities (2). Most patients experience a favourable outcome, with reduced pain, improved function, and quality of life (3, 4). However, one in five patients still experiences pain one year after surgery (5). The decision to undergo surgery is made in collaboration between the surgeon and the patient in a shared decision-making process. It is challenging for the surgeon to provide a balanced patient information about the effect and complications of surgery for that specific patient. Some factors predicting chronic pain following surgery have been identified (6-8), but there is limited research on alternative treatments that may be effective for this patient group (9).

When the Costal Hospital in Hagevik was invited to participate in a research project investigating these issues, and I was asked to participate, I had no doubt that I wanted to be involved. My motivation to participate in the project stemmed from a belief that this research would aid clinicians in assessing who would benefit from surgery and who would benefit from other treatments. I also believed that physiotherapists, nurses, doctors, and other healthcare providers could benefit from this research when treating and advising patients with knee osteoarthritis. However, my primary motivation was

that the research would be beneficial for the patients, allowing more individuals to experience less pain, better function, and improved quality of life in the future.

The MultiKnee trial is a study planned as an extension of Maren Falch Lindberg's doctoral thesis, which examined factors influencing the outcomes of surgery for patients undergoing total knee replacement where she found that 22% of the patients had pain at the pre-operative level one year after surgery (6). The MultiKnee trial, aimed to investigate whether an interdisciplinary treatment approach combining education, exercise therapy and cognitive behavioural therapy (the MultiKnee program) (Figure 1) could be effective for patients at increased risk of prolonged pain after surgery. This treatment was to be tested by randomizing participants into three groups: 1) the MultiKnee program alone, 2) total knee arthroplasty followed by the MultiKnee program, and 3) a control group (surgery followed by standard physiotherapy follow-up). This treatment was inherently complex, with many interrelated factors. Therefore, due to the complexity of the study design and the intervention we chose to perform the study following the UK Medical Research Council's framework for developing and evaluating complex interventions (10). The framework describes the process in four phases: 1) the development phase, 2) the pilot or feasibility phase, 3) the evaluation phase, and 4) the implementation phase. The study was a collaboration between three hospitals in Norway with the highest volumes of knee arthroplasty surgeries (Lovisenberg Diaconal Hospital in Oslo, Martina Hansen’s Hospital in Bærum and The Costal Hospital in Hagevik, Haukeland University Hospital in Bergen)

Figure 1: Overview of the MultiKnee program. Abbreviations: OA=osteoarthritis, CBT=Cognitive Behavioural Therapy, AktivA=active with osteoarthritis, PT=physiotherapist

This thesis is comprised of three papers. Since this is an intervention that requires the use of digital tools, I assessed the digital health literacy in a representative sample of patients who had undergone total hip or knee arthroplasty surgery and examined the association between digital health literacy and health-related quality of life (Paper I). The next two papers are covering the first two phases of the UK Medical Research Council's framework: the development phase (Paper II) and the feasibility and piloting phase (Paper III), so my project has remained within the 6-year timeframe for a PhD project.

1 BACKGROUND

1.1 Osteoarthritis of the knee

Knee osteoarthritis is a chronic degenerative joint disorder and is a common cause of pain, impaired function, and reduced quality of life in adults and the elderly (11, 12).

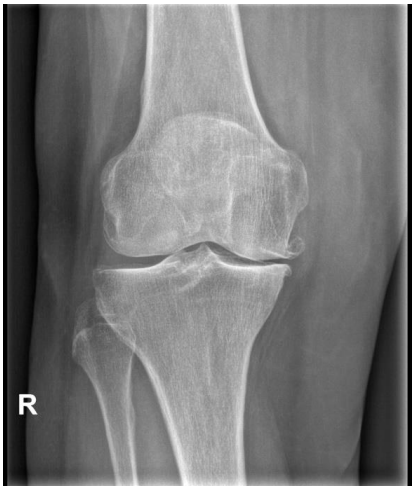


Figure 2 Plain X-ray of a knee with joint space narrowing and osteophytes, published with permission from the patient.

Globally 7.6 % of the population had osteoarthritis in 2020, an increase of 132.2 % since 1990, and the prevalence is projected to increase 74.9 % by 2050 (13). Data from the Framingham Osteoarthritis Study showed that the prevalence of knee osteoarthritis rises sharply with age, affecting nearly 33% of individuals aged 63 and older and women are more likely to develop the disease than men (14). Highest prevalence is found in those 80-89 years of age (15). As a result of demographic changes in the elderly and obese population, the number of people with osteoarthritis has increased in recent years, and this trend is expected to continue (16). The lifetime risk of symptomatic knee osteoarthritis was estimated to be 44.7 % in 2008, and the lifetime risk rose with increasing BMI (17). In the Nordic countries, the number increased by 43% between 1990 and 2015 (18).

Risk factors

Osteoarthritis is a condition that impacts the whole joint, arising from an imbalance between degenerative and regenerative processes. The exact trigger is unknown, most likely it is multifactorial (11). Several risk factors have been associated with the development of osteoarthritis. Age is a clear risk factor (19). Both prevalence and incidence increase with advancing age (14, 20, 21). Some studies indicate that the incidence peaks around 70-80 years of age, then levels off or decreases; this effect is particularly evident in women (22). Loeser et al. (2016) describe age-related changes and osteoarthritic changes as two distinct phenomena, where age-related changes can promote the development of osteoarthritis (23).

Obesity is another well-established risk factor for knee osteoarthritis. A systematic review and meta-analysis by Silverwood et al. (2015) demonstrated a strong association between increased body mass index (BMI) and the development of knee osteoarthritis (19). All 22 studies included in the meta-analysis were consistent in reporting being overweight or obese as a risk factor for the development of osteoarthritis of the knee. High BMI and high weight gain is also a strong risk factor for receiving a total knee arthroplasty (24)

Previous studies have shown increased risk of knee osteoarthritis with prior injury and/or surgery (19, 25). Various single- and multi-structure knee injuries increase the odds of symptomatic osteoarthritis (26), and increase the risk of having a total knee arthroplasty (25, 27).

Muscle weakness is found in knee osteoarthritis patients in muscles around the knee and hip. It has been unclear if this weakness increases the risk of developing knee osteoarthritis or if it is a consequence of the disease. A recent systematic review by Øiestad et al (2022) concluded that knee extensor muscle weakness is a risk factor for the development of knee osteoarthritis (28). Another study found that knee extensor weakness may be a more important risk factor for radiographic knee OA progression in women with neutral alignment of the knee (29). Other risk factors include female gender, occupational factors, and genetic predisposition (19, 30, 31).

Symptoms

Symptoms of osteoarthritis vary, and so does the course of the disease (32). The most common early manifestation is experiencing pain during activity, like prolonged standing or walking, particularly when descending hills and stairs, often relived with rest (33). In severe osteoarthritis, there may be pain at night that can interfere with sleep (34). The knee may exhibit stiffness, especially in the morning and after prolonged periods of immobility (35). Some individuals may notice swelling and a sensation of warmth in the knee, particularly following physical activity (36). Osteoarthritis in the knee can also result in decreased range of motion (37), resulting in difficulties in performing daily activities like kneeling, descending stairs, and putting on socks and shoes. Crepitus in the knee is not uncommon (38), and some individuals may perceive instability and an experience that the knee is "giving way" in various situations, resulting in a feeling of apprehension and lack of confidence in knee demanding activities (39). Other symptoms may include muscle weakness (40) especially the quadriceps muscle, and tenderness (38), particularly along the joint space. Over time, the development of radiological findings such as bony osteophytes along the joint's edges, subchondral sclerosis, gradually increasing cartilage loss and bone-on-bone osteoarthritis leading to malalignment and instability in some cases (41).

Diagnosis

Knee osteoarthritis is diagnosed based on the patient's history and symptoms (persistent knee pain, morning stiffness and functional limitations) and a physical examination (crepitus, swelling, instability, malalignment, restricted or painful movement, joint tenderness, and bony enlargement) (38). Radiographic changes can confirm but is not needed to give the diagnosis (38). The most used classification system for deciding the degree of radiographic osteoarthritic changes in the joint, is the Kellgren and Lawrence system (41). This system grades the radiologic changes from Grade 0 = no changes to Grade 4 = severe changes (bone on bone). (Figure 3)

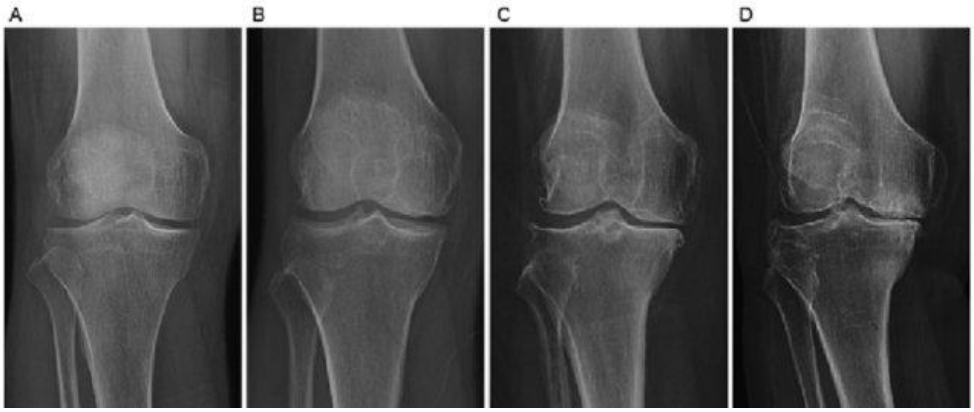


Figure 3 The Kellgren-Lawrence radiographic grading criteria. (A) Grade 1, doubtful narrowing of joint space and possible osteophytic lipping. (B) Grade 2, definite osteophytes, and possible narrowing of joint space. (C) Grade 3, moderate multiple osteophytes, de definite narrowing of joints space, some sclerosis and possible deformity of bone contour. (D) Grade 4, large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour.

Studies have found moderate associations between structural osteoarthritis found by traditional radiographs and the presence of pain (43), and a moderate association with MRI and pain (44). MRI are found to have a sensitivity below clinical and radiographic diagnosis and are not recommended in routine clinical diagnosis (44). Radiographs are not necessary to diagnose osteoarthritis and to start early treatment (45).

1.2 Treatment options for knee osteoarthritis.

At present, there is no cure for osteoarthritis, and available pharmacological interventions have limited efficacy (46). The non-surgical approach that has shown the greatest effect on pain, function, and quality of life is physical activity or exercise therapy. Physical activity is defined as "any bodily movement produced by skeletal muscles that results in energy expenditure" (47). Exercise is a subset of physical activity that is planned, structured, repetitive, and intended to improve or maintain physical fitness (47) while exercise therapy is defined as “A regimen or plan of

physical activities designed and prescribed for specific therapeutic goals. Its purpose is to restore normal musculoskeletal function or to reduce pain caused by diseases or injuries." (48).

Education, exercise therapy and weight loss (if needed) are recommended as core treatment for all individuals with knee osteoarthritis across several guidelines (49-54) (Figure 4). This information should include the importance of maintaining a healthy weight, and patients who are overweight or obese should receive assistance in weight reduction. Weight loss of 5-10% can improve pain, self-reported disability and quality of life significantly in adults with BMI above 30 kgm^2 (55). Lifestyle change programs may be challenging to adhere to over time, necessitating participating in lifestyle modification programs. Weight loss is most effective when combined with exercise therapy. If land-based exercise is too pain provocative in these patients, water-based exercise may be a good alternative (56).

Knee osteoarthritis is no longer perceived as a purely mechanical diagnosis that must be addressed through surgery, but rather as a disease that affects the whole person and therefore requires a biopsychosocial approach from the initial assessment (57). This is also emphasized in EULAR's updated guidelines from 2023 (51).

All patients should be offered an exercise therapy program that is individually tailored with appropriate dosage and progression adjusted to the individual. The exercise program should be combined with education that enhances the patient's understanding of what osteoarthritis is and what to do to manage the disease (58). Such an educational program should include information on what osteoarthritis is, risk factors, the importance of physical activity and exercise, dietary guidance, and training in coping strategies (59).

Some patients may need advice on walking aids or other devices, like stabilizing knee orthosis in case of malalignment, to be physically active. If necessary, home and workplace modifications may be appropriate to maintain physical function levels and avoid work absence. If patients experience significant pain, the use of analgesic medications may be necessary to initiate exercise and physical activity. Topical NSAIDs are recommended, oral NSAIDs can be used for patients without

comorbidities or in combination with a proton pump inhibitor (52). Intra-articular corticosteroids may have a short-term pain-relieving effect (50).

For patients with widespread pain and/or depression, a multidisciplinary treatment program such as CBT with an exercise component is recommended (52). O'Moore et al. (2018) found that a 10-week iCBT program for patients with osteoarthritis and depression reduced depression symptoms at 1 week and 3 months after the end of the intervention. Additionally, they also experienced reductions in pain, stiffness, and physical function (60).

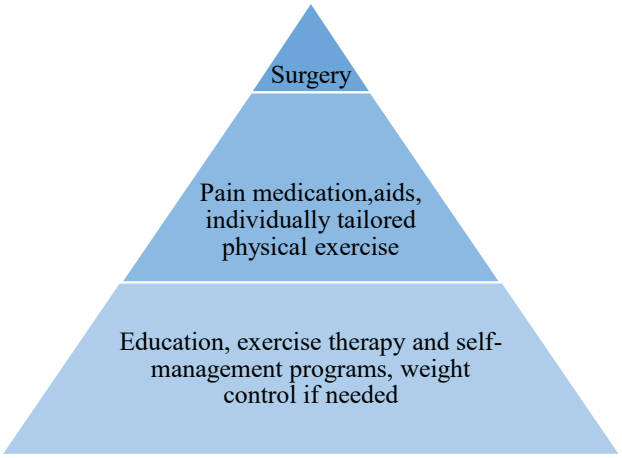


Figure 4 Treatment pyramid based on the OARSI guidelines (52)

1.2.1 Exercise therapy and education

AktivA

AktivA is an evidence and guideline-based implementation program initiated to improve non-surgical treatment for patients with hip and knee osteoarthritis in Norway (61). Similar models have been used in Sweden (BOA) since 2008 (62) and in Denmark (GLA:D) since 2013(63). The programs have shown to be well suited for clinical practise and results show significant improvements concerning pain, physical function, and health-related quality of life in patients with hip and/or knee osteoarthritis (64). In addition, the neuromuscular exercise program used in GLA:D

has previously shown to be effective for patients with moderate to severe osteoarthritis eligible for TKA and after undergoing TKA (3). The program consists of three parts: A one-day educational course for physiotherapists, a treatment program including an educational and physical exercise part and an electronic patient registry (primarily based on patient-reported questionnaires).

1.2.2 Surgery for knee osteoarthritis

For patients with severe radiographic osteoarthritis who have no longer benefit from non-operative treatment, surgery may be offered. There is now an emphasis on involving patients in shared decision-making regarding whether, and if so, when, to undergo knee surgery (65). For patients to participate in this decision, it is crucial that they are well-informed about the benefits and risks of the surgery, potential complications that may arise, and realistic expectations regarding postoperative functional levels. It is also important that they are informed about alternative options to surgery. Although there are evidence-based guidelines for the treatment of osteoarthritis, the recommendations are poorly implemented. For example, in the study by Hagen et al. in 2016, only 40% of the patients reported being referred to or recommended exercise, and 35% reported being offered education and self-management, while 60% reported being referred to an orthopaedic surgeon (66). Brun et al. described in their 2023 study that 23% of the patients referred to an orthopaedic surgeon had received treatment in accordance with the recommendations in various guidelines (64). Ultimately, once patients have received sufficient information, they are the ones who weigh the benefits against the risks and decide whether the surgery should proceed or not.

Knee arthroplasty (unicompartmental or total) is an effective intervention for most individuals, resulting in reduced pain and increased function and quality of life (3, 65) (Figure 5). The procedure involves replacing degenerated joint surfaces in one, two or three compartments, with artificial surfaces made of plastic and metal. There has been significant advancement in prostheses implants since the first duocondylar prothesis was introduced in the 1970s (67), leading to improved durability and outcomes (65). This advancement may have influenced the indication for surgery. For example, it is

now more common than before to perform knee replacements on younger patients (68).

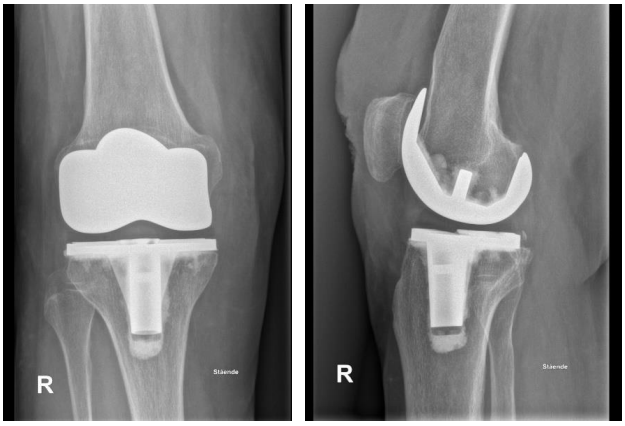


Figure 5 Knee with total knee arthroplasty, front and lateral view. With permission from the patient.

According to the OECD Health Statistics 2021, an average of 137 total knee arthroplasties were performed per 100,000 inhabitants in OECD countries in 2019, with significant variations between countries (69). In Norway, approximately 8,500 total knee arthroplasties are performed annually, with nearly 600 reoperations (7.0%) (1). The number of primary surgeries is increasing, with more than a doubling of total knee arthroplasties in Norway from 2005 to 2022 (1). The lifetime risk of having a total knee arthroplasty vary between countries, with females demonstrating the greatest risk, and a significant rise in lifetime risk over time (70). Most patients undergoing surgery have a diagnosis of osteoarthritis. Patients of all ages undergo total knee arthroplasty surgery, but the average age at the time of surgery in Norway in 2022 was 68.9 years for women and 68.5 years for men. Women constituted 61% of the patients (1).

1.2.3 Perioperative management

Patient education plays a pivotal role in delivering high-quality patient care. Effective preoperative education is essential to manage and align patient expectations regarding their upcoming surgery. It is common for some patients to harbour unrealistic

expectations regarding their postoperative activity levels, making it imperative to address these concerns before the surgery, while patient's satisfaction with surgery is largely determined by patients' expectations (71, 72). Offering guidance on necessary preparations and postoperative planning empowers patients to better navigate their recovery journey. Well-informed patients are more likely to achieve earlier discharge from the hospital (73). Moreover, emphasizing the importance of early mobilization and maintaining physical activity post-surgery is crucial for long-term health outcomes. Preoperative education is particularly beneficial for patients experiencing anxiety, depression, or those harbouring unrealistic expectations (74).

Furthermore, preoperative exercise therapy has been linked to improved postoperative functional outcomes, reduced pain, enhanced mobility, muscle strength, and overall quality of life, as measured from 6 weeks to 3 months post-surgery (75). Patients who underwent preoperative training required less assistance postoperatively and experienced shorter hospital stays (75). However, it is important to note that no significant long-term effects beyond the 3-month mark have been documented (76). Preoperative mobility limitations have been associated with poorer postoperative mobility, highlighting the potential benefits of preoperative mobility training in improving post-surgery outcomes (75).

Following total knee arthroplasty surgery, patients require close monitoring in the immediate postoperative period to address pain management, wound care, and early mobilization. Multimodal analgesia, including opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), and regional anaesthesia techniques, helps alleviate pain while minimizing opioid-related side effects (77). Proper wound care is essential to prevent surgical site complications. Early mobilization with physical therapy guidance aims to prevent postoperative circulatory and respiratory complications such as pneumonia and deep vein thrombosis (DVT) and facilitates functional recovery. Effective pain management is crucial for facilitating rehabilitation and optimizing patient satisfaction following total knee arthroplasty surgery.

There is a consensus that postoperative exercise following total knee replacement surgery is crucial for achieving optimal function and quality of life post-surgery (75).

Most patients undergo physiotherapy both during their hospital stay and after discharge. However, there remains considerable uncertainty regarding the most effective type of exercise, as well as its timing, intensity, and duration (78, 79).

Oatis et al. (2019) examined the content of "usual care" across 112 protocols from thirty different sites in Massachusetts. They found significant variation in the content of exercise, including differences in the type of exercises (open kinetic chain, closed kinetic chain, passive movements), dosage, and progression. Weight-bearing exercises with gradual and frequent progression were associated with favourable functional outcomes but were underrepresented in their study.

Jette et al. (2020) developed guidelines for treating knee replacement patients based on a systematic review of studies on postoperative treatment. These guidelines recommend land-based, high-intensity strength training within 7 days of surgery, individually tailored to patient's tolerance, muscle function, movement quality, and balance. High-intensity exercise is deemed as safe as low-intensity exercise (80). Cryotherapy for early postoperative pain management may offer better pain control (75). Reduced range of motion (ROM) leads to poorer function and can be a postoperative issue (81, 82). Postoperative exercises should include ROM exercises encompassing passive, guided active, and active movements. Functional training such as various forms of balance exercises, gait training, and movement symmetry improves walking function and self-reported function (75).

1.2.4 Surgical complications

After total knee arthroplasty surgery, various complications can arise.

Infection is a serious complication after total arthroplasty surgery. Symptoms include increasing pain, swelling, redness, and fever. Infections may require antibiotic treatment and, in some cases, surgical revision with debridement and exchange/removal of the infected prosthesis. Periprosthetic joint infection is the leading cause of early revision in knee arthroplasty (1, 65, 83).

Deep vein thrombosis (DVT) is a well-known complication after surgery in lower extremities. Blood clots can form in the deep veins of the legs and can potentially

dislodge and lead to pulmonary embolism, which is a life-threatening condition. With proper prophylaxis this complication is minimized to approximately 1-4 % within 90 days of surgery in patients undergoing total knee arthroplasty. (84, 85).

Some patients may experience persistent stiffness with reduced range of motion after surgery. This may require closed manipulation under anaesthesia, intensive physical therapy, and prolonged rehabilitation (86).

Damage to nerves and blood vessels surrounding the knee can occur during surgery, leading to numbness, tingling, weakness in the leg or foot, or circulatory complications.

The polyethylene may wear over time and macrophages will try to digest the polyethylene particles leading to cytokine increase and activation of osteoclasts that increase bone loss which can result in loose prostheses over time, which may require revision surgery to secure or replace the prosthesis (83, 87). Malalignment and poor cementation technique my also lead to loosening of the prostheses and need of revisions surgery.

As much as 20% of knee arthroplasty patients may experience persistent pain after surgery, although this pain may decrease as the rehabilitation process progresses (88, 89). Revision surgery is not recommended based on pain alone, but only if the cause of the pain is known.

It is important to be aware of these potential complications and to closely follow up with healthcare professionals to minimize the risk and ensure successful rehabilitation after total knee arthroplasty surgery.

To monitor the outcomes of joint arthroplasty surgeries, various countries have established national joint registries (1, 90). The purpose of these registries is to ensure that patients receive the best possible care by improving the quality and effectiveness of the treatments offered. Initially, the primary goal was to measure the survival of the implant, with prosthetic revision being the main endpoint. In recent years, many of these registries have also started collecting patient-reported outcome measures (PROMs) to assess patients' perceived pain, function, and quality of life (91). Data

from these joint registries play a crucial role in enhancing patient care and advancing surgical practices.

Price et al (2018) stated that national joint registries reported a revision rate of 3-5 % at 10 years (65). The most common causes for revision were, in order of frequency: implant loosening, infection, pain and instability. The leading cause of early revision was periprosthetic joint infection. In a Norwegian registry study, they found an improvement in survival of the protheses from the period 1994-2004 to the period 2005-2015. Higher risk of revision was found for male sex and age younger than 65 years in the last period (92). In 2022, instability was the most frequent reason for revision in Norway (93).

1.3 Long-lasting pain and reduced function after total knee arthroplasty

Although most patients experience pain reduction and increased function following TKA surgery, studies have shown that 15-35% experience pain and functional problems one-year post-surgery (5, 6). There may be many reasons for persistent pain and reduced function after TKA surgery. Peri-operatively, technical issues during surgery may lead to malalignment, instability, reduced mobility, nerve damage, or peri-prosthetic fractures (92), which may result in poor short- and long-term outcomes and sometimes revision surgery. Postoperative complications such as infection (92, 94), deep vein thrombosis (DVT) , arthrofibrosis (95) and loosening of the prosthesis may also cause pain and decreased function. Also, patient-related factors may contribute to dissatisfaction with the outcome. Patients with high expectations for pain relief and functional recovery may be disappointed (96). Various psychological challenges have also been shown to negatively impact prognosis (97).

To ensure better outcomes for more patients, it is essential to identify preoperative predictors of poor surgical outcomes, allowing for risk reduction or alternative treatments to be considered.

1.3.1 Predictors for long-lasting pain after TKA

Studies have identified multiple preoperative factors, sociodemographic, clinical, psychological, and cognitive factors, associated with postoperative chronic pain after

knee or hip replacement (>6 months after surgery) (6, 8, 98-101). Severe preoperative pain, multiple painful sites and severe anxiety symptoms were associated with increased likelihood of moderate to severe pain five years after total knee arthroplasty surgery (100).

High presurgical BMI was correlated with worse physical function 12 months after surgery, and good presurgical function and high osteoarthritis severity were correlated with better physical function 12 months after surgery (8).

Patients who experienced pain with walking 1 year after TKA surgery had higher preoperative pain, fatigue and depression scores and poorer perception of illness compared to those with no pain (6).

Combined high preoperative pain and low grade of radiological osteoarthritis are associated with higher pain intensity 12 months and 5 years post-surgery (8, 100, 102). This group may have a more complex cause of pain or other reasons for their knee pain such as hip OA, spinal stenosis og non-specific pain such as fibromyalgia.

In summary, not improving from TKA may be due to a complex combination of reasons. Patients identified with the above-mentioned risk factors for not improving, may need a more individualized treatment using a more comprehensive treatment approach based on the biopsychosocial model.

1.4 The Biopsychosocial model

The biopsychosocial model represents a comprehensive framework for understanding health and illness that considers biological, psychological, and social factors (103). Developed in reaction to the limitations of the traditional biomedical model, which focused solely on biological mechanisms of disease, the biopsychosocial model acknowledges the intricate interplay between biological, psychological, and social factors in shaping health outcomes (104).

In the context of knee osteoarthritis, the biological aspect of the model examines factors such as genetics, aging, previous injuries, malalignment, and structural changes

in the knee that may lead to osteoarthritis. This may include issues such as bone marrow lesions and synovitis (11).

The psychological aspect of the model focuses on how the patient's thoughts, feelings, and behaviour can affect their experience of pain and their ability to cope with the disease. This may include issues such as stress, anxiety, depression, and coping abilities (105).

The social aspect of the model looks at how factors such as the patient's social support systems, economic circumstances, education, social class, and cultural background can affect their access to treatment, adherence to treatment, and overall health outcomes (106, 107).

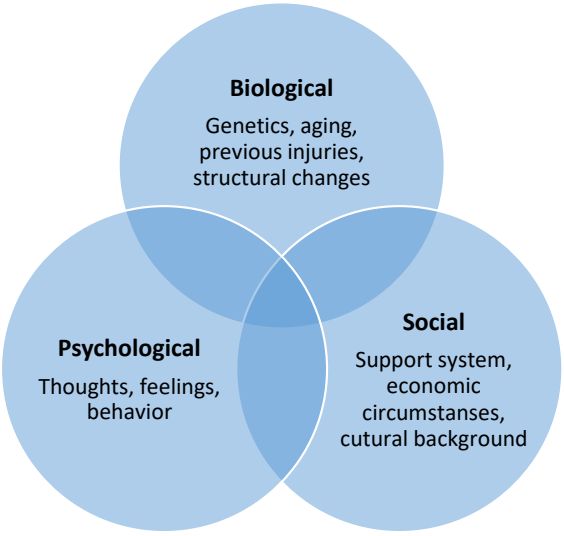


Figure 6 The Bio-Psycho-Social model. Based on Engel's biopsychosocial model and adjusted to knee osteoarthritis patients (103).

The biopsychosocial model has profound implications for healthcare delivery, emphasizing the importance of patient-centred care, interdisciplinary collaboration, and holistic interventions (108). By adopting a biopsychosocial perspective, healthcare professionals can provide a more holistic approach to treating knee osteoarthritis. This may include medications to alleviate pain and inflammation, physical therapy to strengthen the muscles around the knee and improve mobility, as well as psychological

support and social support to help the patient cope with the disease and improve their quality of life.

1.5 Cognitive Behavioural Therapy

Cognitive behavioural therapy has emerged as a promising approach in managing pain, also in knee osteoarthritis patients (60, 109). By targeting maladaptive thinking patterns and behaviours associated with pain, cognitive behavioural therapy aims to enhance participation in physical activities and improve overall functional abilities.

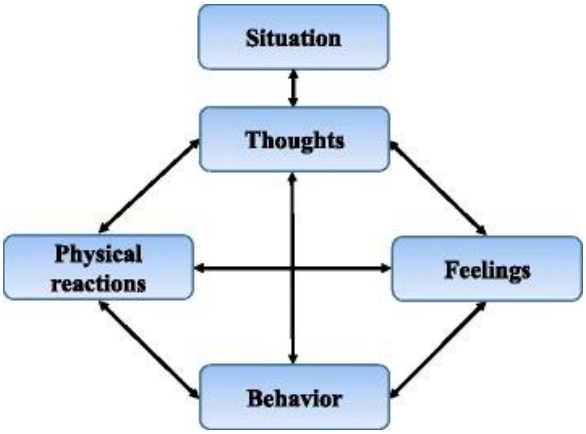


Figure 7 The cognitive triangle – the link between thoughts, feelings, physical reactions, and behaviour. Printed with permission (110).

Cognitive behavioural therapy interventions, such as those developed by Turk et al.(111), systematically address psychological factors that influence pain perception and disability. These factors include catastrophic thinking, fear-avoidance behaviours, low self-efficacy, feelings of helplessness, perceived lack of control, and passive pain coping strategies. Notably, catastrophic thinking and fear related to pain exhibit strong associations with pain intensity and disability among knee osteoarthritis patients (112). Cognitive behavioural therapy represents a promising avenue for enhancing pain management in knee osteoarthritis patients. By addressing psychological factors that contribute to pain intensity and disability, cognitive behavioural therapy can complement traditional physiotherapy interventions and improve overall outcomes for patients undergoing total knee arthroplasty surgery.

1.6 Complex interventions

In contemporary healthcare, the development and evaluation of complex interventions pose significant challenges. While complex interventions, defined as interventions with multiple interacting components (113), hold promise for addressing multifaceted health issues, their efficacy and successful implementation often hinge upon methodological rigor (10). However, a pervasive problem persists within research communities, where substantial resources are expended on studies that yield limited translational impact (114). This phenomenon underscores the pressing need for comprehensive frameworks to guide the development, evaluation, and implementation of complex interventions.

Complex interventions encompass a spectrum of interventions characterized by multiple interacting components (10). Various factors contribute to their complexity:

1. Properties of the intervention itself such as number of intervention components.

These refer to the number of components in the intervention that influence each other. For example, in cognitive behavioural therapy a diversity of techniques is used to identify and modify unfavourable thinking patterns and behaviours including cognitive restructuring, exposure therapy, and relaxation techniques among others (105).

2. Characteristics of those delivering and receiving the intervention.

This encompasses the various ways the intervention is delivered and received. Individual differences such as personality, experience, and expertise can affect how the intervention is delivered. In some cases, special training may be required for those delivering the intervention. There can also be significant individual differences among those receiving the intervention, such as varying levels of competence, motivation, and physical, psychological, and social conditions, which can influence how the intervention is received.

3. Organizational factors.

The way the intervention is organized also impacts its complexity. If the intervention involves multiple levels of healthcare service, it can affect the outcome of the intervention.

4. Outcome variability.

For interventions containing multiple interacting components, it may be necessary to select several outcome variables, and choosing a primary outcome variable can be challenging.

5. Degree of flexibility in intervention delivery.

This refers to the extent to which those delivering the intervention are free to adapt it to the patient's needs, their own preferences, and environmental factors.

Additionally, Brady et al. (2011) emphasized the importance of considering the context in which the intervention is provided (115). No interventions are delivered in isolation from its surroundings. The interaction between the intervention and its environment must be evaluated. The availability of services, facilities, equipment, and expertise, significantly impacts the outcome of the intervention, and is particularly important to consider when implementing research to clinical practice.

As such, developing and testing complex interventions necessitates methodological innovation and interdisciplinary collaboration.

1.6.1 Medical Research Council's framework

The UK Medical Research Council's (MRC) framework provides a foundational structure for the development and evaluation of complex interventions (10). Initially conceived as a linear process (113), the framework has since evolved to acknowledge the iterative nature of intervention development (10). The framework delineates key phases, including development, feasibility or pilot testing, evaluation, and implementation, with an emphasis on stakeholder engagement and program theory refinement (Figure 1). Thomas et al (2010) used this framework in the development and testing of an intervention for patients with Multiple Sclerosis (116). Their work

served as a guide in our effort to develop and test an intervention for patients with knee osteoarthritis.

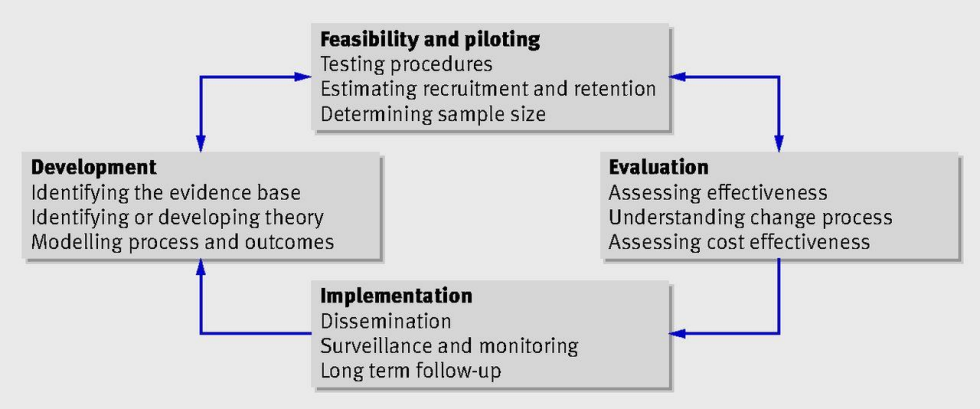


Figure 8 UK Medical Research council's framework (10) for developing and evaluating complex interventions. (Reprinted with permission BMJ)

Since the start of this study, Skiverton et al. (2021) have released an updated version of the framework, which is more detailed and includes some additional elements (117).

1.6.1.1 Development Phase

During the development phase, researchers focus on either creating new interventions or adapting existing ones to novel contexts or patient populations. Central to this phase is the articulation of a program theory - a conceptual framework elucidating how the intervention is expected to achieve its intended outcomes under specific conditions (10). Engaging stakeholders, including patients, clinicians, and developers, facilitates consensus-building and ensures the relevance and feasibility of the intervention.

1.6.1.2 Feasibility and Piloting Phase

In the feasibility or piloting phase, researchers evaluate the feasibility and acceptability of the intervention among the target population. This phase also entails refining the evaluation design to align with research objectives and methodological constraints. Iterative feedback loops enable researchers to iteratively refine the intervention and assessment protocols, ensuring methodological robustness and stakeholder satisfaction.

1.6.1.3 Evaluation Phase

The evaluation phase involves assessing the intervention's effectiveness using rigorous research designs tailored to the research question. Researchers consider contextual factors, stakeholder input, and program theory to inform outcome measures and data analysis strategies. By integrating quantitative and qualitative methods, researchers gain comprehensive insights into intervention impact and implementation challenges.

1.6.1.4 Implementation Phase

In the implementation phase, researchers develop strategies to facilitate the integration of successful interventions into routine practice. This involves addressing organizational barriers, training stakeholders, and fostering a culture of innovation and continuous improvement. Economic evaluations help elucidate the cost-effectiveness and sustainability of interventions, informing resource allocation decisions.

Recent advancements in intervention development, such as O'Cathain's guidance on complex intervention development, underscore the ongoing evolution of methodological approaches (118). Moreover, updates to the MRC framework highlight the importance of contextual considerations, stakeholder engagement, and program theory refinement throughout the intervention development and evaluation process (117). Moving forward, interdisciplinary collaboration, methodological innovation, and stakeholder involvement will be critical for advancing complex intervention research and improving healthcare outcomes.

1.7 Digital health literacy

Digital health literacy is essential for addressing health issues across populations. Defined by Norman and Skinner (2006) (119) as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem," digital health literacy holds particular significance for patients with knee osteoarthritis. These patients require reliable and relevant information about their condition, encompassing symptoms, treatment options, self-management strategies, and lifestyle modifications.

Access to accurate health information positively correlates with improved health outcomes and quality of life (120). Digital health literacy empowers individuals with knee osteoarthritis to effectively navigate online resources, distinguish credible sources from misinformation, and make informed decisions regarding their health. Moreover, digital tools offer avenues for accessing information about knee osteoarthritis symptoms and management strategies, engaging in virtual consultations with healthcare providers, and participating in rehabilitation programs.

Digital health interventions, such as mobile apps, wearable devices, and online platforms, can significantly support knee osteoarthritis patients in adopting healthy behaviours, adhering to treatment plans, and effectively managing their condition. Empowered by digital health literacy, patients understand how to utilize these tools, interpret generated data, and seamlessly integrate them into their daily routines for enhanced self-management.

In the management of knee osteoarthritis, informed decision-making is paramount, as treatment options may vary based on individual preferences, goals, and health status. Digital health literacy enables patients to participate in shared decision-making processes with their healthcare providers, comprehend the risks and benefits of different interventions, and actively contribute to the development of personalized treatment plans aligned with their needs and preferences.

Overall, digital health literacy plays a pivotal role in empowering knee osteoarthritis patients to take charge of their health, make informed decisions, and effectively manage their condition within an increasingly digital healthcare landscape. However, studies indicate that the level of digital health literacy varies and is associated with factors such as gender, age, and education level (120). This discrepancy highlights the unequal opportunity to utilize digital tools among patients, potentially exacerbating disparities within the healthcare system. Thus, it is imperative that digital tools are developed with care and tailored to accommodate varying levels of digital health literacy.

2 REVIEW OF THE LITERATURE

2.1 Literature searches and search strategy

Prognostic factors for persistent pain and reduced function following total knee arthroplasty indicate that patients with these factors need a more comprehensive approach to manage their condition, following the bio-psycho-social model of pain management.

A literature search was performed in PubMed with assistance of a librarian to get an overview of the literature assessing effectiveness of a combined intervention of psychological therapies and exercise therapy, and digital health literacy in total hip and knee arthroplasty patients. It may be a limitation that we have only searched in one database. Although PubMed is a large database, it is possible that we would have found more relevant literature if we had searched in multiple databases. The search elements and search words are presented in Table 1 and 2. We searched for literature published through 2017 when we planned this study and supplemented the search from 2018 until 10.06.2024.

Table 1 Search strategy for psychological interventions for knee osteoarthritis patients and patients with total knee arthroplasty

Seach-element	Osteoarthritis/knee arthroplasty	Psychological intervention	Exercise therapy
Free text (title/abstract)	knee arthroplasty OR knee arthroplasties OR knee replacement OR knee osteoarthritides OR knee osteoarthritis OR osteoarthritis of the knee OR osteoarthritis of knee	psychology OR psychologist* OR Cognitive Behavioral Therapy OR Cognitive Behavioural Therapy OR Cognitive Therapy	Physiotherap* OR Physical Therap* OR exercise therap* OR
MeSH	("Osteoarthritis, Knee"[Mesh]) OR "Arthroplasty, Replacement, Knee"[Mesh]	("Psychology"[Mesh]) OR "Cognitive Behavioral Therapy"[Mesh]	("Exercise Therapy"[Mesh]) OR "Physical Therapy Modalities"[Mesh]

Table 2 Search strategy for digital health literacy in patient with hip or knee arthroplasty

Seach-element	Hip or knee arthroplasty	Digital health literacy
Free text (title/abstract)	knee arthroplasty OR knee arthroplasties OR knee replacement OR knee osteoarthritides OR knee osteoarthritis OR osteoarthritis of the knee OR osteoarthritis of knee OR hip arthroplasty OR hip arthroplasties OR hip replacement OR hip osteoarthritides OR hip osteoarthritis OR osteoarthritis of the hip OR osteoarthritis of hip	digital health literacy OR e-health literacy OR ehealth literacy OR electronic health literacy
MeSH	"Osteoarthritis, Knee"[Mesh] OR "Arthroplasty, Replacement, Knee"[Mesh] "Osteoarthritis, Hip"[Mesh] AND "Arthroplasty, Replacement, Hip"[Mesh]	

2.1 Cognitive behavioural therapy in knee osteoarthritis and total knee arthroplasty patients

Using our search strategy, we identified seven studies (121-127) that examined the effect of psychological interventions combined with exercise therapy for patients with knee osteoarthritis or those who had undergone knee arthroplasty surgery. One of the studies included patients with hip or knee arthroplasty (127), while the others focused on patients with knee osteoarthritis (121-126).

The results from the studies on patients with knee osteoarthritis were mixed. Two studies by Allen et al. (2016 and 2017) evaluated a patient-provider intervention, which included providing information to providers about treatment guidelines for knee osteoarthritis and monthly phone follow-ups with patients for one year (121, 122). The focus areas were physical activity, weight reduction, and cognitive pain management strategies. These studies showed little or no effect on the assessed outcomes. Similarly, Helminen et al. (2015) found no effect from a cognitive behavioural therapy group intervention led by a psychologist and a physiotherapist (125). In these three studies, the role of the physiotherapist was limited to advice on relevant exercises, and instruction in relaxation exercises (121, 122, 125).

Bennell et al. (2016 and 2017) examined the effect of comprehensive pain coping skills training combined with an individually tailored exercise program, followed up by a physiotherapist for 12 weeks (123, 124). In the first study, patients attended in person (123), while the second study was internet-based (124). Both studies involved physiotherapist follow-up. The first study showed that the combination of pain coping skills training and exercise therapy was more effective on physical function than each intervention alone. Although there was no difference in mean pain between the groups, more participants in the combined intervention group experienced clinically significant pain reduction. In the second study the digitally delivered program showed equal effectiveness as the in-person program.

These studies suggest that a combination of exercise therapy and cognitive behavioural therapy may be more effective for patients with knee osteoarthritis than each intervention alone. Physiotherapists can play a crucial role in motivating patients to complete both cognitive and exercise therapy and integrate cognitive skills into daily physical activity.

Only one study addressed a combined intervention for patients undergoing total knee arthroplasty (127). The intervention group received psychological support with four 30-minute meetings with a psychologist: one preoperative, two during the hospital stay, and one during the rehabilitation stay. Additionally, patients received standard physiotherapy during hospital and rehabilitation stays. The results showed reduced anxiety and depression after 45 days and 4 months, and improved function after 4 months, compared to the control group who received the same rehabilitation without psychological support.

In addition, a quasi-experimental study by Riddle et al. (2011) found that pain coping skills training resulted in significantly greater reductions in pain and catastrophic thinking compared to usual care two months after knee arthroplasty surgery (128).

These studies indicate that psychological interventions can reduce anxiety, depression, and catastrophic thinking in patients before and after surgery, potentially lowering barriers to participating in exercise therapy and daily physical activity, leading to better long-term physical function.

We could not find any cognitive behavioural therapy programs specifically tailored for patients with knee osteoarthritis or total knee arthroplasty. Therefore, the aim of this study was to develop an iCBT program in two versions: one tailored for patients with knee osteoarthritis and one for patients with total knee arthroplasty. A feasibility study was planned to examine the possibility of conducting an RCT to test the effectiveness of the program combined with an individually tailored exercise therapy program.

Table 3 List of studies investigating psycological interventions in combination with exercise therapy in patients with knee osteoarthritis or total knee arthroplasty.

Author(s) Year	Aim(s)	Sample N	Design	Follow-up time	Result(s)
Bennell et al 2017(124)	To evaluate the effectiveness of Internet-delivered, physiotherapist-prescribed home exercise and pain-coping skills training.	148 knee OA	RCT	3 months and 9 months	Intervention group reported significantly greater improvement in pain and function at 3 and 9 months than the control group
Allen et al 2017 (121)	To examine whether patient-based, provider-based, and patient-provider interventions improve osteoarthritis outcomes	537 hip or knee OA	A cluster randomized trial	12 months	No differences were seen in objective physical function or depressive symptoms at 12 months in any of the intervention groups compared with usual care.
Tristaino et al 2016 (127)	Determining the effectiveness of psychological support in patients undergoing primary total hip or knee arthroplasty	200 THA and TKA patients	A controlled cohort study	Discharge 45 days 4 months	There was a lower incidence of anxiety and depression and better mental well-being in the group of patients who received the psychological support
Bennell et al 2016 (123)	To investigate the effectiveness of a 12-week physical therapist-delivered combined pain coping skills training and exercise for knee osteoarthritis.	222 knee OA	RCT	12 weeks 32 weeks 52 weeks	No significant between-group differences for reductions in pain comparing PCST/exercise versus exercise and PCST/exercise versus PCST. Significantly greater improvements in function were found for PCST/exercise versus exercise and PCST/exercise versus PCST
Allen et al 2016 (122)	To examine the effectiveness of a combined patient and provider intervention for improving osteoarthritis outcomes.	300 hip or knee OA	RCT	12 months	The combined patient and provider intervention resulted in modest improvement in self-reported physical function in patients with hip and knee osteoarthritis
Helminen et al 2015 (125)	To assess the effectiveness of a six-week cognitive-behavioral	111 knee OA	RCT	3 months 12 months	Results showed no significant differences between the intervention and control group for any measures of pain or function.

	group intervention in patients with knee osteoarthritis pain				
Keefe et al 2004 (125)	Test the effects of spouse-assisted pain coping skills training and exercise training in patients having persistent osteoarthritic knee pain	72 knee OA	RCT		An intervention that combines spouse-assisted coping skills training and exercise training can improve physical fitness, strength, pain coping, and self-efficacy in patients suffering from pain due to osteoarthritis
Studies published from 2018, the onset of this thesis.					
Pitsillides et al 2021 (129)	To identify the effect of combining exercise and CBT when delivered by a physical therapist in knee OA pain	6 studies	Systematic review and meta-analysis		Combining exercise and CBT seems to be an effective method to reduce knee OA pain, although it is based on a small number of studies
Karp et al 2019 (130)	Evaluate the effect of cognitive behavioral therapy and physical therapy in knee osteoarthritis with subsyndromal depressive symptoms	99 knee OA	RCT	12 months	The response rate for physical therapy was higher than for CBT in the first stage. Non-responders had a higher response rate if they increased the dose of the same intervention rather than switching to another intervention.
Mecklenburg et al 2018 (131)	Assess the efficacy of a digital care program for chronic knee pain. In knee OA patients	162 knee OA	RCT	12 weeks 6 months	The digital care program group had a significantly greater reduction in KOOS Pain compared to the control group at the end of the program

2.2 Digital health literacy in total hip and knee arthroplasty patients

Digital solutions can save time and resources for both patients and providers. Thus, we wanted to develop a digital cognitive behavioural program tailored to patients with osteoarthritis or total knee arthroplasty, but there are uncertainties about how this technology can be applied to all patients.

In the study by Bennell et al. (2017), the intervention was delivered online and had similar results as the in-person study (124). We searched for literature following the search strategy in table 2. We found no studies investigating the digital health literacy of patients with hip or knee arthroplasty, which became the goal of the first study in this thesis.

3 AIMS OF THE PHD STUDY

3.1 The overall objective

The overall aim of this study was to develop and test the feasibility of a digital cognitive behavioural therapy program that could be combined with exercise therapy to provide a comprehensive treatment tailored to patients at increased risk of poor outcomes after total knee arthroplasty. Norm data on digital health literacy was described, the program was tailored to the patient group, and the suitability of the digital program was assessed.

Specific objective

I. To describe digital health literacy levels in multiple domains by age and education among patients who have undergone hip or knee arthroplasty and examine the association between digital health literacy and health related QoL controlling for selected sociodemographic factors.

II. To develop an iCBT program to be combined with an exercise therapy and education program for patients with knee OA at increased risk of chronic pain after TKA and thoroughly test and customize the program.

III. To investigate the feasibility of the intervention designed to improve outcomes for patients with knee OA and patients undergoing TKA at risk of poor outcomes after TKA and examine whether a three-armed RCT of such an intervention was feasible regarding 1) recruitment and retention rate, 2) compliance to the intervention and follow-up, 3) cross over and 4) adverse events.

4 MATERIAL AND METHODS

4.1 Study design and study population

This PhD study consists of three different sub-projects with various study designs and study populations. The overarching goal of the study was to develop and test the suitability of a treatment program tailored to patients with osteoarthritis who, based on patient characteristics, were at increased risk of a poor outcome following total knee arthroplasty surgery. Digital solutions are increasingly used in the treatment and follow-up of patients. To adapt this to the patients, the aim of paper I was to assess the digital health literacy of patients who had undergone total hip or knee arthroplasty surgery and examine the association between digital health literacy and health-related quality of life.

Paper I: The first paper had a cross-sectional design. A sample of 800 patients, 18 years and older, who had undergone total hip or knee arthroplasty between 6 to 11 months prior, were randomly selected from the Norwegian Arthroplasty Register in April 2022 and invited to participate in the study. All selected patients received written information about the study, a written consent form and a paper questionnaire sent by regular mail between May and August 2022. No reminder was sent. Those who wished to participate signed the consent form, filled in the questionnaire, and returned both in a sealed, opaque prepaid envelope.

Paper II: The second paper was a method description for the development of an intervention tailored to patients with knee osteoarthritis. We developed an internet-delivered cognitive behavioural therapy program intended to complement an established education and exercise therapy program (AktivA) for the group of knee osteoarthritis patients at increased risk for poor outcomes following total knee arthroplasty surgery. The development process followed the first two phases of the UK Medical Research Council framework for complex interventions. The first phase involved a literature review and discussions within an expert group to establish a program theory. Building on previously established internet-delivered cognitive behavioural therapy programs, the initial draft was tested on three patients with total

knee arthroplasty. Multiple rounds of testing, discussions, and adjustments were performed until the final program was established.

Paper III: Paper three was a randomized feasibility study aimed at testing the suitability of the internet-delivered cognitive behavioural therapy program and the feasibility of an RCT aimed to evaluate the effectiveness of the internet-delivered cognitive behavioural therapy program combined with education and exercise therapy either instead of or in addition to surgery for patients with knee osteoarthritis. We included 15 patients scheduled for total knee arthroplasty surgery at two hospitals in Norway between August 2019 and June 2020. The patients were between 18 and 80 years old, ASA grade 1-3, had radiographically confirmed osteoarthritis (Kellgren&Lawrence grade 3 or 4), BMI below 40, and were able to read and speak Norwegian. Exclusion criteria were previous unicompartmental or patellofemoral knee arthroplasty, large axis deviation or instability requiring use of hinged prosthesis, diagnosis of dementia or diagnosis of sero-positive rheumatic disease. In the beginning of the study, we only included patients with risk factors for poor outcome of total knee arthroplasty surgery based on the appropriateness classification system by Escobar et al 2021(132). Low rate of eligible patients and low recruitment rate led to changes in the inclusion criteria during the feasibility study. We decided to integrate the risk factor screening into the baseline questionnaire so that the risk factors still could be assessed and analysed in the full-scale study.

When patients had signed the consent form, they were randomly assigned to one of three treatment groups in a 1:1:1 ratio using sealed opaque envelopes. The randomization scheme was computer-generated with permuted blocks of three or six, and the envelopes were prepared by an independent staff member and kept in a secure location. Patients in group A were referred to a physiotherapist for education and exercise therapy, while patients in groups B and C were scheduled for total knee arthroplasty. Before the surgery, patients in Group B received education and access to the iCBT program. After being discharged from the hospital, they were referred to physiotherapy for exercise therapy, according to the MultiKnee program. Patients in

Group C underwent surgery with standard postoperative follow-up by a physiotherapist.

4.2 Instruments

Paper I:

Sociodemographic data included age, sex, educational level, and type of surgery (hip/knee).

Digital Health Literacy

Digital health literacy was measured using the Norwegian version of the original eHealth Literacy Questionnaire (eHLQ) (133), which consists of 35 items assessing the 7 domains of the eHealth Literacy Framework: 1) using technology to process health information (Using technology, 5 items), 2) understanding of health concepts and language (Understanding, 5 items), 3) ability to actively engage with digital services (Engage, 5 items), 4) feel safe and in control (Control, 5 items), 5) motivated to engage with digital services (Motivation, 5 items), 6) access to digital services that work (Access, 6 items), and 7) digital services that suit individual needs (Needs, 4 items). The original Danish version of eHealth Literacy Questionnaire has satisfactory construct validity and reliability across a broad range of concepts in various groups (133). Confirmatory factor analysis in a preliminary validity testing of the Norwegian version found that almost all factor loadings were high to acceptable (134). All items are scored on a 4-point Likert scale ranging from 1= strongly disagree to 4= strongly agree, with higher scores indicating higher digital health literacy. Each domain is scored separately by summing the score on each item and dividing it by the number of items scored. If >50% of the items in a domain were missing, a mean score was not calculated for that domain according to the guidelines for the original questionnaire.

Health related quality of life and self-rated health

Health related quality of life was measured using the EuroQol EQ-5D-5L (135), consisting of the EQ index and the EQ VAS. The EQ index includes five items assessing different dimensions of health status (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension is scored on a 5-point Likert scale with five categories from 1=no problems to 5=extreme problems and transformed into an index on a scale ranging from less than 0 (worse than dead) to 1 (no problems). The EQ VAS is a measure of self-rated health using a vertical visual analogue scale from 0 ("The worst health you can imagine") to 100 ("The best health you can imagine") (136). The EQ-5D-5L is reliable and valid for this patient group (137).

Paper III:

Outcome measures was chosen based on the key uncertainties regarding the feasibility of an RCT.

Recruiting and retention rate

Number of eligible patient and numbers included in the study was registered as well as numbers of patient who resigned.

Compliance to the intervention and follow-up

Compliance to the intervention was reported as numbers of compliers for each treatment option. Treatment compliance was defined as acceptable when patients had attended at least 75% of the exercise therapy sessions and had completed at least 75% of the internet-delivered cognitive behavioural therapy tasks.

Compliance to the patient reported outcome measures was described as numbers of patients who completed the patient reported outcome measures.

Overview of the patient reported outcome measures data and measure points in Table 4.

Table 4 Patient reported outcome measures.

	Baseline	3mths	6mths	12mths
Patient Reported Outcome Measures (PROM)				
1. Socio-demographics	x			
2. Self-reported comorbidity	x			
3. Health-related Quality of life (EQ-5D-5L)	x	x	x	x
4. Brief Pain Inventory (BPI)	x	x	x	x
5. Knee injury and Osteoarthritis Outcome Score (KOOS)	x	x	x	x
6. Forgotten Joint Score (FJS-12)	x	x	x	x
7. Fear-Avoidance Belief Questionnaire (FABQ)	x	x	x	x
8. Pain Catastrophizing Scale (PCS)	x	x	x	x
9. Patient-acceptable symptom state (PASS)		x	x	x
10. Treatment failure		x	x	x
11. Global Perceived Effect (GPE)		x	x	x
12. Locus of Control Scale	x	x	x	x
13. Pittsburgh Sleep Quality Index	x	x	x	x
14. Physical activity (SoC[1], HUNT[2])	x	x	x	x
15. Hospital Anxiety and Depression Scale (HADS)	x	x	x	x

Compliance to the physical-performance tests was described as numbers of patients that completed the physical-performance tests. Overview of the physical-performance tests and the measure points is in Table 5.

Table 5 Physical performance tests

	Baseline	3mths	6mths	12mths
1. The 40-meter Fast-paced Walk Test	x	x	x	x
2. The Stair Climb Test	x	x	x	x
3. 30-second sit-to-stand test	x	x	x	x
4. Range of Motion (ROM)	x	x	x	x

Cross-over

Numbers of patients who crossed over to another group during the first year, was registered.

[1] SoC= State of Change physical activity
[2] HUNT= Nord-Trøndelag health study

Adverse events

Adverse events and serious adverse events were registered in three steps: Screening of the medical records at the hospitals, reports by the physiotherapists and self-reported by the patients, using questionnaires. Medical records were screened at 12 months for all adverse events from inclusion until the 12-month follow-up. An adverse event was defined as any undesirable experience during follow-up that led to contact with the health care system. A serious adverse event was defined as any event that led to hospitalization, prolonged in-hospital care or additional surgery, was life-threatening or resulted in permanent disability or damage, or death (138).

4.3 Statistical analyses

In paper I and III, data were analysed using the Statistical Package for Social Sciences (IBM SPSS) version 28 (139).

No statistical analysis was performed in paper two as it was a method description.

Paper I: Descriptive statistics were used to describe the sample's digital health literacy levels, sociodemographic characteristics, and health related quality of life. Digital health literacy norms by age group, sex and educational level were presented as means, standard deviations and ranges. We explored the association between digital health literacy and age, sex, and educational level, and used correlation analysis to describe the strength and direction of the relationship. As the digital health literacy questionnaire score and age are continuous variables, we used the Pearson product-moment correlation to describe the relationship. Pearson product-moment correlation can also be used if we have one continuous variable and one dichotomous variable as is the case with digital health literacy questionnaire score and sex (male/female) and educational level (high/low). Pearson product-moment correlation coefficient can take a level between -1 and 1 where 0 refers to no correlation, -1 refers to perfect negative correlation (as one variable increases, the other decreases) and 1 refers to a perfect positive correlation (as one variable increases, so too does the other). Preliminary analyses were performed to ensure no violation of the assumptions of normality by

inspecting the histogram of scores for each variable, and linearity by inspecting a scatterplot og scores.

There is no consensus on what is defined as “low” and “high” digital health literacy, but Zangger et al. (2024) (140) has in concordance with the eHLQ developer, Lars Kayser and the Region Zealand Health Survey (141) report used a cut-off on ≤2.0 representing “insufficient” (lowest scores) and >2 to 2.5 representing “insufficient”. Based on this, we dichotomized the eHLQ score as low eHL = ≤2.5 and high eHL = >2.5. We used descriptive statistics to describe the proportion (number and percent) of patients with “low” digital health literacy by age, level of education, and type of surgery. Independent-sample proportion test was used to explore the difference in proportions with lower digital health literacy between age groups, levels of education and type of surgery.

Separate multivariable linear regression models adjusting for selected sociodemographic factors (age, sex, education level, and type og surgery) were used to investigate how each of the digital health literacy domains were related to health-related quality of life (EQ-5D-5L, EQ Index and EQ VAS). Preliminary analyses were conducted to ensure no violation of the assumptions of normality, linearity, multicollinearity which exist if the relationship among the independent variables is highly correlated, and homoscedasticity which means that the variance of the residuals around predicted dependent variable should be the same for all predicted scores.

The 7 digital health literacy domains were strongly correlated to each other, with most of the correlations exceeding 0.7. These correlations may suggest multicollinearity which violates the assumptions for multivariable linear regression models. Therefore, for the multivariable regression models we decided to perform separate regression models for each dimension, while controlling for the relevant confounders.

Paper III: Descriptive statistics were used to report the outcome. In categorical variables we used frequencies to tell how many patients gave each response. Continuous variables were reported as means and standard deviation. A low standard deviation means that the data are clustered tightly around the mean, while a high standard deviation means that the data are spread out over a wider range.

Recruitment rate was described as numbers of eligible patients and patients included in each stage of the recruitment process.

Compliance to the intervention was reported as frequency and percent of compliers for each of the treatment options. Treatment compliance was defined as acceptable when patients had attended at least 75% of the exercise therapy sessions and had completed at least 75% of the iCBT tasks.

Outcome measures were described as frequency and percent of patients who completed the PROM and physical-performance tests at baseline and at 3-, 6- and 12-months after the start of the intervention. Crossovers were reported as frequency and percent of patients who crossed over from one group to another within the first year.

Adverse events and serious adverse events were reported as frequency, and types of adverse events were described.

Demographic characteristics were reported as mean and standard deviation (SD). Clinical outcome measures were descriptive and reported as median and interquartile ranges (IQR) which is the amount of spread in the middle 50% of the dataset.

4.4 Ethical issues

This study was planned and conducted according to ethical principles for medical research involving human subjects, as outlined by the World Medical Association Declaration of Helsinki (142). The Regional Medical Research Ethics Committee og Health South-East of Norway approved the study (#2017/968). The Data Protection Officers at Lovisenberg Diaconal Hospital, Coastal Hospital in Hagevik and Martina Hansens Hospital have evaluated and recommended the study.

Consent and inclusion: All patients eligible for this study were capable of giving informed consent. To ensure they did not feel pressured to participate in the study, information about the study was provided by a qualified study staff who had no dependent relationship with the patients. Eligible participants in studies two and three received written and verbal information and an e-mail with link to an electronic written consent form. Participants in the first study received information and consent

forms sent by regular mail. The information included details about the study, the potential benefits, burdens and harms of participating, and the right to withdraw from the study at any time without reprisal.

Confidentiality: All patient data were depersonalized using code numbers and stored in the hospital's research server in accordance with the hospital's regulation for patient data storing.

Data from the electronic questionnaires in study III were directly stored in Services for sensitive data (TSD) at the University of Oslo, which is a secure platform for storing sensitive data. All data were depersonalized with code numbers before statistical analysis. Only study staff had access to the data.

Risk, Burdens, and Benefits: It was considered that patients were not exposed to significant additional risk by participating in the study. Patients in the surgical group were informed about the risks and benefits associated with the operation equivalent to the hospital's standard procedures. Patients in the non-surgical group were informed that they could be re-evaluated by the surgeon at any point during the follow-up, and if both parties agreed, they could be offered total knee arthroplasty surgery.

Patients were informed that by participating in the study, they would need to allocate some time to answer questionnaires and attend additional hospital visits for testing. The MultiKnee program would require slightly more time from the patient than regular physiotherapy treatment.

The more extensive treatment program in the intervention groups could also provide an additional benefit for the patients that they would not receive without participating in the study. The close monitoring of participants could also be advantageous for the patients.

5 MAIN RESULTS

Paper I:

A total of 404 (51%) patients consented to participate in the study and 383 (48%) were included in the analysis. Average age was 70 years (39-94years), 281 (67 %) were female, 229 (60%) had less than 13 years of education and 198 (52%) had a total knee arthroplasty. There were no significant differences in age, sex, and type of surgery between responders and non-responders.

The eHealth Literacy Questionnaire score varied between the 7 digital health literacy domains. Age ≥75 years and education ≤high school showed the lowest digital health literacy (from 2.41 (SD 0.70) in "using technology to process health information ", to 3.12 (SD 0.38) in "feel safe and in control") while age <65 years and education >high school showed highest digital health literacy (from 2.75 (SD 0.53) in "access to digital services that work", to 3.21 (SD 0.59) in "ability to actively engage in digital services"). Overall, domain 4 (Feel safe and in control) had the highest score (3.15, SD 0.50) and domain 7 (Digital services that suit individual needs) had the lowest score (2.64, SD 0.65).

The proportion of patients with "low" digital health literacy varied between the 7 domains with domain 7 (access to digital services that suit individual needs) showing the highest proportion (45.7%) and domain 4 (feeling safe and in control) showing the lowest proportion (7.7%) of patients with "low" digital health literacy.

There was no significant correlation between sex and the digital health literacy domains. Age was negatively correlated ($p<0.01$) with all digital health literacy domains except domain 4 (Feel safe and in control). Education was positively correlated with 3 of the domains (Using technology, Understanding, and Engage).

Results from the separate multivariable linear regression analysis showed that digital health literacy domain 1 (Using technology), 3 (Engage), 4 (Control), 6 (Access), and 7 (Needs) were positively associated with health related QoL, when adjusted for patients' age, sex, education level, and type of surgery.

Paper II:

The development process in study II, ended up with an internet-delivered cognitive behavioural therapy program with 10 modules to be distributed over 10 weeks (Appendix 9). The program was developed in two versions, one for the surgical group, and one for the non-surgical group. The participants had to have access to the internet and an electronic device, and they were given access to the program through a secure website using two-factor authentication.

The cognitive-behavioural model focusing on the link between thoughts, emotions, bodily reactions, and behaviour, was the theoretical framework for the program, and was represented through texts, videos, exercises, and behavioural experiments throughout the program. The patients could follow a "persona", a fictional character, who had undergone either surgery or non-surgical intervention. Early in the program, patients were challenged to identify areas in which they wanted to change and set step-by-step goals for how these goals could be reached. Themes for the different modules were Gate control theory and pain coping strategies, stress and pain, lifestyle, identifying and creating alternative thoughts, mindfulness, selective attention and postponing worry and rumination.

To optimize adherence to the program, physiotherapist supported the patients throughout the program. A physiotherapist manual (Appendix 10) was developed to support the physiotherapists and increase the consistency of mentoring patients. The physiotherapist manual consisted of the same ten modules in the iCBT program with specific learning objectives for each module and a list of themes the physiotherapists should consider discussing with the patients. In addition, two extra learning modules were available for the physiotherapists.

Paper III:

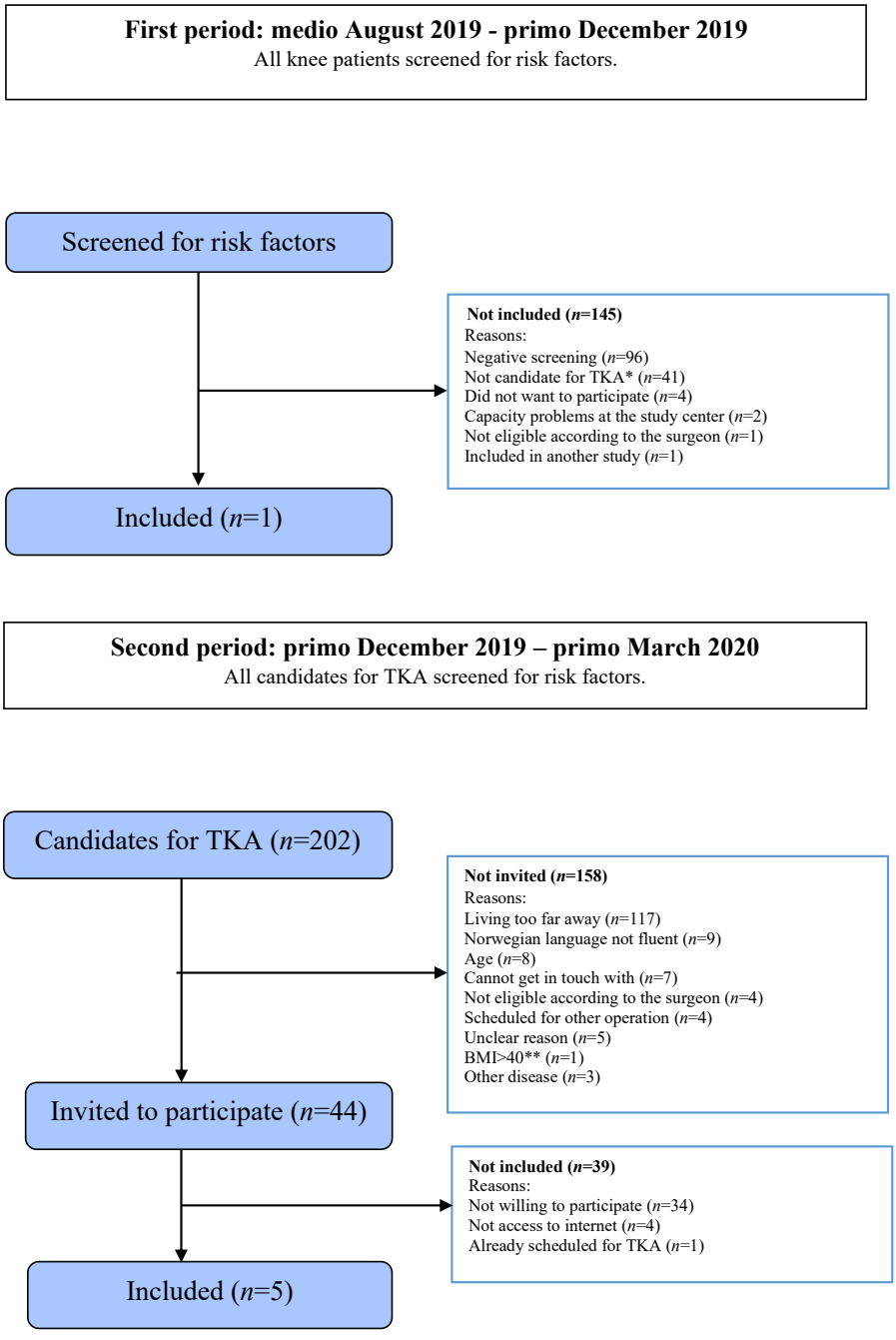
Between August 2019 and June 2020, 350 patients were assessed for eligibility and 15 patients were included in the feasibility study. Due to challenges in the recruitment process, we made changes to the inclusion criteria three times. From the intention to

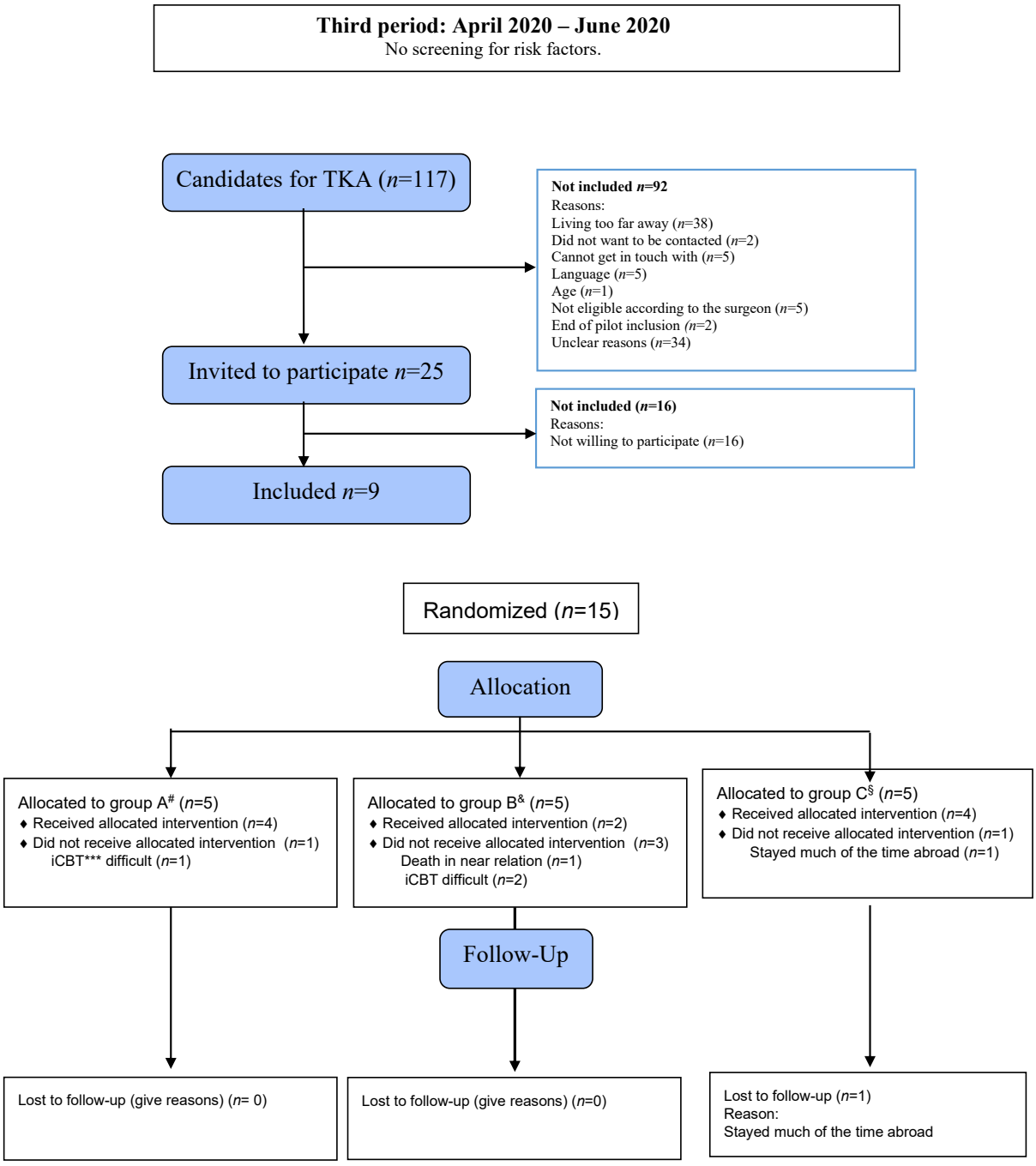
only include patients at risk of poor outcome from total knee arthroplasty surgery, we ended up with no screening for risk factors prior to inclusion (Figure 3).

Compliance with the intervention and follow-up were high. All patients in the intervention groups attended the education. Nine out of ten patients completed at least 75% of the exercise therapy sessions, six out of 10 patients completed at least 75% of the iCBT program and nine out of 10 underwent total knee arthroplasty surgery. Fourteen out of 15 patients answered the baseline and 3-month questionnaire, 13 answered at 6 and 12 months. Fourteen patients completed the physical performance tests at all time points.

No participants crossed to surgery within the first year.

One patient experienced an adverse event during the first year, no one experienced serious adverse events.


First period: medio August 2019 - primo December 2019
All knee patients screened for risk factors.
Screened for risk factors
Not included (n=145)
Reasons:
Negative screening (n=96)
Not candidate for TKA* (n=41)
Did not want to participate (n=4)
Capacity problems at the study center (n=2)
Not eligible according to the surgeon (n=1)
Included in another study (n=1)
Included (n=1)
Second period: primo December 2019 – primo March 2020
All candidates for TKA screened for risk factors.
Candidates for TKA (n=202)
Not invited (n=158)
Reasons:
Living too far away (n=117)
Norwegian language not fluent (n=9)
Age (n=8)
Cannot get in touch with (n=7)
Not eligible according to the surgeon (n=4)
Scheduled for other operation (n=4)
Unclear reason (n=5)
BMI>40** (n=1)
Other disease (n=3)
Invited to participate (n=44)
Not included (n=39)
Reasons:
Not willing to participate (n=34)
Not access to internet (n=4)
Already scheduled for TKA (n=1)
Included (n=5)



*TKA=total knee arthroplasty, **BMI=Body Mass Index, ***iCBT=internet-delivered cognitive behavioral therapy
#Group A= exercise therapy and education (ExE) and iCBT, &Group B=TKA followed by ExE and iCBT, §Group C=TKA followed by physiotherapy as usual

Figure 9 Flow diagram for a randomized feasibility study for patients with knee osteoarthritis.

6 GENERAL DISCUSSION

6.1 Methodological considerations

This study aimed to develop and test the feasibility of an intervention tailored to knee osteoarthritis patients, to be used alone or in addition to total knee arthroplasty surgery. Three different methods were used in the study. A cross-sectional design was used to establish norm data of digital health literacy in patients undergoing total hip or knee arthroplasty and association between digital health literacy and health related quality of life (paper I). Development of the intervention followed the UK Medical Research Council's framework for developing complex interventions (paper II). The feasibility study (paper III) followed a randomized controlled feasibility trial design.

6.1.1 Cross-sectional studies

We aimed to develop an internet-delivered CBT program for patients with knee osteoarthritis or having undergone total knee arthroplasty. Digital programs offer some advantages, as patients can complete the program at home at their own pace, saving both time and money by avoiding travel to a therapist (143). To provide equal healthcare for everyone, it is crucial that all patients can utilize the available programs. We found no studies that examined the digital health literacy of patients who have undergone total hip or knee arthroplasty and the relationship between health-related quality of life and digital health literacy in this patient group. Therefore, the aim of study I was to establish normative data on digital health literacy among patients who had undergone hip or knee arthroplasty surgery that could serve as a baseline for comparison with future studies and as a foundation for tailoring digital services to this patient population. A cross-sectional design was chosen for this study, providing a snapshot of the situation in a given population (144). The advantage of this design is its ability to collect and analyse large amounts of data in a short time (144). This type of study is less demanding for patients since they only need to complete a questionnaire once. However, such studies have limitations; they only provide a

snapshot of the population, is not suitable for investigating causal relationships, and cannot detect changes over time.

6.1.2 Development of complex interventions

The aim of study II was to develop an internet-delivered intervention that could complement education and exercise therapy for patients with knee osteoarthritis who were at increased risk of poor outcomes following total knee arthroplasty surgery. There are many methods that can be used to develop interventions, each with its own advantages and disadvantages (145). In this study, we followed the first two phases of the UK Medical Research Council's framework for developing and testing complex interventions (10). One strength of this method is it emphasize of a thorough groundwork. Thomas et al. (2010) (116) used the same framework when they developed a cognitive behavioural approach to fatigue management in people with multiple sclerosis. As in their study, we established a multidisciplinary advisory group, consisting of individuals with extensive experience in both clinical practice and research, including a user representative. Discussions within the group, along with a review of the literature and experience from previous studies, formed a solid foundation for intervention development, allowing input from both those receiving and delivering the intervention. A revision of the MRC framework (117) emphasizes that the framework does not describe a linear process, but rather a process where one moves back and forth between the different phases. The 2021 revision (117) also includes some key points recommended to consider in each phase (Consider context, develop, refine, and (re)test programme theory, engage stakeholders, Identify key uncertainties, refine intervention, and economic considerations). This aligns well with our experience of the process. O'Cathain et al (2019) highlighted the importance of staying open to adjustments throughout the development process and being prepared to take a step back if needed (118). We had multiple rounds in both the development and testing phases, as well as alternating back and forth between the two phases where key points were discussed in the advisory group. The thorough preparation and the way we worked through the development of the program aimed to increase the likelihood that the intervention was tailored to the patient group and was feasible to be evaluated in an

RCT. Moreover, it increased the possibility of future implementation into clinical practice (118). Numerous factors contribute to the complexity of an intervention, including the interplay of its components, the characteristics of both providers and recipients, organizational aspects, outcome variability, and flexibility in delivery methods (10). These intricacies can significantly impact intervention outcomes and thus necessitate careful consideration during development, which directly influences the study's internal and external validity (146).

Our intervention is grounded in the biopsychosocial model, recognizing the multifaceted nature of illness development and symptomatology influenced by biological, psychological, and social factors (103). Introducing an internet-delivered cognitive behavioural therapy (iCBT) program tailored to this model represents a novel aspect. Cognitive behavioural therapy inherently involves a diverse range of techniques, such as cognitive restructuring, behaviour modification, and mindfulness, making it inherently complex (147).

The personal attributes and expertise of therapists play pivotal roles in intervention delivery, and contributes to the complexity of the intervention (10). The iCBT program is standardized, providing therapists with a template to ensure consistent follow-up across all patients. However, both patients and therapists are unique, with patients facing different challenges and therapists responding to these in diverse ways. The relationship between patient and therapist may play a crucial role in the effectiveness of the intervention.

The organizational structure may affect effectiveness of the intervention and the implementation (148). The MultiKnee program was consisted of three components, iCBT, exercise therapy, and education. The iCBT program was digital, and administered from the study hospitals, while the education and exercise therapy were administered locally in the patients' home municipality. Efforts were made to integrate the components, so that the skills learned in the iCBT program could be integrated in the exercise therapy sessions and daily life. An alternative organization could be that the same physiotherapist delivered all three components. This was considered but deemed impractical due to resource constraints.

In summary, our intervention's complexity underscores the importance of thoughtful planning and adaptation to achieve desired outcomes within the constraints of clinical practice.

6.1.3 Feasibility studies and randomized controlled trials

When testing the effectiveness of an intervention, RCT's are the best design for controlling various biases (149). However, there are many factors to consider when planning large randomized controlled trials. By conducting a feasibility study prior to an RCT, one can reduce uncertainties associated with the study and thus reduce the chances of the study being infeasible or not yielding valuable knowledge (150). In study III, we conducted a randomized controlled feasibility trial to address what we identified as the greatest uncertainties in conducting an RCT to test the combined intervention of education, exercise therapy, and cognitive behavioural therapy for patients with knee osteoarthritis to be delivered alone or in addition to total knee arthroplasty. The main uncertainties in this study were if it would be possible to recruit enough patients to the study and to retain them in the study, if the intervention and follow-up would be manageable for the patients, if patients would stay in the group they were randomized to, and if there would be any adverse events or serious adverse events in any of the groups. It is challenging to recruit patients to randomized studies especially to studies comparing surgery to no surgery (151). In the feasibility study, it was necessary to modify the inclusion criteria during the study to recruit a sufficient number of patients. The most significant change was removing the requirement for risk factors and including all patients scheduled for total knee replacement surgery. The intervention was tailored to patients at higher risk of poor surgical outcomes, thus a new power calculation had to be performed for the full-scale study to allow for subgroup analyses based on risk factors.

6.1.4 Outcome measures

PAPER I

Digital Health Literacy

In the cross-sectional study, the aim was to describe normative data for digital health literacy among patients who underwent total hip or knee arthroplasty surgery. Various measurement instruments exist to assess digital health literacy in different ways (152), each questionnaire with its strengths and limitations. For this study, the eHealth Literacy Questionnaire (eHLQ) was selected, as it is a Patient Reported Outcome Measure (PROM) developed based on the eHealth Literacy framework (153), comprising seven dimensions of digital health literacy.

The eHealth Literacy Scale (eHEALS) (154), is the most used tool for assessing digital health literacy (152). The limitations of eHEALS are that it only measures one dimension of digital health literacy and was developed in 2006, before the widespread use of social media and mobile applications (152).

The advantage of the eHLQ lies in its ability to provide a broader insight into respondents' digital health literacy compared to other instruments, such as eHEALS. On the other hand, a drawback of eHLQ is that it has not been as thoroughly tested for psychometric properties (152), although the Danish, Swedish, and Norwegian versions have shown good psychometric properties so far (133, 134, 155).

In this study, we only used a patient reported outcome measure (PROM) to assess patients' digital health literacy. A limitation of using PROM is that we cannot be certain whether patients have accurately understood the questions, nor if their responses truly reflect their actual digital health literacy. There is a risk that they might overestimate or underestimate their abilities, or not report them honestly.

PAPER III

The selection of outcome measures in a study is determined by its objectives. In our feasibility study we chose outcome measures based on the key uncertainties in conducting a full-scale RCT: recruitment and retention rate, implementation of the intervention and follow-ups, cross over, and adverse events. Results from the feasibility study resulted in amendments to the MultiKnee trial protocol, which will make the full-scale MultiKnee trial more feasible (156).

Recruitment and retention rate

Recruiting participants for a randomized controlled study can be challenging. This has been particularly evident in studies that randomize to surgery or non-surgery (157, 158). The inclusion and exclusion criteria chosen can affect the recruitment rate. This was one of the main uncertainties prior to the RCT study and thus an important factor to address in the feasibility study. We found through the feasibility study that some of the inclusion criteria made it difficult to recruit enough patients (screening for risk factors, requirement for certification of physiotherapists, geographical limitations); by changing these criteria, the recruitment rate increased. These changes also increased external validity by enhancing generalizability and the possibility of implementing the intervention in the future.

According to the Helsinki Declaration, all patients participating in research studies have the right to withdraw from the study at any time (142). In randomized studies, there is a risk that patients prefer one of the study arms (159) and will withdraw after randomization if they end up in the non-preferred arm. During the feasibility study we experienced that this was a problem we needed to address in the inclusion process, with thorough information to the patients.

Compliance to the Intervention and follow-up

The intervention to be tested in the RCT study was a comprehensive mix of education, exercise, and cognitive behavioral therapy. This was a time-consuming treatment (90-120 min education once, exercise therapy 45-60 min twice weekly for 12 weeks, and 1 module iCBT weekly for 10 weeks) and raised concerns about patient adherence and the feasibility of the novel iCBT program. Our outcome measure focused on the proportion of patients completing significant portions (75 %) of the intervention.

The intervention was also complex in that it could affect many different outcome measures (10). When measuring the effect of the intervention, it was important to take this complexity into account. In the RCT study, both objective outcome measures (e.g., activity measurement, physical tests) and patient-reported outcome measures (PROM) were chosen.

Digital PROM collection may be challenging for some patients. In this study, part of the intervention was an internet-based program, which required that study participants had access to the internet and a PC, tablet, or smartphone. Digital questionnaires were therefore suitable for this group. The advantage of using digital forms is that the patient can sit at home and answer the questionnaire without interruptions.

Physical tests required patients to come to the hospital for testing. The choice of test time points can affect the results and attendance. For patients with long travel distances, it may be a burden to come to the hospital several times, while others may feel reassured by being closely monitored. In the RCT study, the measurement time points chosen were 3, 6, 12, and 24 months after the start of the intervention.

The goal was to balance the number of examinations and questionnaires with how much time and effort patients were willing to spend.

Cross-over

Patients enrolled in the study were candidates for surgery, with a 2/3 chance of being randomly assigned to one of the surgical groups. It was conceivable that patients desiring surgery might view this as a risk and withdraw from the study if assigned to the non-surgical intervention arm.

In randomized controlled trials (RCTs), facilitating the option for participants to switch from the non-surgical group to the surgical group presents challenges in result analysis. Therefore, the objective was to minimize crossover occurrences. To achieve this, detailed information was provided to patients before enrolment, aiming to decrease the likelihood of crossovers.

Conducting a feasibility study before the RCT allowed us to refine the information provided to patients based on their needs. Any participants who switched groups within the first year of enrolment were categorized as crossovers, with the number recorded both before and after completing the intervention.

Adverse events

As with any intervention study, adverse events, both minor and serious, may occur. Continuous assessment during the study ensured timely action if the frequency or severity of adverse events raised concerns.

6.1.5 External and internal validity

When testing an intervention, the choice often lies between conducting an explanatory or a pragmatic study (160) . In explanatory studies, the focus is on examining the effect of the intervention when other confounders are controlled for (e.g., drug trials). In this type of study, internal validity (reliability) is high, while external validity (generalizability) is low. Pragmatic studies, on the other hand, aim to measure the effectiveness of an intervention in settings that closely resemble everyday clinical practice. In these studies, external validity is high, but it may come at the expense of internal validity.

In the MultiKnee trial, we aimed for high external validity while also striving for as high internal validity as possible. The iCBT program was developed for patients at increased risk of poor outcomes following total knee replacement surgery. Our goal was to ensure high transferability to clinical practice. During the development process, we had discussions within the advisory group composed of various professionals with extensive clinical experience to make the program suitable for everyday clinical use. The program was also tested on patients during both the development and feasibility phases to enhance its applicability and external validity.

An important factor to consider was the scattered population and shortage of psychologists in Norway, like in many other countries. To ensure equal access for all, we designed a digital program that would be mentored by physiotherapists. Studies have shown that digital programs are as effective as face-to-face programs and that follow-up by other professionals can be as beneficial as follow-up by psychologists. Some studies indicate that the effectiveness of iCBT may be greater when mentored by physiotherapists, suggesting that this approach might better integrate the skills from the psychological intervention with exercise therapy and daily activities.

Through the feasibility study, we could test the feasibility of our planned procedures and make assessments regarding their applicability to a clinical setting.

One issue we had to address was whether the physiotherapists delivering the exercise therapy should have specific certification and how much freedom they should have in providing the treatment they deemed appropriate for the patients. A high level of control over how the intervention was delivered would enhance internal validity but reduce external validity. By creating an information sheet and contacting physiotherapists beforehand and during the study, we ensured that patients received a standard minimum package, while allowing physiotherapists to provide additional treatment if they deemed it beneficial for the patients. This approach maintained high external validity without significantly compromising internal validity.

Another threat to internal validity is the risk of contamination (161). Patients in the control group contacted the physiotherapist themselves for post-operative treatment. We had no information about whether they used the same physiotherapists who also delivered the study intervention. To reduce the risk of contamination, physiotherapists were instructed to treat patients in the control group as if they were not participating in the study.

The number of inclusion and exclusion criteria is another factor influencing internal and external validity. By keeping the number of inclusion and exclusion criteria to a minimum, the sample was made as similar as possible to the population of interest. Few inclusion criteria allowed the surgeon to do clinical judgment on who was eligible for inclusion, while few exclusion criteria ensured that patients with other diseases or challenges were not excluded. This resulted in significant differences among participants, which could decrease internal validity. The surgeon decided who was eligible for the study, but an independent person in the study staff was responsible for the information, inclusion, and randomization. By conducting a thorough randomization process by an independent person, differences could be balanced between groups and thereby increasing internal validity.

Compliance is a factor influencing the outcome of an intervention. In explanatory studies, compliance is crucial for assessing the effect of an intervention. On the other hand, the intervention has no practical benefit if it is not followed. In pragmatic studies, compliance is therefore measured as an outcome. In this study, compliance

was measured and was to some extent influenced by the fact that a physiotherapist in the study group called the patient every second week which could also act as a motivational factor for the patients.

In the cross-sectional study (study I), we examined patients who had undergone total hip and knee replacement surgery. Consequently, they have experience with the healthcare system, which may have influenced their digital health literacy. Therefore, the results cannot be generalized to osteoarthritis patients who have not undergone surgery and thus lack this experience. Generalizability also depends on the selection of the sample. To reduce selection bias, patients were randomly selected from all patients over 18 years old registered in the Norwegian Arthroplasty Register and operated on 6-11 months prior, representing the entire country. In Norway, a high proportion of all patients undergoing total hip or knee arthroplasty surgery are included in the register, with completeness of reporting of 97% for the period 2019-2020 (1).

A low response rate may have affected generalizability, although there were no significant differences in age, gender, and type of surgery between those who responded and those who did not. However, there may have been differences in other factors we did not have an overview of, such as education and comorbidities.

The questionnaire was distributed on paper to avoid excluding patients with low digital health literacy. However, it is possible that those with low digital health literacy were overrepresented in the group of non-responders. General health literacy and digital health literacy are related meaning that patients with low digital health literacy may also have low general health literacy. The questions in the digital health literacy questionnaire might have been difficult to understand for some patients, resulting in none-responding.

The questionnaire in this study was only available in Norwegian. Thus, patients not understanding Norwegian were not included in the study. This may have affected the outcome and reduced the generalizability to a broader population.

6.2 Discussion of the main results

In this study we have described the digital health literacy in a representative sample of patients who have undergone hip and knee arthroplasty surgery and the association with health-related quality of life. We have developed an internet-delivered cognitive behavioural therapy (iCBT) program specifically tailored to patients with knee osteoarthritis who are at risk of persistent pain and poor function following TKA surgery. In a randomized feasibility trial, we tested the feasibility of a planned RCT to investigate the effectiveness of a combined intervention consisting of iCBT, education and exercise therapy delivered either alone or in combination with TKA.

Study I

We chose to use an internet-delivered cognitive behavioural therapy program. This choice may have excluded some patients from being able to complete the program. Generally, digital health literacy in Norway is high (162). However, in our cross-sectional study, which assessed digital health literacy among a random sample of patients who had undergone hip or knee arthroplasty surgery, we found that digital health literacy was lowest among older patients and those with lower education levels. The prevalence of osteoarthritis increases with age, meaning there are more older individuals in the osteoarthritis group compared to the general population.

To our knowledge this is the first study to describe the digital health literacy in patients with total hip and knee arthroplasty and the association with health-related quality of life in this population. Results from our study show that digital health literacy was lowest in the oldest patients with low level of education. This is in line with studies on other populations (163-165).

In 2024, Andersen et al. conducted a cluster analysis of digital health literacy among patients hospitalized in surgical or medical departments at a university hospital in Norway (163). They found that those with the lowest scores on the eHLQ questionnaire were the oldest and had the lowest levels of education. The domains with the lowest scores were the domains related to access to digital services that work (domain 6) and digital services that suit individual needs (domain 7) which depend

mainly on the characteristics of the e-health systems (153). Similarly, in our study, “digital services that suit individual needs” had the lowest digital health literacy scores regardless of age and education. This suggests that to improve digital health literacy, it is not sufficient to focus solely on patient-related factors; the system must also be adapted to the population's competencies. “Feeling secure and in control” (domain 4), had the highest score in our study regardless of age and education, a finding consistent with Andersen et al.'s study. This indicates that the Norwegian population has a high level of trust in data security, this may not be true in all countries.

Our study results indicate a correlation between certain domains of digital health literacy and health-related quality of life in patients who have undergone hip or knee arthroplasty surgery. Similar correlations have been observed in other patient groups by various studies. For instance, Keles et al. identified a link between postoperative quality of life and digital health literacy (eHEALS) in patients who had undergone retrograde intrarenal surgery (166) or prostate cancer surgery (165). Filabadi et al. (2020) found a positive correlation between digital health literacy and quality of life among patients at a health centre in Tehran (167). However, these studies did not elaborate on the nature of this relationship. It is plausible that patients with higher digital health literacy are more adept at finding and adhering to general health advice and specific disease-related recommendations, leading to improved health-related quality of life.

Liu et al.(2023) demonstrated a positive correlation between digital health literacy, health-promoting lifestyle, and health-related quality of life in Chinese community-dwelling older adults, where a health-promoting lifestyle was found to be a mediator to the relationship between digital health literacy and health-related quality of life (168). Other studies have also shown an association between digital health literacy and health-promoting lifestyles (169, 170). Additionally, a Danish study by Zangger et al. (2024) examined the association between digital health literacy (eHLQ domains 1, 4, and 5) and physical activity among 19,231 individuals over the age of 16, with an average age of 56 years (140). They found that higher digital health literacy was associated with higher self-reported levels of physical activity. These studies confirm

the theory that there is a connection between digital health literacy, health-promoting lifestyle, and health-related quality of life. If the goal is to improve the health-related quality of life in the population, digital health literacy must be taken into consideration.

Study II

The program developed in study II, is an iCBT program consisting of 10 modules and is available in two versions: one for patients who have undergone surgery and another for those who have not. Additionally, a physiotherapy manual has been created to guide physiotherapists in supporting the patients through the program.

Patients experiencing prolonged symptoms after TKA exhibit various physical and psychological factors (5, 6). Thus, the traditional biomedical model of understanding illness and injury is insufficient for this patient group (103). Instead, a biopsychosocial approach is more appropriate (57, 103). A multidisciplinary approach combining education, exercise therapy, and CBT, either as a standalone treatment or in combination with surgery, may therefore be effective for these patients.

A recent systematic review by Liu et al. 2024, examined the effects of CBT post-TKA (171). The review, which included seven studies with a total of 608 patients, showed a significant reduction in fear of movement in the intervention group compared to usual care, but no difference in postoperative pain and knee function. The CBT interventions in these studies were short-term and primarily administered while patients were hospitalized. A longer duration of CBT may be necessary to achieve significant effects. The CBT intervention we developed lasted for 10 weeks, running parallel with exercise therapy, and included follow-ups with a physiotherapist via phone every second week. One study in the review (172) indicated that CBT administered by physiotherapists improved early postoperative knee function, whereas CBT delivered by other professionals did not show the same effect.

Bennell et al. (2016 and 2017) demonstrated that a program combining Pain Coping Skills Training and exercise therapy for patients with knee osteoarthritis improved outcomes (123, 124). After 12 weeks, there was no difference in average pain, but

there was a significant improvement in function in the combined treatment group compared to each treatment alone. These differences persisted at 32 and 52 weeks. Although the average pain levels did not differ, more patients in the combined group experienced pain reduction than in the other groups.

This suggests that integrating cognitive skills into physical exercise may be more effective when physiotherapists deliver the CBT intervention.

Studies have shown that exercise and physical activity can improve pain and physical function for patients with knee osteoarthritis (3, 46). Postoperatively, exercise and physical activity are crucial for achieving good outcomes (75, 173). However, not all patients adhere to the advice given by healthcare professionals, and various factors can influence adherence. Jack et al. (2010) conducted a systematic review of quantitative studies examining barriers and facilitators for participating in physiotherapy among patients with various musculoskeletal issues (174). The findings revealed that low self-efficacy, depression, anxiety, helplessness, and poor social support were among the factors limiting participation. CBT, aimed at identifying and altering maladaptive thinking patterns, may address these limiting factors, thereby increasing participation in exercise therapy. In this way, the two treatment modalities can positively reinforce each other.

The iCBT program we developed targets patients with risk factors that predict poor surgical outcomes. Patient representatives participated in the planning, development, and testing of the program, providing valuable feedback. However, these representatives were not selected based on the presence of risk factors. Qualitative interviews with patients who had these risk factors could have provided a deeper understanding of their specific needs.

Study III

The primary purpose of conducting a feasibility study was to determine whether it was possible to carry out a randomized controlled trial (RCT) to assess the effectiveness of a combined intervention of cognitive behavioural therapy (CBT), education, and

exercise therapy for patients with osteoarthritis, either alone or in addition to surgery. The major uncertainties involved recruiting enough patients for the study and ensuring their retention throughout the follow-up period. Additionally, we aimed to test the feasibility of the iCBT program we developed, ensuring that the combined intervention and planned follow-ups could be successfully implemented. We also investigated whether patients remained in their assigned groups and monitored for any adverse events.

The results highlighted the necessity of this feasibility study before launching a full-scale RCT. Recruitment was particularly challenging, necessitating several adjustments during the study. Out of 350 patients evaluated for inclusion between August 2019 and June 2020, 15 patients were included.

The selection of inclusion criteria significantly influenced the number of eligible participants. Our study targeted patients at high risk of poor outcomes after total knee arthroplasty (TKA). Initially, we aimed to include only those with risk factors for poor surgical outcomes and those living near the two hospitals participating in the study. Screening for these factors were done before the surgeon had seen the patient which resulted in that several patients were screened who were not TKA candidates. These inclusion criteria were time consuming and limited the potential pool of participants substantially. Adjusting these criteria, resulted in an increased the number of eligible patients. Another challenge was the randomization process and obtaining informed consent. Giving a balanced information about the different interventions can be challenging while both the patient and the healthcare provider may have their own preferences. This is a known critical factor for increasing recruitment in randomized studies (175).

Recruiting patients for randomized studies is notoriously difficult (176, 177), particularly in orthopaedic studies comparing surgical and non-surgical treatments (151). Previous studies have shown that less than 50% of eligible patients are included, with some studies reporting inclusion rates as low as under 3% (151). More recent studies, such as Skou et al., have achieved better recruitment rates, including approximately 80% of eligible patients (3). Ensuring sufficient recruitment is essential

for the study to answer the research questions. Studies have shown that about half of all RCTs fail to meet their planned participant numbers (178, 179). Various interventions have been tested to improve recruitment rates, but demonstrating their effectiveness has been challenging (175).

A Rapid Review by Ninomiya et al (2023) identified key barriers to patient recruitment for RCTs, including patient treatment preferences, unwillingness to be randomized, and misunderstandings about clinical equipoise (180). Both patients and healthcare providers may have preferences for certain treatment arms, hindering participation in randomization (151, 177). The information provided to patients is crucial for their decision to participate and remain in the study and their assigned groups throughout the follow-up period. It is not enough to provide information; patients must understand it. Factors influencing patient understanding include the time available to convey information, patients' knowledge levels, and their health status. Study staff must be trained to provide balanced information and ensure it is understood before consent is given.

Experience from the feasibility study showed that good collaboration with the surgeons evaluating patients for inclusion was crucial for providing balanced information about the benefits and drawbacks of both treatment options. An independent study staff member, who had more time, provided additional information, and answered questions, enabling patients to make well-informed decisions. Regular meetings in the study group throughout the feasibility study continually improved collaboration with surgeons and patient information. These experiences were invaluable for the future RCT.

Effective information delivery is also critical for the study's progress. Well-informed patients about what the study entails and what to expect from each treatment arm are more likely to comply with the study requirements. A good relationship with study staff increases the likelihood of patient retention (151). Compliance with the feasibility study was good. Thorough information and phone call every second week, likely contributed to the high participation rates. Participation in the iCBT intervention was slightly lower than in the education and exercise therapy intervention. Feedback from

participants and the guiding physiotherapists led to further improvements in the program before the RCT commenced.

The small number of participants means that the results from the feasibility study cannot be generalized to the larger RCT population. However, the feasibility study provided valuable insights, confirming the possibility of conducting an RCT with the proposed adjustments that led to adjustments in the RCT protocol (156).

6.3 Summary of the main results

In this study, we assessed the digital health literacy of patients who had undergone total hip and knee arthroplasty surgeries. The results indicate that older patients with lower education levels have the lowest digital health literacy. Among the various domains of digital health literacy, those related to engagement in digital services and feeling safe and in control, had the strongest association with health-related quality of life. We developed a digital cognitive-behavioural therapy (iCBT) program tailored to patients with knee osteoarthritis, particularly targeting those at increased risk of persistent pain following total knee arthroplasty surgery.

We conducted a feasibility study, which revealed challenges in recruiting patients; however, with the modifications made during the feasibility phase, it was deemed feasible to conduct a full-scale RCT. Several adjustments, such as simplification of the language and making it easier to navigate in the program, were suggested for the iCBT program to better accommodate patients with low digital health literacy. The adherence to the therapy sessions and follow-ups were high. No patients crossed over to another group during the study, and no serious adverse events were reported.

6.4 General conclusions and clinical implications

A key focus in modern healthcare is involving patients in shared decision-making regarding their treatment. However, this process can be challenging for both clinicians and patients. For patients to actively participate in decisions about their health, it is crucial that they are engaged and trust their healthcare providers, enabling them to express their uncertainties and preferences honestly. Patients with low health literacy

may struggle to comprehend the information provided and understand the implications of different treatment options. This situation places a significant demand on clinicians' communication skills, requiring them to tailor information to each patient, which can be very time-consuming. While digital tools can support the shared decision-making process for some patients our study shows that up to one in three hip and knee arthroplasty patients have low digital health literacy. As a result, these patients may face challenges in utilizing these resources effectively and may require additional support.

Despite the rapid and positive advancements in surgical techniques and joint implants, a significant proportion of patients undergoing total knee arthroplasty (TKA) remain dissatisfied with the results after one year. This dissatisfaction is a substantial burden for the affected patients and represents a significant cost to society. A wide range of physical and psychological factors can increase the risk of prolonged issues following TKA, suggesting that a biopsychosocial model is beneficial in approaching these patients. The internet-delivered cognitive behavioural therapy (iCBT) program we developed in this study, combined with education and an individual adjusted exercise therapy program, may be beneficial for the most vulnerable patients. The program has been through multiple adjustments to tailor it to patients with lower digital health literacy, although they may need some support to getting started. The ongoing RCT (156) is investigating the effectiveness of the combined intervention and will hopefully provide an answer as to whether this intervention will be beneficial for patients with knee osteoarthritis and total knee arthroplasty.

6.5 Future perspectives

The ongoing RCT study which has completed the recruitment and expect to complete 12-month follow-up in 2025 is testing the effectiveness of the combined intervention of iCBT, education, and exercise therapy, either alone or in addition to surgery. This study will determine if this is a viable treatment for patients with knee osteoarthritis. This comprehensive treatment is probably not necessary for all patients with knee osteoarthritis. Therefore, in the future, it is crucial to establish criteria for identifying

those who are at risk of a poor result after total knee arthroplasty surgery and may benefit from this complex intervention. Developing a screening instrument that undergoes thorough validity and reliability testing could assist healthcare providers (doctors, surgeons, physiotherapists, nurses, and others involved with these patients) in guiding patients to the best treatment for everyone.

To provide quality healthcare to everyone, it is essential to consider the digital health literacy of the population when developing and implementing new digital tools and services. Normative data can thus be helpful in tailoring digital tools and services to a specific group of patients. Efforts to improve digital health literacy, especially for older patients with low education levels, are crucial to ensuring equal opportunities for all in an increasingly digital society.

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PAPERS

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PAPER I

Digital Health Literacy in Norwegian Patients Undergone Hip and Knee Arthroplasty Surgery – Normative data from a cross-sectional study.

Rognsvåg T, Nordmo IK, Bergvad IB, Fenstad AM, Furnes O, Lerdal A, Lindberg MF, Skou ST, Badawy M.

Acta Orthopaedica - in review

Digital Health Literacy in Norwegian Patients Undergone Hip and Knee Arthroplasty Surgery – Normative data from a cross-sectional study.

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Abstract

Background and purpose

As digital health services become increasingly important in osteoarthritis treatment, understanding patients' digital health literacy (eHL) is crucial, including those undergoing total hip and knee arthroplasty (THA/TKA). We aimed to 1) provide eHL norms in a representative group of Norwegian patients, and 2) examine the relationships between eHL and health related Quality of Life (QoL).

Methods

We invited 800 randomly selected THA/TKA patients from the Norwegian Arthroplasty Register to complete a paper-based questionnaire which included sociodemographic variables. eHL was measured using the eHealth Literacy Questionnaire (eHLQ) with 7 domains: Using technology, Understand, Engage, Control, Motivation, Access, and Needs, scored from 1 (strongly disagree) to 4 (strongly agree). The EuroQol EQ-5D-5L measured health related QoL. We used multivariable regression to examine relationships between eHL domains and health related QoL controlling for sociodemographic variables.

Results

Respondents' (N=383, 48%) mean age was 70 years (SD=9.00) and 246 (64%) were female. Mean eHLQ and the proportion of patients with low eHL (≤2,5) were Technology 2.74 (34.3%), Understanding 3.00 (14.3%), Engage 2.86 27.6%), Control 3.15 (7.7%), Motivation 2.75 34.6%), Access 2.80 32.7%), and Needs 2.64 (45.7%). Lower eHL correlated with older age and lower education, but not with sex or type of surgery. Regression analyses showed that lower scores on the domains Technology, Engage, Control, Access, and Needs were associated with poorer QoL after adjusting for sociodemographic factors.

Conclusion

About one-third of THA/TKA patients have lower eHL, and lower eHL was associated with QoL. Findings from this study should be considered when developing digital health services for THA and TKA patients.

Keywords: digital health literacy, osteoarthritis, knee arthroplasty, hip arthroplasty

Introduction

The aging population (1) is projected to increase the burden of osteoarthritis (OA), and the incidence of total hip and knee arthroplasty (THA/TKA) procedures worldwide is growing (2). To avoid overburdening the health care system, patients are increasingly expected to manage their condition using digital health resources, including internet-delivered educational material and videoconferencing sessions with physiotherapists (3), cognitive behavioral programs (4) or smartphone applications for home exercise programs (5). Communication with healthcare providers increasingly occurs digitally. To develop digital services that provide equal healthcare for all patients, it is essential to have knowledge regarding the competency within the specific patient group.

Digital health literacy refers to "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" (6). Studies have demonstrated that high general and digital health literacy are associated with enhanced self-perceived health in Chinese community-dwelling older adults (<65 years) (7) and improved health related quality of life (QoL) in European Union citizens aged 15 and older (8). A large European survey of residents in 13 European countries, aged ≥18, (9) suggests that older individuals (>76 years) and those with lower educational levels tend to have lower digital health literacy (9). However, little is known about digital health literacy among patients with OA and THA/TKA. This is important to know to tailor health interventions and services to the patient group and form a basis for later studies.

To address this knowledge gap, this study aimed to 1) describe digital health literacy levels in multiple domains by age and education among patients who have undergone hip or knee arthroplasty and 2) analyze how digital health literacy was related to their health related QoL controlling for selected sociodemographic factors.

Methods

Participants

A sample of 800 patients, at least 18 years of age, who had undergone primary total hip (n=400) or knee (n=400) arthroplasty between 6 to 11 months prior, were randomly selected from the Norwegian Arthroplasty Register (NAR) in April 2022. A sample size of 800 was chosen based on an anticipated response rate of approximately 50%, and we intended to divide the sample into subgroups based on age, sex, and education level. This sample

consisted of patients from all counties in Norway to match the Norwegian hip and knee arthroplasty population.

All selected patients received written information about the study, a written consent form and a paper questionnaire by mail between May and August 2022. Due to slow mail delivery and time constraints in the study, no reminder was sent. Those who wished to participate signed the consent form, filled in the questionnaire, and returned both in a sealed, opaque prepaid envelope.

Measures

Sociodemographic variables

The sociodemographic data included age, sex, educational level, and type of surgery (hip/knee). For describing norm data age was divided into three groups: younger age (<65 years) medium age (65-74 years) or older age (≥75 years). In the other analysis age was used as a continuous variable. Educational level was dichotomized as low = ≤high school (level 0-4 according to International Standard Classification of Education 2011 (ISCED-11)) (10) or high = university (ISCED-11 level 5-8).

Digital Health Literacy

Many questionnaires are available that measure digital health literacy (11). The most widely used questionnaire (eHEALS) was developed by Skinner et al. in 2006 (12), before the widespread use of social media and mobile applications. This questionnaire measures the ability to find and evaluate information on the internet but lacks information on other dimensions of digital health literacy. We chose the eHealth Literacy Questionnaire (eHLQ) (13) in this study because it was developed based on the digital health literacy framework described by Nordgaard et al. in 2015 (14), and since it better reflects eHealth of today. The disadvantage of the eHLQ, is that it has not been as thoroughly tested for psychometric properties as the eHEALS instrument. However, recent tests conducted in Denmark, Sweden, and Norway show good properties (13, 15, 16). We used the Norwegian version of the original eHealth Literacy Questionnaire (eHLQ) (13), which consists of 35 items assessing the 7 domains of the eHealth Literacy Framework: 1) using technology to process health information (Using technology, 5 items), 2) understanding of health concepts and language (Understanding, 5 items), 3) ability to actively engage with digital services (Engage, 5 items),

4) feel safe and in control (Control, 5 items), 5) motivated to engage with digital services (Motivation, 5 items), 6) access to digital services that work (Access, 6 items), 7) digital services that suit individual needs (Needs, 4 items). The original Danish version of eHLQ has satisfactory construct validity and reliability across a broad range of concepts in various groups (13). Confirmatory factor analysis in a preliminary validity testing of the Norwegian version found that almost all factor loadings were high to acceptable (15). All items are scored on a 4-point Likert scale ranging from 1= strongly disagree to 4= strongly agree, with higher scores indicating higher digital health literacy. Each domain is scored separately by summing the score on each item and dividing it by the number of items scored. If >50% of the items in a domain were missing, a mean score was not calculated for that domain according to the guidelines for the original questionnaire. There is no consensus on what is "low" or" high" digital health literacy. Zangger et al. (2024) (17) have in concordance with the eHLQ developer Lars Kayser and the Region Zealand health Survey report (18) used a cut-off on ≤2.0 representing "insufficient" (lowest scores) and >2 to 2.5 representing "insufficient". Based on this, we dichotomized the eHLQ score as low eHL = ≤2.5 and high eHL = >2.5.

Health related Quality of Life and self-rated health

Health related QoL was measured using the EuroQol EQ-5D-5L (19), consisting of the EQ index (Health related QoL) and the EQ VAS. The EQ index includes five items assessing different dimensions of health status (mobility, selfshowing-care, usual activities, pain/discomfort, anxiety/depression). Each dimension is scored on a 5-point Likert scale with five categories from 1=no problems to 5=extreme problems and transformed into an index on a scale ranging from less than 0 (worse than dead) to 1 (no problems). The EQ VAS is a measure of self-rated health using a vertical visual analogue scale from 0 ("The worst health you can imagine") to 100 ("The best health you can imagine") (20). The EQ-5D-5L is reliable and valid for this patient group (21).

Statistics

Data were analyzed using the Statistical Package for Social Sciences (IBM SPSS) version 28 (22). Descriptive statistics were used to describe the sample's digital health literacy levels, sociodemographic characteristics, and health related QoL. Digital health literacy norms by age group, sex and educational level are presented as means, standard deviations and ranges. The proportion of patients with "low" digital health literacy, is presented as number and percent,

by age, level of education, and type of surgery. Independent-sample proportion test was used to explore the difference in proportions with low digital health literacy between age groups, levels of education and type of operation. Correlations between the 7 digital health literacy domains and age, sex, and educational level were investigated using a Pearson product-moment correlation coefficient which can take a level between -1 and 1 where 0 refers to no correlation, -1 refers to perfect negative correlation (as one variable increases, the other decreases) and 1 refers to a perfect positive correlation (as one variable increases, so too does the other). Preliminary analyses were performed to ensure no violation of the assumptions of normality and linearity.

Univariable and separate multivariable linear regression models adjusting for selected sociodemographic factors (age, sex, education level, and type of surgery) were used to investigate how each of the digital health literacy domains were related to health related QoL (EQ-5D-5L) and self-reported health (EQ VAS). Preliminary analyses were conducted to ensure no violation of the assumptions of normality, linearity, multicollinearity, and homoscedasticity. The 7 digital health literacy domains were strongly correlated to each other (Table 4), with most of the correlations exceeding 0.7. These correlations may suggest multicollinearity which violates the assumptions for multivariable linear regression models. Therefore, for the multivariable regression models we decided to perform separate regression models for each dimension, while controlling for the relevant confounders.

Results

Response rate

A total of 404 (51%) patients consented to participate and returned the questionnaire. 21 (5%) of the responders had more than 50% missing values on the eHLQ and were excluded. The remaining 383 patients (48%) of the original sample were included in the analysis, 198 (52%) had knee arthroplasty and 185 (48%) had hip arthroplasty.

Patient characteristics

Sample characteristics are presented in Table 1. Age, sex, and type of surgery of non-responders did not differ significant from the responders. Patients' age and sex are consistent with those of the OA population undergoing hip and knee arthroplasty in Norway (23). eHLQ scores by age group and education level for each of the 7 domains are presented in Table 2

and divided in each sex in Supplementary tables 1 and 2. Age ≥75 years and education ≤high school show the lowest digital health literacy score (from 2.41 (SD 0.70) in "use technology", to 3.12 (SD 0.38) in "control"), while age <65 years and education >high school show highest digital health literacy score (from 2.75 (SD 0.53) in "access", to 3.21 (SD 0.59) in "engage"). Domain 4 (Feel safe and in control) has the highest score (3.15, SD 0.50) and domain 7 (Digital services that suit individual needs) has the lowest score (2.64, SD 0.65) regardless of age and education level.

The proportion of patients with low eHLQ score by age, education and type of surgery and the difference between age groups, levels of education and type of surgery, are presented in Table 3. 46% of the responders did not agree that the digital services suit individual needs (Domain 7) while only 7% did not agree that they feel safe and in control (domain 4). There was no difference between hip and knee arthroplasty patients except for domain 1 (using technology to process health information) where more patients with knee arthroplasty had low score.

Correlations

The correlations between the digital health literacy domains and age, sex, educational level, and health related QoL, are shown in Table 4. There were no significant correlations between sex and the digital health literacy domains. Age was negatively correlated ($p<0.01$) with all digital literacy domains except domain 4 (Control). Educational level was positively correlated with digital health literacy domains 1 (Using technology), 2 (Understanding) and 3 (Engage). Health related QoL (EQ Index) was positively correlated with domain 3 (Engage) and 4 (Control), 6 (Access) and 7 (Needs). The correlation was small according to the guidelines suggested by Cohen (1988) (small = 0.10 to 0.29, medium = 0.30 to 0.49, large = 0.50 to 1.00).

Multivariable linear regression analysis

Results from the separate multivariable linear regression analysis showed that digital health literacy domain 1 (Using technology), 3 (Engage), 4 (Control), 6 (Access), and 7 (Needs) were positively associated with health related QoL, when adjusted for patients' age, sex, education level, and type of surgery (Table 5). The strongest association was found in domain 3 (engage) and 4 (control), where the unstandardized coefficient (B) tells us that for each unit change in eHLQ there will be 0.04 unit change in health related QoL. The association between digital health literacy and self-reported health (EQ VAS) is shown in Supplementary table 3 and

demonstrated associations with most domains, with the strongest association with domain 3 (Engage).

Discussion

In this study, we analyzed digital health literacy by age and education in a population that has undergone THA and TKA surgery. We presented norm data and found that digital health literacy in this population varied by age and educational level with younger patients with high educational level having the highest digital health literacy score. Health related QoL were associated with some of the digital health literacy domains.

To the authors' knowledge, norm data for digital health literacy was not available for THA/TKA patients prior to our study. A scoping review by Wang et al. et al. (2022) (24) summarized that digital health literacy among older adults was lower in those with lower education levels. This is comparable to the findings in our study. Cerid et al. (2020) (25) showed in their study on people ≥50 years with recent fractures, that there was no difference in digital health literacy between the male and female and between age groups of 50-64 years and 65-74 years, while the age group over 75 years had lower digital health literacy. However, they did not account for education level. We have described digital health literacy in three age categories (<65, 65-74, and ≥75) by education level and sex. Our data can therefore be used to compare digital health literacy with other studies across various age groups, sex, and educational levels. The results from our study can form the basis for observing changes in digital health literacy over time. The goal is to offer equal health treatment and service to all patients. The findings from this study can contribute to tailoring services for THA and TKA patients.

Our study demonstrated an association between health related QoL and some domains of digital health literacy. This is similar to what Filabadi et al. (2020) (26) showed in their study on 400 clients of different community health centers in Teheran, aged 17-75 years, where they found that digital health literacy was positively correlated with patients' health related QoL. The relationship between digital health literacy and health related QoL demonstrated in this study is valuable knowledge when developing interventions tailored to improve health related QoL in the population. By enhancing digital health literacy and tailoring services and treatment to the health literacy of the specific patient group, it can contribute to improving the quality of life within that group.

Norway is a country with a high degree of digitalization in the society. 9 out of 10 use the BankID which is an electronic signature solution, and in 2020 80% of the Norwegian citizens were active users of the national health portal (Helsenorge.no) to get access to health care services, communicate with health professionals and get access to health information. Holt et al. (2019) (27) showed in their study that active users of corresponding services in Denmark, had higher digital health literacy than non-users. The high degree of digitalization in society may result in higher digital skills among the citizens. The European survey described great differences between European countries (9). Thus, the result in our study may not be generalizable to other countries with lower grade of digitalization.

A strength of this study is the large number of participants randomly selected from the Norwegian Arthroplasty Register (NAR) and representing all counties in Norway. Sociodemographic variables matched all THA and TKA patients registered in the NAR (23), and the distribution of age and sex in non-responders were not different from the responders.

Another advantage was that the questionnaires were on paper and sent by regular mail, thus not excluding individuals who do not have access to a digital device or those with low digital competence.

This study also had some limitations. Although all counties in Norway were represented and the age and sex distribution in our study were similar to all patients registered in NAR, it is possible that this sample was not representative for the entire Norwegian THA/TKA population with regard to other variables such as education or physical status.

The response rate in this study was 48%. According to a recent review by Edwards et al. (2023) (24) contacting patients in advance, sending reminder letters, or offering an incentive to patients who respond can increase response rate. However, due to limited time and resources, we were unable to apply these methods. To achieve the highest possible response rate, we emphasized making the questionnaire as short as possible, providing an explanation in simple language, and including a prepaid return envelope. The low response rate may have influenced the representativeness. Cognitive function declines with increasing age in the general population and among patients with osteoarthritis (25). We have not tested cognitive function in this population. We also do not have information on the education level of the non-responder group. It is possible that patients with reduced cognitive function and low educational level are overrepresented in the non-responder group, hence affecting representativeness.

This is a cross-sectional study that cannot establish a causal relationship between health related QoL and digital health literacy. It also does not provide information on how digital health literacy changes over time.

We examined digital health literacy in patients who had undergone total joint arthroplasty 6-11 months ago. In another study, general health literacy in TKA patients increased from before surgery, to 3 and 6 months after surgery (28). Hence, the results from our study may not be representative for OA patients without knee and hip arthroplasty.

Another limitation is that we only used self-reported data to measure the patients' digital health literacy. Self-reported competence may not reflect the patients' actual competence. Some patients may overestimate their abilities, while others may underestimate them. Additionally, patients with low digital health literacy might be over- or under-represented among non-responders, even though we used paper questionnaires.

In conclusion, findings from our study are useful for clinical practice and the development of future interventions and services. In the clinic, it may be beneficial to assess patients' digital health literacy to tailor services according to their competencies and to offer support for the use of digital services to those with low digital health literacy and ensuring that there are non-digital alternatives. Nearly half of the patient group in this study reported that digital services do not suit their needs. This should have implications for how we develop new digital services, for example, by actively involving user representatives throughout the entire development process. Future studies may investigate whether improving digital health literacy levels may contribute to improved health related QoL in this patient group.

Authors' contributions

TR: Conceptualization, Methodology, Writing - Original Draft

IKN: Data collection, Writing - Review & Editing

IBB: Data collection, Writing - Review & Editing

AMF: Data Collection, Writing – Statistics, Review & Editing

OF: Supervision, Writing - Review & Editing

AL: Conceptualization, Methodology, Writing - Review & Editing

MFL: Conceptualization, Methodology, Statistics, Supervision, Writing – Review & Editing

STS: Supervision, Writing - Review & Editing,

MB: Supervision, Writing – Original Draft

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Ethics approval and consent to participate.

The study has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki and the regulations of the US Health Insurance Portability and Accountability Act (HIPAA).

The Regional Medical Research Ethics committee of Health East of Norway approved the study (2017/968).

Written informed consent was obtained from all subjects.

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Table 1 Sociodemographics and health related QoL[i] score of responders (n=383) and age, sex, and surgery of non-responders (n=417)

	Responders	Non-responders	
			p[ii]
Age: mean (max, min) SD	70 (39,94) 9	69 (40,92)11	0.32
	n (%)	*n (%)*	
<65 years	98(26%)	127 (30%)	
65-74 years	152(40%)	137 (33%)	0.11
≥75	133 (34%)	153 (37%)	
Sex			
Male	137(36%)	136 (33%)	0.35
Female	246(64%)	281 (67%)	
Operation			
Hip	185 (48%)	214 (52%)	0.40
Knee	198 (52%)	203 (48%)	
Education			
Lower education (less than 13 years)	229 (60%)		
Higher education (13 years and more)	151 (39%)		
Health related QoL (EQ Index): mean (max, min (SD)	0.88 (0.07,1.00) 0.14		

[i] QoL=quality of life
[ii] Pearson Chi-Square

Table 2 Digital Health Literacy Questionnaire mean scores by age group and level of education.

	Age	Education level		
		≤high school	>high school	All education levels.
		Mean (SD) Range	Mean (SD) Range	Mean (SD) Range
Domain 1 Using technology to process health information	<65	2.81 (0.63) 2.60	3.06 (0.48) 1.80	2.95 (0.59) 2.60
	65-74	2.73 (0.70) 3.00	2.95 (0.44) 2.20	2.81 (0.61) 3.00
	≥75	2.41 (0.70) 3.00	2.61 (0.74) 2.80	2.49 (0.72) 3.00
	All ages	2.65 (0.69) 3.00	2.87 (0.59) 3.00	2.74 (0.66) 3.00
Domain 2 Understanding of health concepts and language	<65	3.02 (0.52) 2.20	3.17 (0.42) 1.60	3.08 (0.48) 2.20
	65-74	2.98 (0.53) 3.00	3.14 (0.45) 1.80	3.04 (0.50) 3.00
	≥75	2.85 (0.46) 2.20	2.97 (0.57) 3.00	2.89 (0.50) 3.00
	All ages	2.94 (0.51) 3.00	3.09 (0.49) 3.00	3.00 (0.50) 3.00
Domain 3 Ability to actively engage with digital services	<65	2.86 (0.66) 3.00	3.21 (0.59) 2.00	3.02 (0.69) 3.00
	65-74	2.80 (0.66) 3.00	3.19 (0.48) 2.20	2.96 (0.62) 3.00
	≥75	2.50 (0.73) 3.00	2.74 (0.75) 3.00	2.59 (0.62) 3.00
	All ages	2.72 (0.71) 3.00	3.05 (0.64) 3.00	2.86 (0.70) 3.00
Domain 4 Feel safe and in control	<65	3.19 (0.48) 1.80	3.12 (0.52) 2.60	3.17 (0.50) 2.60
	65-74	3.20 (0.50) 2.20	3.16 (0.57) 3.00	3.18 (0.53) 3.00
	≥75	3.12 (0.38) 2.00	3.04 (0.60) 3.00	3.09 (0.47) 3,00
	All ages	3.17 (0.45) 2.20	3.11 (0.57) 3.00	3.15 (0.50) 3.00
	<65	2.87 (0.61) 2.25	2.87 (0.43) 1.80	2.87 (0.54) 2.25

Domain 5 Motivated to engage with digital services	65-74	2.79 (0.64) 3.00	2.91 (0.47) 2.00	2.83 (0.58) 3.00
	≥75	2.54 (0.66) 3.00	2.57 (0.61) 3.00	2.55 (0.64) 3.00
	All ages	2.72 (0.65) 3.00	2.79 (0.53) 3.00	2.75 (0.60) 3.00
Domain 6 Access to digital services that work	<65	2.93 (0.57) 2.20	2.75 (0.53) 2.50	2.56 (0.56) 2.50
	65-74	2.89 (0.62) 3.00	2.92 (0.42) 1.80	2.90 (0.54) 3.00
	≥75	2.63 (0.59) 2.83	2.62 (0.61) 2.83	2.63 (0.59) 3.00
	All ages	2.81 (0.61) 3.00	2.78 (0.53) 3.00	2.80 (0.58) 3.00
Domain 7 Digital services that suit individual needs	<65	2.86 (0.63) 2.75	2.78 (0.51) 2.25	2.77 (0.58) 2.75
	65-74	2.68 (0.69) 3.00	2.90 (0.56) 2.50	2.44 (0.64) 3.00
	≥75	2.42 (0.65) 2.00	2.39 (0.64) 3.00	2.41 (0.64) 3.00
	All ages	2.60 (0.67) 3.00	2.70 (0.61) 3.00	2.64 (0.65) 3.00

Tabell 3 Differences in proportions with low digital health literacy[iii] by age, education level and type of surgery.

Domain		*n (%)*	95% CI of the difference	Total sample *n (%)*
1 Using technology to process health information	Age <65	*26 (6.9)*	-0.10/0.06	*130 (34.3)*
	Age ≥65	*104 (27.4)*		
	Low education[iv]	*93 (41.2)*	**0.08/0.27**	
	High education[v]	*35 (23.3)*		
	THA[vi]	*52 (28.6)*	**-0.20/-0.15**	
	TKA[vii]	*78 (39.6)*		
2 Understanding of health concepts and language	Age <65	*19 (5.0)*	-0.20/-0.01	*54 (14.3)*
	Age ≥65	*86 (22.6)*		
	Low education	*39 (17,3)*	**0.001/0.14**	
	High education	*15 (10.0)*		
	THA	*23 (12.6)*	-0.10/0.04	
	TKA	*31 (15.8)*		
3 Ability to actively engage with digital services	Age <65	*19 (5.0)*	**-0.20/-0.01**	*105 (27.6)*
	Age ≥65	*86 (22.6)*		
	Low education	*79 (34.8)*	**0.09/0.26**	
	High education	*26 (17.3)*		
	THA	*48 (26.4)*	-0.11/0.07	
	TKA	*57 (28.8)*		
4 Feeling safe and in control	Age <65	*9 (2.4)*	-0.04/0.09	*29 (7.7)*
	Age ≥65	*20 (5.3)*		
	Low education	*13 (5.8)*	-0.11/0.01	
	High education	*16 (10.7)*		
	THA	*13 (7.1)*	-0.07/0.04	
	TKA	*16 (8.2)*		
5 Motivated to engage with digital services	Age <65	*26 (6.9)*	**-0.21/-0.003**	*130 (34.6)*
	Age ≥65	*104 (27.7)*		
	Low education	*85 (38.1)*	-0.003/0.19	
	High education	*43 (38.1)*		
	THA	*62 (34.4)*	-0.10/0.09	

[iii] Low digital health literacy=≤2.5
[iv] Low education= ≤high school (level 0-4 according to International Standard Classification of Education 2011 (ISCED-11)
[v] High education= >high school. University (ISCED-11 level 5-8)
[vi] THA= Total hip arthroplasty
[vii] TKA= total knee arthroplasty

	TKA	*68 (34.7)*		
6 Access to digital services that work	Age <65	*29 (7.7)*	-0.15/0.07	*124 (32.7)*
	Age ≥65	*95 (25.1)*		
	Low education	*71 (31.6)*	-0.13/0.07	
	High education	*52 (34.4)*		
	THA	*62 (34.1)*	-0.07/0.12	
	TKA	*62 (31.5)*		
7 Digital services that suit individual needs	Age <65	*36 (9,6)*	**-0.23/-0.01**	*171 (45.7)*
	Age ≥65	*135 (36.1)*		
	Low education	*111 (50.2)*	**0.01/0.21**	
	High education	*59 (39.3)*		
	THA	*83 (46.4)*	-0.09/0.11	
	TKA	*88 (45.1)*		

Table 4: ***Pearson correlations between eHLQ[viii] and age, gender, education, EQ VAS[ix]***

					eHLQ Domain						
		Age	Female	Education	1	2	3	4	5	6	7
Female		0.04									
Education		**-0.18[x]**	-0.04								
eHLQ Domain[xi]	1	**-0.29x[x]**	-0.01	**0.21[x]**							
	2	**-0.17[x]**	-0.00	**0.19[x]**	**0.75[x]**						
	3	**-0.30[x]**	-0.04	**0.29[x]**	**0.87[x]**	**0.70[x]**					
	4	-0.09	-0.01	-0.05	**0.47[x]**	**0.59[x]**	**0.45[x]**				
	5	**-0.21[x]**	-0.05	0.09	**0.85[x]**	**0.75[x]**	**0.74[x]**	**0.56[x]**			
	6	**-0.17[x]**	-0.04	-0.01	**0.76[x]**	**0.67[x]**	**0.70[x]**	**0.65[x]**	**0.81[x]**		
	7	**-0.24[x]**	-0.06	0.09	**0.81[x]**	**0.67[x]**	**0.78[x]**	**0.55[x]**	**0.85[x]**	**0.84[x]**	
EQ VAS		0.10	-0.07	0.13	**0.13[x]**	0.12	**0.23[x]**	0.08	0.11	0.13	**0.16[x]**
EQ Index		0.03	-0.02	0.12	0.07	0.10	**0.17[x]**	**0.14[x]**	0.07	0.11	0.12

[viii] eHLQ=eHealth Literacy Questionnaire

[ix] EQ VAS=self-reported health on a 0-100 visual analogue scale

[x] correlation is significant at the 0.01 level (2-tailed)(**bold**)

[xi] eHLQ Domains= 1. Using technology to process health information, 2. Understanding of health concepts and language, 3. Ability to actively engage with digital services 4. Feel safe and in control, 5. Motivated to engage with digital services, 6. Access to digital services that work, 7. Digital services that suit individual needs

Table 5 Linear regression analyses of associations between the eHealth literacy domains and health-related quality of life.

	Univariable regression coefficients			Separate multivariable regression coefficients adjusted for covariates		
eHLQ domain	**B[1]**	**Beta[2]**	**95% CI[3]**	**B[1]**	**Beta[2]**	**95% CI[3]**
1 Using technology	0.02	0.07	-0.01, 0.04	**0.01**	**0.07**	**0.01, 0.04**
2 Understand	0.03	0.10	-0.001, 0.06	0.02	0.08	-0.01, 0.05
3 Engage	**0.03**	**0.17**	**0.01, 0.06**	**0.04**	**0.18**	**0.01, 0.06**
4 Control	**0.04**	**0.14**	**0.01, 0.07**	**0.04**	**0.15**	**0.02, 0.07**
5 Motivation	0.02	0.07	-0.01, 0.04	0.02	0.07	-0.01, 0.04
6 Access	**0.03**	**0.11**	**0.001, 0.05**	**0.03**	**0.12**	**0.004, 0.06**
7 Needs	**0.03**	**0.12**	**0.003, 0.05**	**0.03**	**0.13**	**0.01, 0.05**
Covariates						
Age	0.0005	0.03	-0.001, 0.002			
Sex (Male=0, Female=1)	-0.01	-0.02	-0.04, 0.03			
Education	0.03	0.09	-0.004, 0.06			
Surgery (THA=1, TKA=2)	-0.03	-0.10	**-0.06, -0.001**			

Dependent variable: EQindex. [i] The unstandardized coefficient B = change in EQ Index by each unit change in eHLQ. [2]Standardized beta coefficients. [3]Confidence intervals are for the unstandardized coefficients.

Abbreviations: CI= Confidence Interval. eHLQ=eHealth Literacy Questionnaire. Health Literacy domains = 1. Using technology to process health information, 2. Understanding of health concepts and language, 3. Ability to actively engage with digital services 4. Feel safe and in control, 5. Motivated to engage with digital services, 6. Access to digital services that work, 7. Digital services that suit individual needs, THA=total hip arthroplasty, TKA= total knee arthroplasty

PAPER II

Development of an internet-delivered cognitive behavioural therapy program for use in combination with exercise therapy and education by patients at increased risk of chronic pain following total knee arthroplasty.

Rognsvåg T, Lindberg MF, Lerdal A, Stubberud J, Furnes O, Holm I, Indrekvam K, Lau B, Rudsengen D, Skou ST, Badawy M.

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Development of an internet-delivered cognitive behavioral therapy program for use in combination with exercise therapy and education by patients at increased risk of chronic pain following total knee arthroplasty

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Abstract

Background: Approximately 20% of patients experience chronic pain after total knee arthroplasty (TKA). Due to the growing number of TKA procedures, this will affect an increasing number of people worldwide. Catastrophic thinking, dysfunctional illness perception, poor mental health, anxiety and depression characterize these non-improvers, and indicate that these patients may need individualized treatment using a treatment approach based on the bio-psycho-social health model. The present study developed an internet-delivered cognitive behavioral therapy (iCBT) program to be combined with exercise therapy and education for patients with knee osteoarthritis (OA) at increased risk of chronic pain after TKA.

Methods: The development process followed the first two phases of the UK Medical Research Council framework for complex interventions. In the development phase, the first prototype of the iCBT program was developed based on literature review, established iCBT programs and multidisciplinary workshops. The feasibility phase consisted of testing the program, interviewing users, condensing the program, and tailoring it to the patient group. A physiotherapist manual was developed and adapted to physiotherapists who will serve as mentors.

Results: The development process resulted in an iCBT program consisting of 10 modules with educational texts, videos and exercises related to relevant topics such as goalsetting, stress and pain, lifestyle, automatic thoughts, mindfulness, selective attention, worry and rumination. A physiotherapist manual was developed to guide the physiotherapists in supporting the patients through the program and to optimize adherence to the program.

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Conclusions: The iCBT program is tailored to patients at risk of chronic pain following TKA, and may be useful as a supplement to surgery and/or exercise therapy. A multicentre RCT will evaluate the iCBT program in combination with an exercise therapy and education program. This novel intervention may be a valuable contribution to the treatment of OA patients at risk of chronic pain after TKA.

Trial registration: The RCT is pre-registered at ClinicalTrials.gov: NCT03771430 11/12/2018.

Keywords: Osteoarthritis, Total knee arthroplasty, Cognitive behavior therapy, Physical exercise

Background

Total knee arthroplasty (TKA) for osteoarthritis (OA) is quite a successful procedure, with improvements in pain, function and quality of life [1, 2]. However, studies consistently show that 20% of patients have questionable benefit from TKA and continue to experience pain and poor function without clinical explanation [3, 4] and without any effective treatments available [5]. The incidence of TKA procedures worldwide is growing [6], with more than 700,000 procedures annually in the United States alone [7], and is estimated to increase by 143% by 2050 [8]. Thus, TKA non-responders represent a large and growing number of patients who continue to suffer from unrelieved pain and poor function [9, 10]. Consequently, they are less likely to return to work and more likely to be high consumers of health care services [11–13]. Current treatment modalities for knee OA are based on the Osteoarthritis Research Society International (OARSI) recommendations for evidence-based treatment, which include education, exercise, lifestyle alterations, weight loss when relevant, and analgesics [14]. The effectiveness of exercise is comparable to that of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), with effects lasting at least 2 to 6 months [15]. Patients with moderate to severe OA who do not benefit from non-surgical interventions may be considered candidates for TKA surgery. A recent study by Skou and colleagues tested a non-surgical treatment program based on the OARSI recommendations alone or as postoperative follow-up after TKA. While the TKA group had larger improvements in pain and function over time, the non-surgical group also showed clinically relevant improvements. Only 26 and 32% of them decided to undergo surgery 12 and 24 months after the intervention, respectively [1, 16]. These results demonstrate the beneficial impact of non-surgical interventions on OA symptoms.

However, the OARSI-based treatment modalities alone may not be sufficient for all patients. A growing literature suggests that non-improvers following TKA have a distinct preoperative psychological profile characterized by catastrophic thinking [17], dysfunctional illness perception [4], poor mental health [18], anxiety [19] and depression [20]. These factors may hamper engagement in physical activity and rehabilitation due to pain-related fear of movement or motivational problems [21, 22]. Such factors can represent a pathway that may cause a poor outcome following TKA surgery. As such, these patients may need individualized treatment using a more comprehensive treatment approach based on the bio-psycho-social health model [23].

In cognitive behavioral therapy (CBT), pain is recognized as a complex, subjective phenomenon, and the use of CBT in the management of chronic pain thus fits well with the bio-psycho-social health model [24, 25]. Research has shown that, whether administered alone or in combination with medical or interdisciplinary rehabilitation treatment, CBT improved pain and related problems in chronic pain patients [26, 27]. The gate control theory [28], although not correct in detail [29], forms the basis of psychological treatment of pain and emphasizes the importance of cognitive and affective, as well as sensory, influences on pain. The premise for CBT in relation to pain is to identify and modify pain-enhancing thinking patterns, or cognitions, maladaptive behavior and situations that contribute to the maintenance of psychological distress, which may lead to further progression of pain [30]. The aim of CBT utilization is to reduce pain and psychological distress, in addition to increasing adaptive behaviors such as participation in exercises and day-to-day activities. A CBT protocol developed by Turk et al. [31] addresses a number of psychological factors that may impact pain intensity and disability, such as catastrophic thinking [32, 33], fear-avoidance [34], low self-efficacy, helplessness and lack of perceived control [35–38], in addition to passive pain coping strategies [39]. Among these, pain-related catastrophic thinking and pain-related fear had the strongest associations with pain intensity and disability in patients with knee OA [40]. Various pain coping skill programs have shown promise in OA patients [41–44] and can be effectively delivered as internet-based CBT [45].

Our research team aimed to take these results one step further and develop an evidence-based and internet-delivered CBT (iCBT) program for all OA patients who are candidates for TKA, but specifically targeted for patients less likely to benefit from standard TKA treatment. The program was designed to be combined with an exercise therapy and education program based on

AktivA [46], consisting of a 90-min patient education session followed by exercise therapy twice a week for 12 weeks. To support patients and enhance the treatment's effects, specially trained physiotherapists will also serve as patient mentors throughout the program. Based on this prior evidence, we expect that such a combined program may result in better treatment outcomes for the large and growing number of non-responders after TKA surgery.

The aims of the present research were to:

1) Develop an iCBT program to be combined with an exercise therapy and education program for patients with knee OA at increased risk of chronic pain after TKA (Phase 1)
2) Thoroughly test and customize the program (Phase 2)

Methods

This paper originates from the MultiKnee multi-center randomized controlled trial (pre-registered at ClinicalTrials.gov: NCT03771430 11/12/2018), investigating the effectiveness of an exercise therapy and education program combined with iCBT on pain and functional outcomes in patients with higher risk of chronic pain following TKA. The development process is presented according to guidance for reporting intervention development (GUIDED) [47].

The UK Medical Research Council (MRC) framework for complex interventions [48] served as a foundation for the program's development process. The MRC framework is a stepwise approach that focuses largely on preliminary groundwork to optimize the development of complex interventions. The framework is flexible and consists of distinct, but iterative phases. First, the development phase was used to identify the evidence base and theory, and model underlying pathways. Secondly, a feasibility phase was performed with input from users and clinicians. The stages in the development of the iCBT intervention is presented in Fig. 1. The program is based on general principles for CBT [24] and adapted to reflect causes and treatment of OA pain and pain after TKA surgery. A literature search was performed to ensure that the program was grounded in current evidence. Furthermore, OA patients' opinions of the program were sought through individual user interviews.

Phase 1: development phase – creating a first prototype of the iCBT program

A multidisciplinary intervention development advisory group was established. The group was broadly composed of national and international representatives consisting of nurses ($n = 3$), physiotherapists ($n = 3$), orthopedic surgeons ($n = 4$), psychologists ($n = 2$), a pain specialist and a health economist, all with long-term experience in clinical practice and research. The group met regularly to identify and define the topic and discuss theoretical and practical questions. Furthermore, a core group consisting of a physiotherapist, a nurse and an orthopedic surgeon with long-term experience from the TKA field, in addition to two psychologists with extensive experience in CBT and internet-based therapy, were responsible for designing the iCBT program.

Literature review

To identify the available evidence, a literature review was conducted on the following topics (results in parenthesis):

- Guidelines for the management of OA patients [14, 49].
- Psychological interventions in OA and TKA patients [41, 42, 44, 50–52].
- Internet-based CBT interventions for OA and TKA patients [44, 45, 53–56].
- The relationship between psychological factors and pain in OA and TKA patients [35, 36, 57–59].

Discussions in the advisory group and results from the literature review formed the rationale, theory and goal for the intervention and the selection of included elements.

Rationale, theory and goal

The core treatment for knee OA is exercise therapy combined with education and weight reduction if needed [14]. OA patients may face significant challenges in initiating and maintaining these treatments in the long term. Barriers to physical activity and exercise may include pain during exercise, low self-efficacy, depressive symptoms, anxiety, feeling of helplessness, and low social support or activity [21, 22]. Some of these factors are also shown to be predictors of poor outcome after TKA [60]. However, using CBT, these barriers may be reduced by developing more adaptive cognitions and behaviors. Consequently, adherence to exercise and physical activity may be improved [25]. Importantly, because physical activity and psychological treatment methods likely have synergistic effects, adding iCBT to exercise therapy and education may result in better treatment outcomes [26, 27]. The core premise of CBT is that maladaptive cognitions contribute to the maintenance of emotional distress and behavioral problems. Hence, in CBT a variety of techniques are combined in order to develop more adaptive cognitions and behaviors, including psychoeducation, cognitive restructuring, relaxation therapy and guided imagery (e.g. reduce muscle tension and autonomic arousal), mindfulness training, problem-

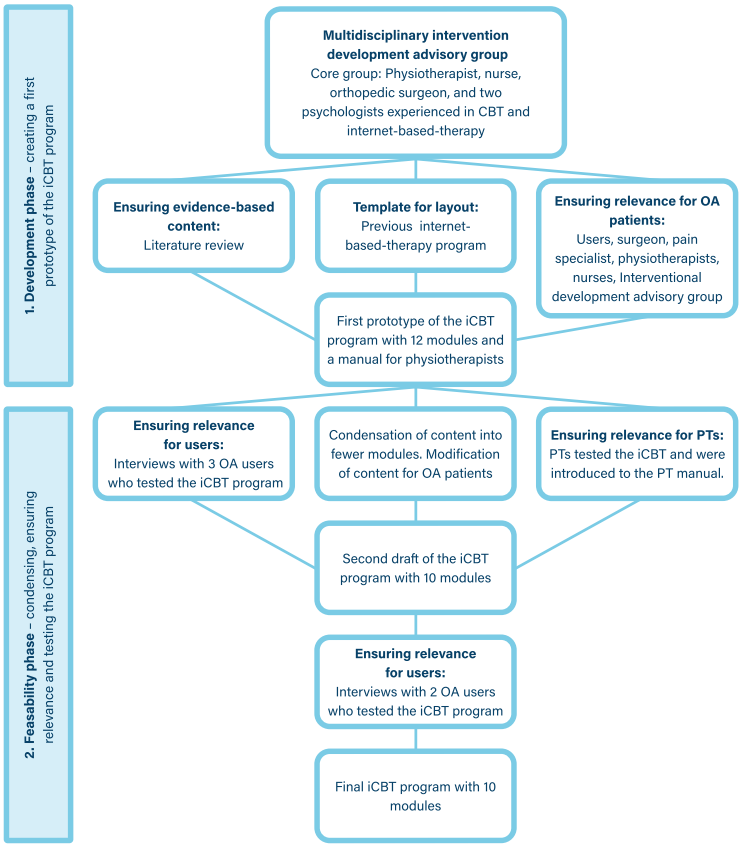

Fig. 1 Flow chart describing the process of developing the electronic version of a Cognitive Behavioral Theory-based (iCBT) intervention

solving, and stress management [24, 25]. In particular, in the context of pain, CBT focuses on reducing pain and distress by modifying physical sensations, catastrophic and ruminative thinking, and maladaptive behaviors [30], in addition to enhancing self-efficacy [35, 36].

Hence, the goal of the intervention is to increase patients' awareness of their own thoughts and behavior, and to learn and practice new ones so they can initiate, maintain or resume their normal physical and social activities. Further learning goals are to increase patients' confidence in making their own assessments and to learn techniques for dealing with pain in an appropriate way.

Template for layout

The first draft of the iCBT program was designed from relevant elements of the commercially-available Braive program [61], which is based on well-documented treatment principles.

Relevance for OA patients

Since the iCBT program elements from Braive were not specifically designed for OA patients, it was necessary to tailor and adjust the content by emphasizing OA pain and cognitions associated with OA pain. Two versions of the iCBT program were developed, one non-surgical version for OA patients, and one version for patients undergoing TKA surgery. A persona, an animated figure based on a typical OA or TKA patient, was created for each version of the program. The personas represent a figure that OA or TKA patients can identify with, and appear in all modules throughout the programs. To help patients see the relevance of the iCBT exercises in each module and how to implement them into their exercise therapy program, the iCBT exercises in both versions

included lists of relevant examples for OA and TKA patients. Both versions were identical in content except for minor differences in the examples and personas. The interventional development advisory group, users and physiotherapists were consulted and contributed their input throughout development of the program. This phase yielded a prototype of an iCBT program with 12 modules and a manual for physiotherapists serving as patient mentors.

Phase 2: feasibility phase – condensing, ensuring relevance and testing the iCBT program

In this stage, we evaluated whether the program was relevant, manageable and understandable for the patients and whether the program and the clinician manual were relevant for the physiotherapists. This process was characterized by feedback-loops where users and researchers were challenged to give input to refine the program.

Relevance for patients

To evaluate the program's relevance for OA patients, and its feasibility and acceptability, we conducted interviews with users in two rounds. For planning and conducting the interviews, Norman and Skinner's eHealth literacy model [62] was employed. Of particular interest were users' experiences with navigating the program, understanding the information and instructions, and appraising the usefulness of the program for the target group.

The first draft of the program was distributed to three users, two men and one woman, who had undergone TKA surgery, followed by individual interviews conducted by a physiotherapist. The interview guide and results from the first round of interviews are described in Table 1. Two of them were positive to the program and would have joined if given the opportunity. Their input was used to improve the program, and resulted in a more condensed and manageable iCBT program. Consequently, the examples and information pages became

Table 1 Inteview round 1

Interview guide:	Results:
What are your immediate thoughts on this program now that you have seen an overview of all the modules?	*"This seems exciting. I liked the video about Kathrine, recognized myself in her story."* *"I oppose this "dehumanization". I am in favor of personal contact and that not everything should happen online. I think many, especially the elderly, will have trouble completing the course because lack of computer knowledge."* *"Exciting, I would have been keen on it!"*
Is the content per module manageable to complete in 1 week?	*"… manageable …"* *"… too extensive, takes a lot of time"* *"… .may seem overwhelming to some, important to only get one module a week"*
Is the presentation understandable? Words, expressions etc.	*"… change some expressions..."* *"… very good information, some information becomes too philosophical … want more specific information related to osteoarthritis"* *"..some of the terms are incomprehensible, some bad wording and bad language …"*
Are the examples recognizable?	*"the story about Kathrine is recognizable … some of the other examples should be changed to make them more recognizable to osteoarthritis patients"* *"… some examples become incomprehensible for osteoarthritis patients"* *"… some of the examples do not fit this patient group"*
Will this cause the patients to get the spikes out thinking that we think "it is only in your head" or that we do not take their pain seriously?	*"… important to emphasize that physiotherapy is the main element of this intervention"* *"… clarify how thoughts, attitudes and stress affect pain"* *"… I don't think the module about values is relevant, and can be provocative, must either be removed or come later in the program …. I also perceive the module on Rest Networks more as psychotherapy … can be provocative for this patient group"*
What do you think about the level / difficulty of the content - easy to follow or advanced?	*"… easy to follow, manageable"* *"The program is too comprehensive … too difficult for many due to lack of computer skills"* *"I had trouble logging into the program the first time … it was easy to navigate in the program … intuitive and easy to know where to press to move forward … the layout and ease of use is good … the hand that drew the drawings was disturbing … still image would have been better."*
Would you be willing to do this if you were told that you were in the target group?	*… would think this was exciting* *… would not join … no need for "everything" to take place on the internet"* *"… this seemed exciting, I would want to join"*

Table 2 Interview round 2

	Interview guide:	Results:
Find	How was it to log into and navigate in the program?	*"no problem"*
	Is the content per module manageable to complete in 1 week?	*"no problem"* *"some of the modules are demanding, important that the patients are prepared, suggest to divide into two parts"*
Understand	How is the presentation? Words, expressions etc.	*"good explanations, understandable"* *"they talk too fast, suggestion: work through the sequences twice and more"* *"some typos"*
	How were the exercises? Did you understand what to do?	*"OK exercises"* *"some of the exercises are demanding, suggest to split them"*
	Are the examples recognizable?	*"have not seen the examples"* *"good examples, there is a possibility that patients will copy the examples instead of thinking what is relevant for them"*
	What do you think about the level / difficulty of the content - easy to follow or advanced?	*"the level of difficulty is OK"* *"some of the modules and exercises are demanding"*
Apprise	How relevant is the content for you as an OA/TKA[a] patient?	*"good program as part of a larger context"* *"good program, important to emphasize that the rehabilitation period lasts for several months"*
	How will the content impact the users? Will this cause the patients to think that we do not take their pain seriously?	*"unsure if it is too optimistic and moralizing, important to emphasize that it is part of a larger package"*
Useful	How useful will this program be for you?	*"useful as a supplement following the operation"* *Useful to manage day to day life"*
	How useful do you think this program will be for others?	*"I think this program will be useful for many patients"*

[a] *OA* Osteoarthritis, *TKA* Total knee arthroplasty

more relevant and understandable to the patients. When the second draft of the iCBT program was completed, a second round of interviews was conducted with two of the same users. The results (Table 2) were used to further refine the revised version of the program. The conclusion from the user interviews was that the iCBT program would be useful for many patients as a supplement to surgery and/or exercise therapy.

Condensation of content

To discuss further condensation of the content, the professionals in the research group arranged a workshop. The aim was to tailor the program to the patient group and condense it to the most essential CBT elements. Priorities were made based on the literature [31], feedback from user interviews and knowledge about the patient group. The condensation included a reduction of modules from 12 to 10. Topics such as goal setting, relaxation techniques, mindfulness and worry and rumination were prioritized, while content related to values, core beliefs, and rules and assumptions for living, in addition to body scan and autogenic training, were omitted.

Ensuring relevance for physiotherapists

A physiotherapist manual was developed in order to ensure treatment fidelity. Four physiotherapists experienced in treating patients undergoing TKA surgery were introduced to the iCBT program and the physiotherapist manual to optimize their relevance and usefulness. A workshop was arranged where the physiotherapists discussed the relevance and feasibility of all elements of the manual. Revisions were made accordingly, such as clarification of the physiotherapist's role and customization of the information sheet.

Phase 2 resulted in a final version of the iCBT program consisting of ten modules (Table 3), accompanied by a physiotherapist manual (Table 4) containing a brief introduction to CBT and basic motivational interviewing (MI) [63] techniques, in addition to instructions for each module. The iCBT program and manual are presented in detail in the Results section.

Results

Description of the iCBT program

The iCBT program is presented according to the template for intervention description and replication (TIDieR) checklist and guide [64]. To use the iCBT program, participants must have access to the internet and an electronic device (computer, tablet or smartphone). The program will be delivered as a guided, tailored iCBT program in ten modules to be distributed over 10 weeks as shown in Table 3. Patients will be given access to the program through a secure website using two-factor authentication, where they will be introduced to the program and receive further instructions.

Table 3 Overview of the content in each of the 10 sessions of the cognitive-behavioral intervention

Session	Theme	Content	Exercise	Theory and goal
1.	Getting started	• Gate control theory (video) • Learn to know Kathrine (video) • The relation between thoughts, feelings and behavior (video) • Relaxation technique	• Try the relaxation technique • Writing exercise: Life Story	• Knowledge about pain mechanisms and the interaction of thoughts, emotions and behavior form the basis of change • Learn relaxation technique to reduce muscle tension and autonomic arousal
2.	Goals for the recovery	• Five key elements important for coping with pain (medical, mental wellbeing, lifestyle, life story, physical activity) (video) • FAQ physical activity • Follow Kathrine • Goals for recovery	• Make a pie chart; important areas to focus on • My goal for recovery • Writing exercise: Affirmative Writing • Reminder: relaxation technique	• Awareness of how it is possible to cope with pain form the basis of changing unhelpful behavior • Knowledge about physical activity reduce fear-avoidance behavior • Goalsetting increase motivation and adherence to the program
3.	Stress and pain	• How to change habits (video) • Understanding and managing stress (video) • Identifying main stressors • Locus of control (video)	• Identifying main stressors • Writing exercise: How has pain affected you? • Update goals for recovery • Reminder: relaxation technique	• Understanding stress, how to change habits and locus of control promotes changing processes • Reflective practice to increase awareness of own stressors
4.	Lifestyle	• How different kind of lifestyle can contribute to the symptoms (training and restitution) (video) • How worry and anxiety influence behavior (video) • Safety behavior (video)	• Identify and challenge safety behavior • Writing exercise: Safety behavior and lifestyle • Update goals for recovery • Reminder: relaxation technique	• Knowledge about how lifestyle factors, worry and anxiety influence behavior, can motivate to change behavior • Be aware of own safety behavior and challenge it to start the process of changing behavior
5.	Identifying automatic thoughts	• Thinking errors (video) • How challenging situations can be perceived as threat, loss or challenge (video) • The inner dialogue (video)	• Exploration of internal dialogue • Writing exercise: Pain triggers and alternative thoughts • Update goals for recovery • Reminder: relaxation technique	• Education about thinking errors and internal dialogue to start reflecting on own thoughts • Use the writing exercise to raise awareness about pain triggers and generate alternative thoughts
6.	Creating alternative thoughts	• Common thinking errors (video)	• Identify thinking errors and generate alternative thoughts • Writing exercise: Emotional expression • Update goals for recovery • Reminder: relaxation technique	• Practice in identifying thinking errors and generating alternative thoughts to continue the process of changing thoughts and behavior
7.	Be more mindful	• Default Mode Network (DNM) and mental habits (video) • Focused attention (video) • Conscious refocusing (audio file)	• Practice conscious refocusing • Writing exercise: Going Deeper • Update goals for recovery • Reminder: relaxation technique	• Practice focused attention and conscious refocusing to reduce DNM activity
8.	Selective attention	• Becoming more mindful (video) • Selective attention (video)	• Mindfulness exercise: "Floating leaves" (audio file) • Writing exercise: Choose perspective • Update goals for	• Practice guided imagery and selective attention to reduce muscle tension and autonomic arousal

Table 3 Overview of the content in each of the 10 sessions of the cognitive-behavioral intervention *(Continued)*

Session	Theme	Content	Exercise	Theory and goal
			recovery • Reminder: relaxation technique	
9.	Postponing worry and rumination	• Worry and rumination • Why worry escalates • Postponing worry and rumination • Postponement log	• Make worry postponement log • Writing exercise: Living with loss and changes • Update goals for recovery • Reminder: relaxation technique	• Learn about worry and rumination. • Practice making a worry postponement log • Reflecting on how loss and changes in life affect you, and how to live with it
10.	What's next?	• What have I learned? • What's next?	• Writing exercise: What have I learned	• Reflection on what that has been learned and future plans

The iCBT user interface

The iCBT program consists of ten modules. Participants are encouraged to complete one module before moving on to the next. Each module follows a similar structure, consisting of psychoeducational texts and videos that present relevant topics for the module. Most of the modules include a video where the patients can follow the "persona" – the fictional character with OA or TKA, who undergoes either non-surgical treatment (version A) or TKA surgery (version B). Each module includes tasks related to the topics covered. Some tasks can be performed immediately (e.g. writing exercise, relaxation exercise); others are expected to be done as behavioral experiments between the modules.

The purpose of the first two modules is to help patients change their habits and lifestyles, and set new goals in areas that are important for pain management. Based on various psychoeducational texts and videos, patients are challenged to identify areas in which they want to change, and to set step-by-step goals for how the goals can be reached. Throughout the program, patients are challenged to continue to revise their goals in the subsequent sessions by describing the strategies they chose to apply and the progress they have made, and by setting additional goals for their rehabilitation.

Physiotherapist manual

To optimize adherence to the program, physiotherapists will support the patients through telephone contact every second week. Using physiotherapists as mentors is intended to facilitate integration of the iCBT and exercise therapy, and increase the likelihood of generalization to daily life. The physiotherapists will participate in a one-day course, led by an experienced psychologist, to be able to support the patients throughout the program. The course includes an introduction to the iCBT program and the physiotherapist manual, in addition to education about CBT principles. The physiotherapist manual will support the physiotherapists and increase the consistency of mentoring the patients. The physiotherapist manual contains the same ten modules from the iCBT program, specific learning objectives for each module, and a list of themes the physiotherapist should consider discussing with the patients, including recommendations as to how each theme might be addressed. In addition, two extra learning modules are available for the physiotherapists. The first module contains an introduction to basic CBT and MI principles. The second module provides guidance on how to handle patients' resistance and address challenges (Table 4). Furthermore, if the patient grants permission, the physiotherapists can access a secure website to monitor each patient's progress, and provide support and assistance when necessary.

Theoretical content and psychoeducation

The cognitive-behavioral model focusing on the "cognitive diamond", which illustrates the link between thoughts, emotions, bodily reactions and behavior [24], is the theoretical framework for the program. The model is represented through texts, videos, iCBT exercises, and behavioral experiments throughout the program. For example, the CBT model hypothesizes that when exposed to a stressful situation or condition, such as pain, our self-image and perception of the world tend to become negatively biased. Thus, at the beginning of the program, participants learn to identify negative automatic thoughts and beliefs that arise in painful situations. They are then introduced to how those thoughts can be challenged and modified. In later modules, participants learn about various forms of thinking errors, safety behaviors, internal dialogue, perceiving challenging situations as threats, losses or challenges, locus of control, stressful situations [24, 25, 65], and the gate control theory of pain [28]. At a later session, participants are introduced to a metacognitive theoretical view of worry and

Table 4 Physiotherapist Manual

Week	Theme	Topics to address	Learning goals
1	Get started	• Help patient to get started • Ask if they have tried the relaxation technique • Ask if they have completed diary exercise.	• Learn about the relation between thoughts, feelings and behaviour • Learn a relaxation technique
2	Goals for the recovery	• Ask if the patient has started to fill in pie chart and the Goal podium. • Remind about relaxation technique and writing exercise.	• Be able to support patient in setting goals and using strategies to cope with pain
3	Stress and pain	• Discuss what they consider to be their main stressors • Help to fill in the goal podium and reminder about relaxation techniques and writing exercise.	• Learn about stress and pain, and be able to support patients to change habits
4	Lifestyle	• Ask if the patient has completed the exercise about "safety behaviour" • Help to revise the goal podium • Remind about relaxation techniques and writing exercise.	• Learn about safety behaviour and be able to help patient to be aware of how different kinds of lifestyles can contribute to symptoms
5	Identifying automatic thoughts	• Discuss how it was to do the exercise about "Inner dialogue" • Remind about writing exercise: Pain triggers and alternative thoughts. • Remind about relaxation techniques	• Be able to help patient to be aware of their own thinking errors and automatic thoughts
6	Creating new thoughts	• Ask about what he/she gets out of the information about thinking errors • Ask what experiences he/she had when identifying their own thinking errors • Remind about writing exercise: Emotional expression • Remind about relaxation techniques	• Be able to support patient to identify their own thinking errors and create alternative thoughts
7	Becoming more mindful	• Ask if patient experiences having selective attention directed against threat and loss in relation to their OA • Ask what experiences he/she has in relation to the exercise "conscious refocusing" • Remind about the writing exercise: Going deeper • Remind about relaxation techniques	• Learn about Default Mode Network (DNM) and mental habits to be able to support the patient to become more mindful
8	Selective attention	• Ask patient what they think about the exercise "Floating leaves" • Remind about the writing exercise: Choose Perspective • Remind about relaxation techniques	• Learn about selective attention and be able to support the patient to be more mindful
9	Postponing worry and rumination	• Ask patient if he/she can distinguish between worry and rumination • Ask if he/she can postpone the worry and rumination by creating a "Postponement log" • Remind about writing exercise: Living with loss and changes in life • Remind about relaxation techniques	• Learn about worry, rumination and why worry escalates. Be able to support patient to postpone worry and rumination and make a postponement log
10	What next?	• Discuss what the patient has learned, what he/she has achieved and what remains. • Encourage the patient to look back on previous exercises. • Remind about writing exercise: What have I learned • Discuss what to do next	• Be able to support the patient to use what they have learned and to create new goals in life.
11	Specialization for physiotherapists	• Understanding the concept • The learning model • Key elements in CBT • Home exercises	• Increase physiotherapist's knowledge about the elements of the intervention
12	Conversation with the participants	• Motivating interview (MI) (video) • MI techniques (video) • Resistance • When users experience challenges • Getting stuck in unhelpful thoughts – encourage meta-perspective • Pitfalls in building alliances • Unhelpful assumptions	• Improve the quality of the interaction between the physiotherapist and the participant

rumination [25]. It is explained how worry tends to escalate, and participants learn how to create a postponement log for both worrying and rumination.

iCBT exercises

Some iCBT exercises are carried out throughout the program. A diary writing exercise is introduced at the beginning of the program, and patients are asked to write on different topics in the coming sessions. They are also introduced to a relaxation technique (progressive muscle relaxation) and are encouraged to practice it regularly. In a later module, they learn about mindfulness, including selective attention and conscious refocusing, and undergo an exercise in mindfulness that they are encouraged to use repeatedly [66].

Discussion

In the present paper, we have described the development process of an iCBT program for knee OA and TKA patients at increased risk of chronic pain after TKA surgery, to provide clinicians and researchers with enough details to replicate the program. The developmental process following the MRC framework resulted in an iCBT program consisting of ten modules and a manual to guide the physiotherapists mentoring the patients.

One in five patients undergoing TKA have limited or no effect of the surgery when it comes to pain and function [5]. They are characterized by having one or more psychological factors that may contribute to increased pain and reduced quality of life [40]. CBT aims to help participants develop more adaptive cognitions and behavior [31]. Combined with an evidence-based exercise therapy and education program, we hypothesize iCBT will lead to less pain, better function and improved quality of life for these patients. The evaluation of the effectiveness of the combined program will be performed in a randomized controlled trial.

We base our study on current evidence suggesting that several of the risk factors for a suboptimal TKA outcome are modifiable (e.g., catastrophic thoughts about pain, pain-related anxiety, generalized anxiety, and depression). Because these psychological factors, combined with pain, may constitute significant barriers to participation in exercise therapy [21], we expect that by modifying the risk factors, patients may increase their adherence to exercise and physical activity. Furthermore, exercise can also have a positive effect on mental health [67]. Therefore, as found in patients with hip and knee OA [42, 43], a biopsychosocial approach that combines psychological and physical interventions might produce the best outcome [31].

CBT-based treatment for persons at risk of poor outcome following TKA has been evaluated in several recent studies, which concluded that CBT alone is likely insufficient to improve TKA outcomes [68–70]. While the CBT programs in these prior studies consist of basic CBT elements relatively similar to our study, they were not combined with an individually tailored exercise therapy and education program. Our program builds on these prior studies by combining iCBT with CBT-trained physiotherapists who serve as mentors to help patients integrate their new skills both in the exercise therapy sessions and in daily life. Our iCBT program is also specifically adapted for OA and TKA patients and it has two versions, one for OA patients in general and one specific to patients undergoing TKA.

Because the program is intended to be combined with an exercise therapy and education program, physiotherapists will mentor the patients through the program. Thus, the physiotherapists' manual was designed to clarify and support the role of the physiotherapists. Using physiotherapists as mentors is in line with findings from a recent study [44], which demonstrated that patients achieved better functional outcome when physiotherapists combined exercise with Pain Coping Skills training compared to either treatment alone. Accordingly, we expect that the combined psychological intervention and exercise therapy mentored by physiotherapists will optimize patients' results. Using trained physiotherapists as mentors is designed to help patients integrate their skills from the iCBT to cope with pain during their exercise therapy.

This study is the first to create an iCBT program for patients with knee OA and patients undergoing TKA, to be combined with exercise therapy and education. In a recent systematic review, Calbring et al. demonstrated that iCBT targeting psychiatric and somatic conditions is as effective as face-to-face treatment for all conditions studied [53]. For our patient group, iCBT has only been tested in a smaller randomized controlled trial of 69 participants. O'Moore [55] found that a 10-week iCBT depression program effectively reduced depression, and improved self-efficacy, pain, stiffness, and physical function in patients with OA and severe depression.

Internet-based CBT programs have been evaluated in other populations with chronic pain [71, 72] and have shown promising results. However, these prior programs are largely self-directed, requiring minimal, if any, clinician involvement. In contrast, the target population for our iCBT program consists of patients at risk of poor TKA outcome, and these patients may benefit from more clinician involvement to stay motivated and to integrate their new skills both in the exercise program and in daily life. Although our iCBT program consists of many of the same CBT elements as prior studies, our program is uniquely tailored to OA and TKA patients and is specifically designed to be combined with exercise

therapy and mentored by specially trained physiotherapists.

Schuster et al. [73] listed several advantages of iCBT. Bridging geographic distances was one of them. Participants in the present study may potentially save time and money participating in iCBT compared to face-to-face therapy. For those patients who have recently undergone surgery, it is an advantage not to travel long distances to a therapist. Another advantage is that they can work through the program and materials whenever it suits them.

However, using online treatment programs may be challenging for patients without internet access or for those who are unfamiliar with using a computer or smartphone. It is therefore likely that the program is more applicable to younger patients who are familiar with using tablets, smartphones or computers. However, the user interface of our program is designed to be as simple and intuitive to use as possible and the program is supported by mentor physiotherapists, which may limit potential barriers to using such a program.

It is estimated that 85% of research activity is wasted [74]. The strength of our work is that it has followed the first two phases in the MRC framework for developing complex interventions. Bleijenberg et al. [75] stated that improving the development of complex interventions "would reduce research waste and enhance the likelihood of success", and recommended adding four elements to the MRC framework: 1) problem identification and definition, 2) determination of recipients' and providers' needs, 3) examination of current practice and context, and 4) intervention design. These elements have been taken into account in our study through the detailed work of the multidisciplinary intervention development advisory group and the core group, consisting of clinicians, researchers and users with extensive experience from the field, representing both recipients and providers.

Conclusions

We have developed an iCBT intervention tailored to patients at risk of chronic pain following TKA. The development process followed the first two phases of the MRC framework for complex interventions. The iCBT program consists of 10 modules with educational texts, videos and exercises related to relevant topics. A physiotherapist manual guides physiotherapists in mentoring patients through the program. A planned multi-centre three-armed RCT will test the effectiveness of iCBT combined with an exercise therapy and education program.

The iCBT intervention developed in this study may be a valuable contribution to the treatment of knee OA. It is easy to use and less time-consuming for patients and therapists than face-to-face programs. The result of the RCT may contribute to the general knowledge of how to treat patients at risk of an unfavorable TKA outcome. The intervention may benefit a substantial number of patients every year, as well as society by reducing costs associated with chronic pain.

Abbreviations

CBT: Cognitive Behavioral Therapy; GUIDED: Guidance to reporting intervention development; iCBT: Internet-delivered Cognitive Behavioral Therapy; MI: Motivational Interviewing; MRC: Medical Research Council; NSAID: Non-Steroidal Anti Inflammatory Drugs; OA: Osteoarthritis; OARSI: Osteoarthritis Research Society International; RCT: Randomized Controlled Trial; TIDieR: Template for Intervention Description and Replication; TKA: Total Knee Arthroplasty

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Authors' contributions

Turid Rognsvåg: Conceptualization, Methodology, Writing - Original Draft. Maren Falch Lindberg: Conceptualization, Methodology, Writing - Original Draft. Anners Lerdal: Conceptualization, Methodology, Supervision, Writing - Review & Editing. Jan Stubberud: Methodology, Writing - Original Draft. Ove Furnes: Writing - Review & Editing. Inger Holm: Writing - Review & Editing. Kari Indrekvam: Writing - Review & Editing. Bjørn Lau: Conceptualization, Methodology, Writing - Review & Editing. Daniil Rudsengen: Software, Writing - Review & Editing. Søren T Skou: Writing - Review & Editing, Supervision. Mona Badawy: Writing - Review & Editing, Supervision. The author(s) read and approved the final manuscript.

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Availability of data and materials

All data generated or analysed during this study are included in this published article.

Declarations

Ethics approval and consent to participate

The study has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki and the regulations of the US Health Insurance Portability and Accountability Act (HIPAA).
The Regional Medical Research Ethics committee of Health East of Norway approved the study (2017/968).
Written informed consent was obtained from all subjects.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

PAPER III

Exercise therapy, education, and cognitive behavioural therapy alone, or in combination with total knee arthroplasty, in patients with knee osteoarthritis: A randomized feasibility study.

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Pilot and Feasibility Studies

RESEARCH

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Exercise therapy, education, and cognitive behavioral therapy alone, or in combination with total knee arthroplasty, in patients with knee osteoarthritis: a randomized feasibility study

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Abstract

Background One in five patients experience chronic pain 1 year after total knee arthroplasty (TKA), highlighting the need for enhanced treatment strategies to improve outcomes. This feasibility trial aimed to optimize the content and delivery of a complex intervention tailored to osteoarthritis (OA) patients at risk of poor outcome after TKA and assess the feasibility of initiating a full-scale multicenter randomized controlled trial (RCT).

Methods Patients scheduled for TKA were included between August 2019 and June 2020 and block-randomized into one of three groups: (a) 12-week exercise therapy and education (ExE) and 10-module internet-delivered cognitive behavioral therapy (iCBT), (b) TKA followed by ExE and iCBT and (c) TKA and standard postoperative care. Outcomes were (i) recruitment and retention rate, (ii) compliance to the intervention and follow-up, (iii) crossover, and (iv) adverse events, reported by descriptive statistics.

Results Fifteen patients were included in the study. Only 1 out of 146 patients screened for eligibility was included during the first 4 months. During the next 3 months, 117 patients were not included since they lived too far from the hospital. To increase the recruitment rate, we made three amendments to the inclusion criteria; (1) at-risk screening of poor TKA outcome was removed as an eligibility criterion, (2) patients across the country could be included in the study and (3) physiotherapists without specific certification were included, receiving thorough information and support. No patients withdrew from the study or crossed over to surgery during the first year. Nine out of 10 patients completed the ExE program and six out of 10 completed the iCBT program. Fourteen out of 15 patients completed the 1-year follow-up. One minor adverse event was registered.

Conclusions Except for recruitment and compliance to iCBT, feasibility was demonstrated. The initial recruitment process was challenging, and necessary changes were made to increase the recruitment rate. The findings informed how a definitive RCT should be undertaken to test the effectiveness of the complex intervention.

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Trial registration The MultiKnee RCT, including the feasibility study, is pre-registered at ClinicalTrials.gov: NCT03771430 11/12/2018.

Keywords Knee osteoarthritis, Physical exercises, Cognitive behavioral therapy, Feasibility trial

Key messages regarding feasibility

1) Uncertainties existed regarding the recruitment of patients and compliance with the intervention.
2) Challenges regarding recruitment were identified and improved during the feasibility study.
3) Revision of the iCBT program was needed to increase compliance with the intervention.

Background

Hip and knee osteoarthritis (OA) is among the major causes of disability in the elderly population. The prevalence of OA is expected to increase due to increasing obesity and the aging population [1] indicating the importance of optimizing treatment options. The Osteoarthritis Research Society International (OARSI) guidelines state that the first-line treatment for knee OA includes education and structured exercise programs with or without dietary weight management. If non-surgical care is not sufficiently effective in terms of improving pain and function, it is recommended to refer patients to knee replacement surgery [2]. Total knee arthroplasty (TKA) surgery is a well-documented treatment for patients with moderate to severe knee OA. Most patients report very good clinical outcomes with improvement in pain, physical function, and quality of life [3, 4]. Projected estimates show an increasing demand for TKA for the treatment of OA with a steady increase in national registries [5, 6]. However, studies show that as many as 20% of patients undergoing TKA still have pain and poor function 1 year following surgery [7–9], leading to an increased number of revision procedures [10]. Psychological factors, such as catastrophic thinking [11], poor mental health [12], anxiety [13], and depression [14], have been associated with poor results after TKA. Skou et al evaluated the effectiveness of adding TKA to a combined non-surgical treatment program including education and exercise therapy. Even though the patients who received TKA experienced greater improvement than those without TKA, both groups experienced clinically relevant improvements in pain, function, and quality of life. Only 26% and 32% of patients who received education and exercise therapy alone had decided to undergo TKA at the 12- and 24-month follow-up, respectively [4, 15] suggesting that it is possible to reduce willingness to undergo surgery through engagement with guideline-recommended first-line care.

Exercise therapy and physical activity are also recommended in the rehabilitation after surgery [16]. There are uncertainties about to what degree individual patients adhere to these recommendations. Patients experiencing anxiety, depression, and catastrophic thinking regarding physical activity may have problems performing a prescribed exercise program [17]. Increased pain is a barrier to physical activity and exercise and may be related to the above-mentioned psychological factors [18]. A mental health treatment program tailored to these psychological risk factors, combined with an individually tailored education and exercise therapy program, could have the potential to improve outcome measures for patients with OA and patients undergoing TKA at increased risk of chronic pain and poor function following surgery. Hence, we designed an internet-delivered cognitive behavioral therapy (iCBT) program specially tailored to patients with OA and patients undergoing TKA [19] to be combined with exercise therapy. As advised by the UK Medical Research Council (MRC) we used their framework for developing and evaluating complex interventions [20]. The framework is particularly useful to ensure a systematic and thorough developing process before testing complex interventions in large resource-demanding randomized controlled trials (RCT), to avoid research waste. As recommended, we designed a feasibility study to identify uncertainties around recruitment and retention rate, as well as acceptability and expected adherence to the intervention itself.

The aim of this randomized feasibility trial was to investigate the feasibility of the intervention designed to improve outcomes for patients with knee OA and patients undergoing TKA at risk of poor outcomes after TKA and examine whether a three-armed RCT of such an intervention was feasible regarding (i) recruitment and retention rate, (ii) compliance to the intervention and follow-up, (iii) cross over and (iv) adverse events.

Methods

Study design

We planned a three-armed multicenter RCT evaluating the effectiveness of a combined 12-week exercise therapy and education (ExE) program and a 10-module iCBT program delivered either alone (group A) or in combination with TKA (group B), compared to TKA

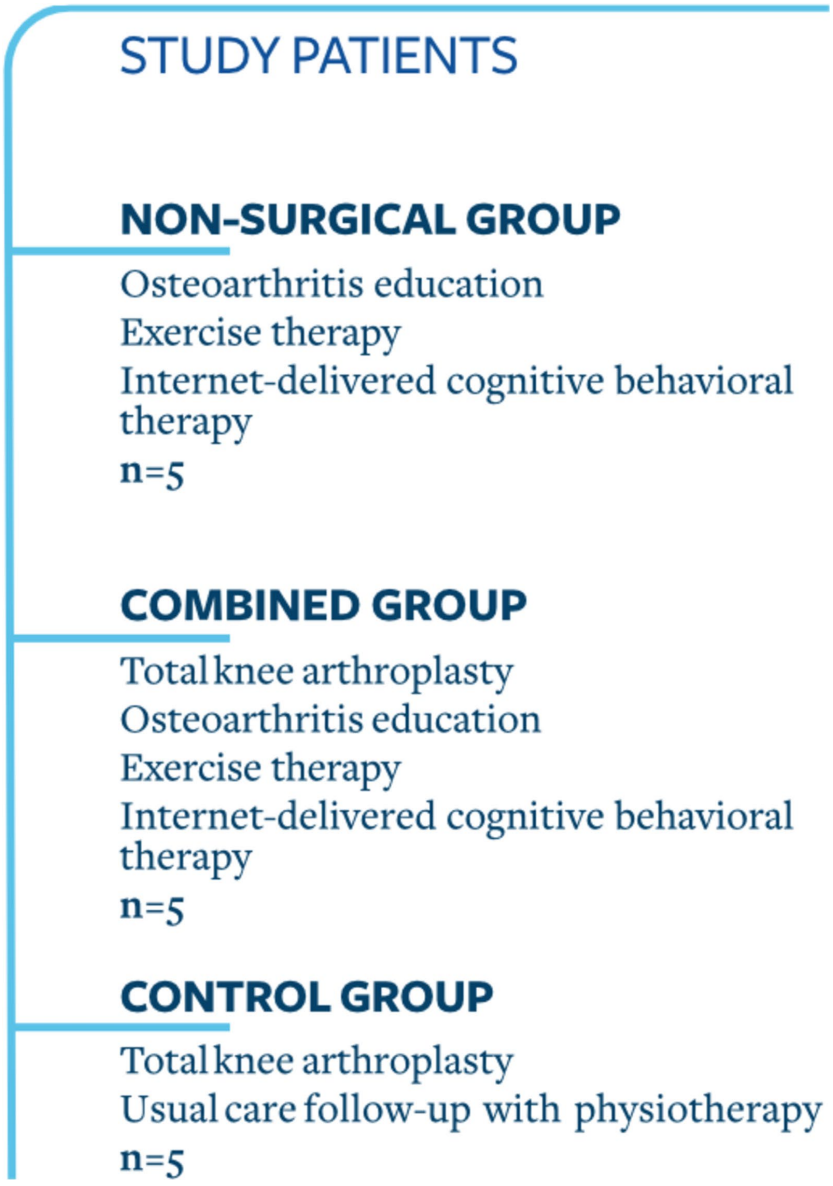

Fig. 1 Groups in a randomized feasibility study for patients with knee osteoarthritis

with standard postoperative care (group C). This study is called The MultiKnee trial (Fig. 1). A randomized, three-armed, feasibility trial was conducted to assess the feasibility of such an RCT. The trial is reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement extension to randomized pilot and feasibility trials [21].

Participants

Patients with knee OA scheduled for primary TKA in two high-volume hospitals in the Western and Eastern parts of Norway between August 2019 and June 2020 were asked to participate. With this, we aimed for a sample consisting of patients from urban and rural areas of Norway thereby providing a geographically and socially diverse sample.

Eligibility criteria

Patients scheduled for primary TKA, aged ≥ 18, ≤ 80, with American Society of Anesthesiologists (ASA) grade 1–3, radiographic evidence of osteoarthritis (Kellgren-Lawrence grade 3 or 4), Body mass index (BMI) < 40 and were able to read and write in Norwegian, were to be recruited to the feasibility trial. Patients with previous unicompartmental or patellofemoral knee arthroplasty, large axis deviation or instability requiring the use of hinged prosthesis, diagnosis of dementia, or diagnosis of seropositive rheumatic disease, were excluded from the study.

Recruitment

Initially, we wanted to include only patients at risk of poor outcomes following TKA. All patients scheduled for TKA were screened for potential risk factors prior to eligibility assessment. The screening instrument used to identify patients at risk was based on prior studies on predictors of poor outcomes following TKA [22, 23] (Table 1). The evidence behind the instrument was weak. We therefore decided to include the screening questions in the baseline questionnaire, instead of including them in the eligibility criteria, so that the risk factors could be further assessed and evaluated.

During a consultation at the outpatient clinic, the orthopedic surgeon assessed the patients for inclusion and exclusion criteria.

Eligible patients were thoroughly informed about the study, the randomization process, the interventions, and the possibility of withdrawing from the study. Patients who wanted to participate received an e-mail with a link to an electronic written consent form. The number of patients screened and reasons why potential participants were ineligible were recorded. Eligible patients who were approached but who declined to participate were anonymously recorded and the reason(s) for declining participation was recorded.

Randomization and blinding

Once the patients had signed the consent form, they were randomized by sealed opaque envelopes to one of three treatment groups in the ratio 1:1:1. The randomization scheme was computer-generated using permuted blocks of three or six, and the envelopes were prepared by an independent staff member and kept in a locked location. Patients in group A were referred to a physiotherapist for education and exercise therapy while patients in group B and C were scheduled for TKA.

Blinding of participants and physiotherapists who deliver the intervention was not possible due to the nature of the intervention.

Intervention

The MultiKnee program is a combination of an individually tailored ExE program led by a physiotherapist, in addition to an iCBT program (Fig. 2). This complex intervention was to be tested in the MultiKnee trial. The ExE program is based on "AktivA", which is an evidence-based and guideline-based implementation program to improve

Table 1 An overview of the screening instrument

	Instrument:	Cutoff[a]:
Age		< 55
Preoperative pain and function	The Knee Injury and OA Outcome Score (KOOS) pain and physical scale combined[b]	≤ 22
Widespread pain	Number of painful sites	≥ 2
Pain catastrophizing	Pain Catastrophizing Scale (PCS)[c]	≥ 30
Pain-related fear avoidance	Fear-Avoidance Belief Questionnaire (FABQ)[d]	> 14.9
Depression/anxiety	Hospital Anxiety and Depression Scale (HADS)[e]	> 11

[a] Scores below/above the cutoff point gave one point on each topic. Patients with two points or more were rated as at risk of poor outcomes and could be included in the study

[b] Higher score=more pain

[c] Higher score=more catastrophizing

[d] Higher score=more fear avoidance beliefs

[e] Higher score=more anxiety and depression

Fig. 2 Overview of the MultiKnee program. Abbreviations: OA=osteoarthritis, CBT=Cognitive Behavioral Therapy, AktivA=active with osteoarthritis, PT=physiotherapist

nonsurgical treatment for patients with knee OA in Norway [24]. Initially, we included only patients living near the hospitals to receive the exercise therapy at the hospitals. This largely limited the patient's eligibility. We therefore extended the residential area nationwide, but the patients still had to be connected to the original two hospitals.

To standardize the intervention as much as possible, we preferred certified AktivA physiotherapists to deliver the ExE program. A study center AktivA physiotherapist delivered the education part of the program at the study center. However, a shortage of available AktivA-certified therapists resulted in the delay in the delivery of the 12-week exercise therapy program for several patients. We then also allowed physiotherapists without AktivA certification to deliver this part of the intervention. In such cases, the following was done to ensure standardization of the intervention: The AktivA certified study center physiotherapist contacted the non-certified physiotherapists and informed them thoroughly about the study and which principles to follow regarding pain management, dosage, and progression, and provided an informational leaflet including a selection of exercises with suggestions on individual tailoring and progression. Furthermore, the non-certified physiotherapists were contacted by the AktivA physiotherapist every second week to provide support and supervision through the intervention period. With these changes, we were able to recruit patients from across the country, ensuring that they received exercise therapy according to the AktivA principles.

Education

The education part of the intervention was based on the same as used in the AktivA program [24]. A study center AktivA certified physiotherapist led the patient education at one of the study centers, before the start of the exercise therapy program. A PowerPoint educational presentation was used by all physiotherapists to standardize the education sessions. The content of the educational part (the OA school) was developed based on previous published scientific papers, and clinical experience, and focused on updated knowledge about OA, risk factors, symptoms, managing life with OA, and possible treatment options. The beneficial effect of exercise on symptoms, physical function, and general health, and the effect of weight reduction and self-management strategies were highlighted. Patients were encouraged to engage and communicate, share experiences, identify possible obstacles, and discuss how to overcome them. The educational sessions lasted 60–90 min and were performed either in groups or individually depending on the number of participants in each clinic. Themes from the education session were discussed further by the physiotherapists during the exercise therapy and iCBT sessions.

Exercise therapy

The physiotherapy-guided AktivA program [24] was implemented individually or in group training sessions of 45–60 min × 2 per week for 12 weeks and individually adjusted with regard to dose and progression of exercises. The aim was to strengthen lower extremity muscles, increase range of motion (ROM), and improve balance and functional stability of the knee. Appropriate position of the joints, with hip, knee, and footwell aligned, was emphasized. The pain monitoring system described by Thomee in 1997 [25], was used. The pain was measured with a Visual Analog Scale (VAS) from 0 to 10 where zero is no pain and 10 is the worst possible pain. VAS 0-2 was considered safe and 2–5 was acceptable. If the patient experienced pain above five during or immediately after exercising, the exercises were adjusted. Pain should return to normal within 24 hours after exercise, if not, the dosage should be reduced.

Cognitive behavioral therapy

The iCBT program used in this trial is developed for, and targeted to improve pain and function for, patients with OA and patients undergoing TKA at risk of poor outcome [19] by targeting known psychological risk factors (i.e., anxiety, depression, and catastrophic thinking). The program was developed according to the first two steps in the Medical Research Council framework for complex interventions. The details of the program and its developmental process were previously published [19]. The program consists of 10 modules and a total of 86 tasks to be completed during the program. Each module follows a similar structure, with psychoeducational texts and videos presenting relevant topics, and tasks and exercises. A fictional character, receiving non-surgical or surgical treatment is presented and followed throughout the program. The theme and content for each module are presented in Table 2. In addition, the patients are mentored with telephone support sessions every second week, from the study center physiotherapists, trained by an experienced CBT psychologist. Furthermore, a manual was developed for the physiotherapists to ensure consistency. It contained the 10 modules from the iCBT program, and two extra learning modules developed specifically for the physiotherapists (modules 11 and 12). Module 11 introduced basic CBT and Motivational Interviewing (MI) principles, and module 12 provided guidance on how to handle patients' resistance to the program and address potential challenges.

Standard postoperative care

Patients were mobilized to standing on the day of surgery whenever possible, and full weight bearing on the operated knee was permitted. Standardized physiotherapy, including both active and passive flexion and extension exercises, was initiated on the day after surgery. Patients used crutches for mobilization and were typically discharged on the second-day post-surgery. Within 2 weeks after discharge, patients in group B started the MultiKnee program. Patients in group C received standard care physiotherapy in the municipalities, typically involving

Table 2 The iCBT[a] program, modules, themes, and content

Module	Theme	Content
1	Getting started	Introduction Port control theory Relaxation technique
2	Goals for the recovery	Five key elements important for coping with pain FAQ[b] about exercise and activity Goals for recovery
3	Stress and pain	Change habits Stress and pain Locus of control
4	Lifestyle	How type of lifestyle can contribute to the symptoms Safety behaviour
5	Identifying automatic thoughts	Thinking errors Automatic thoughts The inner dialogue
6	Creating alternative thoughts	Twelve common thinking errors Generating alternative thoughts
7	Be more mindful	Default mode network and mental habits Focused attention
8	Selective attention	How to be more mindful Selective attention Unhelpful assumptions
9	Postponing worry and rumination	Worry and rumination How to make a postponement log
10	What's next?	Summary What have you learned?
Learning modules for physiotherapists:		
11	Basic CBT[c] for physiotherapists	Key elements for CBT
12	Talking to the patients	Motivational Interviewing techniques

[a] *iCBT*=internet-delivered cognitive behavioral therapy

[b] *iCBT*=internet-delivered cognitive behavioral therapy

[c] *CBT*=cognitive behavioral therapy

exercise therapy with varying levels of supervision, aimed at improving range of motion, strength, balance, and gait.

Outcomes and statistics

Three main changes were performed in the recruitment process: (1) screening all patients for risk factors from the middle of August 2019 to the beginning of December 2019. (2) Screening only candidates for TKA for risk factors from the beginning of December 2019 to the middle of March 2020. (3) No screening for risk factors from April 2020 to July 2020. Numbers and percentages describe the recruitment rate.

Compliance with the intervention was reported as the number of compilers for each of the treatment options. Treatment compliance was defined as acceptable when patients had attended at least 75% of the exercise therapy sessions and had completed at least 75% of the iCBT tasks.

Outcome measures included both Norwegian versions of Patient Reported Outcome Measures (PROM) [26] and physical-performance tests (Table 3) and are described as numbers of patients who completed the PROMs and physical-performance tests at baseline and at 3-, 6- and 12 months after the start of the intervention. Crossovers are reported as numbers of patients who crossed over from one group to another within the first year.

Adverse events and serious adverse events were registered in three steps: screening of the medical records at the hospitals, reports by the physiotherapists, and self-reported by the patients, using questionnaires. Medical records were screened at 12 months for all adverse events from inclusion until the 12-month follow-up. An adverse event was defined as any undesirable experience during follow-up that led to contact with the health care system. A serious adverse event was defined as any event that led to hospitalization, prolonged in-hospital care or additional surgery, was life-threatening or resulted in permanent disability or damage, or death [27]. Numbers and types of adverse events were described.

Demographic characteristics are reported in mean and standard deviation (SD). The analysis of clinical outcome measures was descriptive and reported as median and interquartile ranges (IQR).

Table 3 Patient-reported outcome measures and clinical assessments

	Baseline	3 months	6 months	12 months
Patient-reported outcome measures (PROM)				
1. Socio-demographics	x			
2. Self-reported comorbidity	x			
3. Health-related Quality of life (EQ-5D-5L)	x	x	x	x
4. Brief Pain Inventory (BPI)	x	x	x	x
5. Knee Injury and Osteoarthritis Outcome Score (KOOS)	x	x	x	x
6. Forgotten Joint Score (FJS-12)	x	x	x	x
7. Fear-Avoidance Belief Questionnaire (FABQ)	x	x	x	x
8. Pain Catastrophizing Scale (PCS)	x	x	x	x
9. Patient-acceptable symptom state (PASS)		x	x	x
10. Treatment failure		x	x	x
11. Global Perceived Effect (GPE)		x	x	x
12. Locus of Control Scale	x	x	x	x
13. Pittsburgh Sleep Quality Index	x	x	x	x
14. Physical activity (SoC[a], HUNT[b] 2)	x	x	x	x
15. Hospital Anxiety and Depression Scale (HADS)	x	x	x	x
Clinical assessments				
16. ActiGraph GT3X-BT Activity monitor	x		x	x
17. The 40-meter Fast-paced Walk Test	x	x	x	x
18. The Stair Climb Test	x	x	x	x
19. 30-second sit-to-stand test	x	x	x	x
20. Range of Motion (ROM)	x	x	x	x
21. Body Mass Index (BMI)	x	x	x	x
22. X-rays	x			x

[a] *SoC* State of change physical activity

[b] *HUNT* Nord-Trøndelag health study

Sample size

The sample size for this feasibility study was based on practical considerations, budgetary constraints, and the number of participants needed to reasonably evaluate the feasibility goals, as recommended by the National Center for Complementary and Integrative Health (NCCIH) [28]. In its nature, this work is qualitative and descriptive, and we did not aim to evaluate group differences or effect sizes. Thus, a sample of less than 30 may be adequate [29]. For this complex trial, we considered that 5 participants per group would be sufficiently large to inform our research questions, and realistic given our timeline.

The sample size for the full-scale trial was revised as a result of the feasibility trial. Before the feasibility trial, the sample size was estimated to be 62 patients per group, allowing for a 20% dropout we would need 223 patients. The revised sample size was based on an estimated minimal clinical perceptible improvement of 10 points in the primary outcome KOOS. Based on a previous study, we set the standard deviation of change to 16 [30]. This revised calculation revealed that we would need 78 patients in each treatment group. To allow for a 20% dropout, 282 patients will be recruited in the full-scale trial. The details of sample size estimation are described elsewhere [26].

Results

Between August 2019 and June 2020, 350 patients were assessed for eligibility. Fifteen patients were included in the feasibility study and randomized into three groups. The inclusion of patients and attrition at follow-up is shown as a flow diagram in Fig. 3. Demographic characteristics of the patients included are shown in Table 4.

Recruitment of participants

The recruitment process is thoroughly described in three time periods based on the changes we made (Fig. 3).

> 1) Screening all patients for risk factors from the middle of August 2019 to the beginning of December 2019.

This screening procedure was found too demanding for both the study staff and the patients. Many patients who did not fulfill the other inclusion criteria, such as indication for surgery, were screened for risk factors to no avail.

> 2) Screening only candidates for TKA for risk factors from the beginning of December 2019 to the middle of March 2020.

The recruitment rate remained too low to justify initiating a large RCT, indicating that the screening algorithm might be too strict and reduced the number of potential candidates significantly. However, a less strict screening algorithm may lead to higher imprecision. Thus, the research team decided to include all patients who were candidates for TKA and instead incorporate the screening questionnaire into the baseline questionnaire.

At this time, the country was locked down due to the COVID-19 pandemic, and recruitment to the study was paused for 2 months.

> 3) No screening for risk factors from May 2020 to July 2020.

Since the major reason for not being included was living too far away, we changed this criterion at the end of May 2020. Recruitment for the pilot study was completed on June 10, 2020.

Compliance with the intervention and follow-up

In total, nine out of 10 completed at least 75% of the ExE sessions, six out of 10 patients completed at least 75% of the iCBT program, and nine out of 10 underwent TKA surgery.

Education

All patients in groups A and B attended the education session at one of the study hospitals.

ExE

All five patients in the non-surgical group A attended all ExE sessions. In surgical group B, four patients attended all ExE sessions; one patient attended 12 sessions (50%) due to bereavement. In total, 9 out of the 10 participants completed at least 75% of the ExE program and were defined as compliers.

iCBT

One patient, included early in the study period, received the prototype version of the program with 12 modules and 113 tasks. This patient completed 26 of 113 tasks (32%). The other nine patients received the second version of the program with 10 modules and 86 tasks. They completed a mean of 68 out of 86 tasks (79%). Six out of 10 patients completed more than 75% of the tasks.

In total, patients in group A completed 83% of the tasks, four out of five patients completed more than 75% of the tasks, one patient thought the program was too demanding and completed 60% of the tasks. In total, all patients in group B completed 57% of the tasks, one patient got the prototype version of the program with more tasks. One had back problems and was unable to sit by the computer, and one experienced death in near relation. Two out of five patients in group B completed more than 75% of the iCBT program.

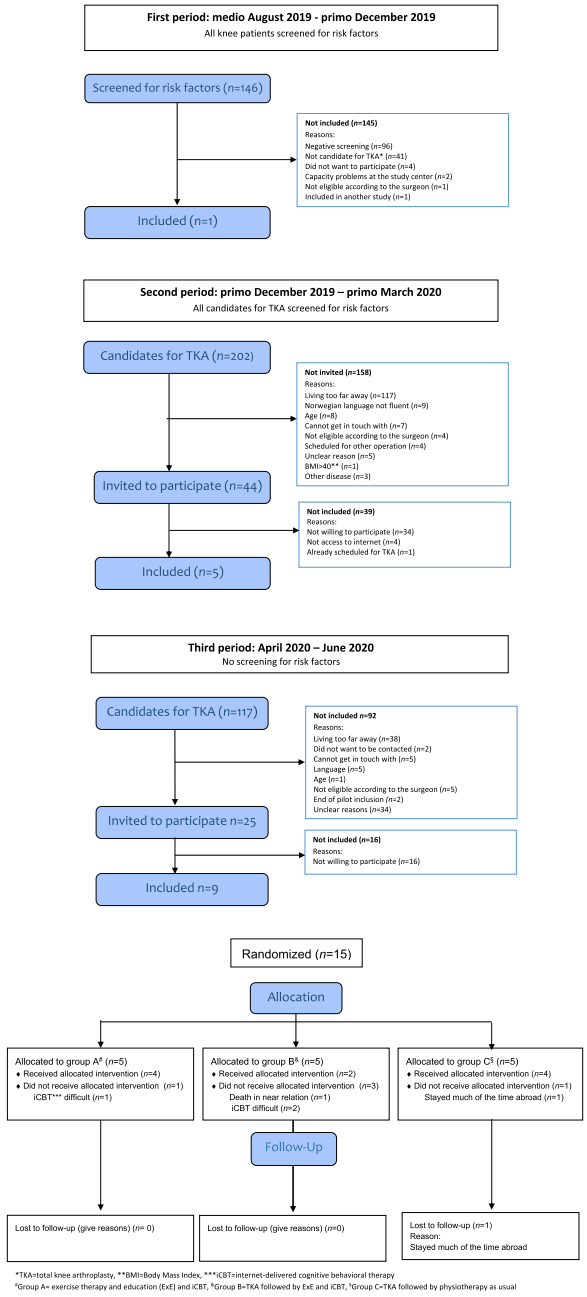

Fig. 3 Flow diagram for a randomized feasibility study for patients with knee osteoarthritis

Table 4 Demographics in a randomized feasibility study for patients with knee osteoarthritis[a]

	Group A[b] (*n* = 5)	Group B[c] (*n* = 5)	Group C[d] (*n* = 5)	Total (*n* = 15)
Female sex—*n*	3	3	2	8
Age—years	61.6 ± 6.19	63.8 ± 7.19	66.0 ± 9.08	63.8 ± 7.26
Weight—kg	81.4 ± 7.60	86.3 ± 8.08[e]	97.5 ± 12.24[f]	88.5 ± 11.99[g]
Body mass index—kg/m^2	28 ± 2.64	29 ± 2.58 [e]	32 ± 4.4[f]	30 ± 3.6[g]

[a] Plus-minus values are means±SD

[b] Group A=exercise therapy and education(ExE)+internet-delivered cognitive behavioral therapy (iCBT)

[c] Group B=total knee arthroplasty (TKA) followed by ExE+iCBT

[d] Group C=TKA followed by physiotherapy as usual

[e] *n=3*

[f] *n=4*

[g] *n=9*

Follow-up

Fourteen out of 15 patients answered the baseline and 3-month questionnaire, 13 answered at 6 months and 12 months. Median and IQR for the key outcomes are presented in Table 5.

Fourteen patients completed the physical performance tests at baseline and at 3-, 6-, and 12 months (Table 6).

Cross over

No participants crossed to surgery within the first year.

Adverse events

One participant in group B experienced hyperesthesia in part of the scar, treated by the surgeon with local anesthesia and cortisone. No other adverse events were registered.

Discussion

The lessons learned in this feasibility study were crucial to refine the procedures, as well as the acceptability of the complex intervention itself, prior to testing and evaluating the intervention in a future RCT. In particular, the feasibility study provided critical insights into serious threats to the recruitment rate.

These insights resulted in important changes for the improvement of the recruitment strategy for the ongoing MultiKnee RCT [26].

Recruitment and retention rate

Challenges regarding recruitment to surgical trials are common and have been described in other studies [31, 32]. Initially, we attempted to recruit patients at risk for a poor outcome based on screening using the validated appropriateness classification system developed by Escobar et al. [22] and studies on risk factors. However, our screening tools' accuracy in identifying patients at higher risk for a poor outcome had not been evaluated, and the low recruitment rate indicated that it was not reliable enough to identify patients relevant to the study. We therefore decided to integrate the risk factors into the baseline questionnaire and stop recruiting based on the risk factors. To ensure sufficient statistical power to identify significant differences between groups in the full-scale trial, a new sample size estimation was performed to account for a revised sample, including patients with and without a higher risk for a poor outcome. This change in the inclusion criteria increased the recruitment rate significantly.

Preference for either surgical or non-surgical treatment was considered a potential threat to inclusion in our study that we wanted to test in the feasibility trial. In a qualitative synthesis study, Davies and colleagues [33] found that many patients and healthcare professionals had a strong preference for either surgery or non-surgical treatment. Preoperative decision-making is a complex process for both clinician and patient. Despite the large number of knee replacements undertaken, no clear consensus exists within the surgical community about exact indications, particularly in terms of severity of preoperative symptoms, obesity, and age [34]. Based on our experiences in the recruitment process, it is essential to inform patients in a way that they understand the pros and cons of each treatment to be able to make a well-informed choice regarding trial participation. Recruitment of patients to the study depends on the surgeons' participation. Training and support can make them more comfortable in the recruitment process [35].

As the guidelines state that exercise therapy is the first-line treatment for patients with OA, many patients may have tried this before they were referred to the orthopedic surgeon. However, Bruhn et al [36] found in their study that only 41% of patients had received supervised

Table 5 Outcome in PROMS data and clinical examination

		Baseline			3 months			6 months			12 months	
	Group[a]	*N*	Median	IQR[b]	*N*	Median	IQR	*N*	Median	IQR	*N*	Median	IQR[a]
KOOS[c] pain	A	5	41.67	31.94	5	62.89	26.39	5	66.67	23.61	4	62.50	17.36
	B	5	47.22	25.00	5	75.00	30.56	5	88.56	26.39	5	88.89	23.61
	C	4	44.44	54.86	4	62.50	34.03	3	66.67		4	80.56	49.31
KOOS symptoms	A	5	50.00	26.79	5	71.43	26.79	5	67.86	30.36	4	69.64	32.14
	B	5	60.71	12.50	5	60.71	28.57	5	78.57	30.36	5	85.71	12.50
	C	4	50.00	55.36	4	66.07	35.71	3	53.57		4	73.21	38.39
KOOS adl[d]	A	5	54.41	33.82	5	76.47	20.59	5	75.00	33.09	4	69.12	28.68
	B	5	57.35	38.24	5	83.82	21.32	5	91.18	22.06	5	94.12	12.50
	C	4	52.94	46.69	4	70.59	33.82	3	64.71		4	83.82	54.78
KOOS sport/recreation	A	5	15.00	27.50	5	35.00	20.00	5	20.00	32.50	4	35.00	17.50
	B	5	25.00	32.50	5	35.00	20.00	5	35.00	17.50	5	50.00	22.50
	C	4	20.00	25.00	4	37.50	22.50	3	30.00		4	35.00	40.00
KOOS qol[e]	A	5	37.50	40.63	5	50.00	37.50	5	50.00	28.13	4	50.00	40.63
	B	5	37.50	15.63	5	68.75	21.88	5	62.50	25.00	5	87.50	18.75
	C	4	34.38	39.06	4	56.25	31.25	3	50.00		4	59.38	48.44
PCS[f] total	A	5	10.00	3.50	5	18.00	18.00	5	5.00	5.00	4	5.50	7.25
	B	4	10.50	14.50	5	18.00	3.00	5	3.00	9.00	5	2.00	1.50
	C	4	18.00	29.25	4	19.50	13.25	3	8.00		4	8.50	16.25
HADS[g] anxiety	A	5	5.00	2.00	5	2.00	5.00	5	3.00	3.50	4	2.00	2.00
	B	3	7.00		5	3.00	3.50	5	3.00	3.00	5	3.00	3.50
	C	4	4.00	8.00	4	2.50	4.50	3	2.00		4	0.50	7.00
HADS depression	A	5	3.00	3.00	5	2.00	3.00	5	1.00	1.50	4	1.50	4.00
	B	3	3.00		5	2.00	2.50	5	1.00	1.00	5	2.00	1.50
	C	4	4.00	7.25	4	3.50	7.50	3	3.00		4	3.00	8.50
HADS sum	A	5	8.00	2.00	5	6.00	6.00	5	4.00	5.00	4	3.50	5.50
	B	3	10.00		5	5.00	4.00	5	4.00	2.00	5	3.00	3.00
	C	4	8.00	15.25	4	6.00	12.00	3	4.00		4	3.50	15.00
FJS[h]	A	5	12.50	35.42	5	22.91	23.96	5	22.91	25.00	4	33.33	16.15
	B	5	12.50	33.33	5	39.58	65.63	5	64.58	40.62	5	64.58	35.42
	C	4	19.79	17.71	4	22.91	38.54	3	27.08		4	27.08	72.92
FABQ[i]	A	5	6.00	7.00	5	5.00	6.00	5	4.00	6.00	4	6.00	5.25
	B	5	14.00	15.50	5	3.00	6.50	5	0.00	1.50	5	2.00	6.00
	C	4	18.00	10.75	4	9.50	10.00	3	10.00		4	10.00	18.00
Stair test (s)	A	5	9.94	3.85	5	8.32	2.27	5	9.16	2.67	5	8.53	1.43
	B	5	10.97	8.82	5	10.22	5.55	4	9.19	3.20	5	8.22	5.02
	C	4	12.89	31.13	4	18.10	9.27	4	15.58	12.59	4	14.88	16.89
Sit to stand	A	5	20.00	6.50	5	24.00	6.50	5	22.00	12.50	5	24.00	9.50
	B	5	13.00	5.00	5	17.00	6.00	4	16.50	4.75	5	21.00	11.00
	C	4	12.50	10.50	4	11.50	6.25	4	11.50	10.25	4	14.50	10.50
40-m walk test (s)	A	5	19.24	7.35	5	19.37	6.84	5	18.75	3.93	5	18.33	5.47
	B	5	27.73	5.63	5	23.37	6.69	4	21.53	7.61	5	18.21	10.13
	C	4	25.93	44.20	4	27.03	7.69	4	28.09	13.05	4	27.58	26.00
Active flexion	A	5	130.00	10.00	5	125.00	12.50	5	125.00	15.00	5	120.00	7.50
	B	5	120.00	10.00	5	110.00	2.50	4	112.50	12.50	5	115.00	22.50
	C	4	122.50	23.75	4	117.50	12.50	4	110.00	17.50	4	115.00	10.00
Active extension	A	5	− 5.00	10.00	5	0.00	15.00	5	− 5.00	7.50	5	− 5.00	5.00
	B	5	− 10.00	10.00	5	− 10.00	10.00	4	− 5.00	7.50	5	0.00	7.50
	C	4	− 17.50	12.50	4	− 7.50	8.75	4	− 6.00	8.00	4	− 7.50	8.75

Table 5 (continued)

[a] *Group A* MultiKnee program, *Group B* total knee arthroplasty followed by the MultiKnee program, *Group C* total knee arthroplasty followed by physiotherapy as usual

[b] *IQR* interquartile range

[c] *KOOS* Knee Injury and Osteoarthritis Outcome Score 0–100-higher score=less problems

[d] *adl* activity of daily living

[e] *qol* quality of life

[f] *PCS* Pain Catastrophizing Scale—higher score=more catastrophizing

[g] *HADS* Hospital Anxiety and Depression Scale—higher score=more anxiety and depression

[h] *HADS* Hospital Anxiety and Depression Scale—higher score=more anxiety and depression

[i] *FABQ* Fear-Avoidance Belief Questionnaire—0–24-higher score=more fear avoidance beliefs

Table 6 Data completeness for physical performance tests from baseline to 1 year, *n* (%)

	Baseline ***n*** **(%)**	**3 months** ***n*** **(%)**	**6 months** ***n*** **(%)**	**12 months** ***n*** **(%)**
Group A* $n = 5$	5 (100)	5 (100)	5 (100)	4 (80)
Group B[a] $n = 5$	5 (100)	5 (100)	4 (80)	5 (100)
Group C[b] $n = 5$	4 (80)	4 (80)	4 (80)	4 (80)
Total $n = 15$	14 (93)	14 (93)	13 (87)	13 (87)

*Group A=exercise therapy and education(ExE)+internet-delivered cognitive behavioral therapy (iCBT)

[a] Group B=exercise therapy and education(ExE)+internet-delivered cognitive behavioral therapy (iCBT)

[b] Group C=TKA followed by physiotherapy as usual

land-based exercise, and 23% of patients had participated in patient education prior to consultation with the orthopedic surgeon. Some of the patients in the current study may have declined to participate because they had already attended exercise therapy programs similar to the exercise program in this study.

In the recruitment process, when informing patients about the study, some patients decided to decline randomization which could lead to being randomized to surgery, as they had not tried the supervised exercise of sufficient dose and length first.

Compliance with the intervention and follow-up

We found that compliance with the ExE program was higher than compliance with the iCBT program. Some patients found it hard to understand how a psychological intervention could help their knee problems whereas the rationale behind exercise therapy seemed easier to understand.

The iCBT program was therefore revised and shortened to be more accessible, relevant, and understandable during the feasibility study [19]. This cyclic process of refinement included tailoring the intervention even more to patients with OA and patients undergoing TKA, simplifying the language, and making navigation in the program easier, in line with the MRC framework [20] before implementing it in the definite RCT.

Crossover

Patients in non-surgical group A were asked to delay the operation for at least 1 year. Although we had anticipated a potential risk that some patients would decide to undergo TKA surgery before a year had passed, no one crossed over during the first year. This may be due to the small sample size in this study. Skou and colleagues [4] reported that 26% crossed over from non-surgical to surgical group within the first year. Some precautions can be made to reduce crossover or discontinuation. In-depth information about the study and its implications for the participants is crucial. Informational videos can be a valuable supplement to oral and written information [37].

Adverse events

All surgical procedures involve a potential risk of serious adverse events [38]. No serious events were registered in this study. This is most likely due to the small sample size. Skou and colleagues found that the incidence of adverse events was higher in the surgical group than in the non-surgical group [4].

Strengths and limitations

Randomized controlled trials (RCT) are expensive and time-consuming endeavors. To avoid waste in research, developing studies with high methodological quality has been highlighted [39], which was especially relevant in the process of developing this complex intervention trial. Our study illustrates the importance of following a systematic process including feasibility testing, as recommended in the MRC framework [20]. The complex intervention in this trial is a strategic selection of treatment modalities. The ExE program is based on AktivA, a well-documented program based on international guidelines for the nonsurgical treatment of patients with OA in Norway [24]. Similar models have been in use in Sweden (BOA) [40] since 2008 and in Denmark (GLA:D) [41] since 2013, and these programs have shown to be well

suited for clinical practice and results show significant improvements concerning pain, physical function, and health-related quality of life in patients with hip and/or knee osteoarthritis [41, 42]. In addition, the neuromuscular exercise program used in GLA:D has previously been shown to be effective for patients with moderate to severe osteoarthritis eligible for TKA and after undergoing TKA [15].

The iCBT program has been through a thorough development process, following the UK Medical Research Council framework for developing complex interventions [20]. By conducting a feasibility trial, we ensure the feasibility of a future RCT, and that the intervention is relevant and acceptable for its target group. The refining of the iCBT program will probably increase compliance with the intervention. The feasibility trial was not powered to investigate the effect of the intervention. The ongoing RCT will provide valuable information on the potential this treatment has to improve outcomes in knee OA and TKA patients [26].

The sample size in this study was small, which is a limitation. However, the feasibility trial was not intended to have the power to investigate the effect of the intervention. Therefore, we believe that a sample of 15 patients was sufficient to address our research questions.

The inclusion criteria in this study can have resulted in reduced generalizability. Recruitment of patients was conducted at two hospitals in different parts of Norway. This ensured participants both from urban and rural areas in Norway. The criteria for Norwegian writing and reading competence can have excluded a portion of the OA and TKA patients with other native languages.

We limited our pool by including only patients with a combination of radiographic and clinical manifestations of OA. Because 2 of 3 participants were randomized to surgery, we needed to be sure that all patients had radiographic changes compatible with OA. Without such changes, there would not be an indication for surgery, and it would be unethical to allow them to undergo surgery. Because of this, our findings may not be generalizable to patients with low-grade radiographical OA.

A feasibility study has an important role in designing an RCT [43]. Our study revealed weaknesses in the recruitment process and possible threats to patients' compliance with the intervention. The adjustments made on the inclusion and exclusion criteria were crucial to ensure an appropriate recruitment rate and will strengthen the planned RCT. This study illustrates the importance of evaluating the feasibility of complex interventions in terms of recruitment procedures, retention rate, and acceptability of the intervention, as suggested by the MRC framework for complex interventions [20]. Findings from this study resulted in further development and improved feasibility of our protocol, thus leading to a feasible and well-managed full-scale RCT [26].

Conclusions

The findings from this study suggested that it was feasible to conduct a definite and methodologically robust RCT evaluating the effectiveness of a combined education, exercise therapy, and cognitive behavioral therapy program in patients with osteoarthritis eligible for TKA, either instead of or in addition to TKA. The recruitment process was challenging initially and several changes during the study were necessary to increase recruitment. While compliance with the education, exercise therapy, and follow-up was high, revision of the developed iCBT program was necessary to increase compliance.

Abbreviations

CONSORT	The Consolidated Standards of Reporting Trials
ExE	Exercise therapy and education
iCBT	Internet-delivered cognitive behavioral therapy
IQR	Inter-quartile range
MI	Motivational interviewing
OA	Osteoarthritis
OARSI	The Osteoarthritis Research Society International
PROM	Patient reported outcome measures
RCT	Randomized controlled trial
ROM	Range of motion
TKA	Total knee arthroplasty
VAS	Visual analog scale

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Authors' contributions

TR: conceptualization, methodology, writing—original draft. IBB: writing—review and editing. OF: writing—review and editing. KI: writing—review and editing. AL: conceptualization, methodology, writing—review, and editing. MFL: conceptualization, methodology, supervision, writing—review and editing. STS: supervision, writing—review, and editing. JS: writing—review and editing. MB: supervision, writing—original draft. All authors read and approved the final manuscript.

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Availability of data and materials
Due to Norwegian ethical and legal restrictions, the dataset generated and analyzed during the current study is stored at the Service for Sensitive Data (TSD) at the University of Oslo. Requests for access to an anonymized data set can be sent to Anners Lerdal (anle@lds.no). Requests must specify what the data will be used for, who will be responsible for storage, and how it will be stored. Final approval from the Data Protection Officer and the Regional Committees for Medical and Health Research Ethics will be required prior to the release of the anonymized minimal dataset.

Declarations

Ethics approval and consent to participate
The study has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki and the regulations of the US Health Insurance Portability and Accountability Act (HIPAA).
The Regional Medical Research Ethics Committee of Health East of Norway approved the study (2017/968).
Written informed consent was obtained from all subjects.

Consent for publication
Not applicable

Competing interests
Dr. Skou has received personal fees from Munksgaard TrustMe-Ed and Nestle Health Science, all of which are outside the submitted work. He is co-founder of Good Life with Osteoarthritis in Denmark (GLA:D®), a not-for-profit initiative hosted at the University of Southern Denmark aiming at implementing clinical guidelines for patients with osteoarthritis in clinical practice. All other authors declare that they have no competing interests.

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Publisher's Note

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Gjøril Bergva	22845529	27.06.2017	2017/968 REK sør-øst D
			Deres dato:	**Deres referanse:**
			09.05.2017	

Vår referanse må oppgis ved alle henvendelser

Anners Lerdal
Lovisenberg Diakonale Sykehus

2017/968 Kneproteseoperasjoner - Screening av pasienter og behandlingsresultater

Forskningsansvarlig: Lovisenberg Diakonale Sykehus
Prosjektleder: Anners Lerdal

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst D) i møtet 07.06.2017. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10.

Prosjektleders prosjektbeskrivelse
Årlig opereres omlag 5400 med total kneprotese (TKP) for å lindre smerte hos pasienter med kneartrose, men 20% har kroniske smerter ett år etter inngrepet. Dette prosjektet består av to studier. Studie 1: Hensikten er å utvikle et klinisk screeningsverktøy som identifiserer pasienter med høy risiko for kroniske smerter etter TKP. En rekke spørsmål fra validerte spørreskjema med potensiale til å fange opp risikofaktorer for kroniske smerter vil bli testet ut blant pasienter og ortopeder. Basert på svarene vil listen revideres og prøves ut i en longitudinell studie blant 200 TKP-pasienter. Studie 2 vil teste effekten av fysioterapi og mental trening i kombinasjon, som et tillegg til og som erstatning for TKP i en tre-armet randomisert studie. Totalt 210 pasienter på venteliste for TKP vil bli inkludert i studien fra fire sykehus/helseregioner i Norge. Resultatmålet vil være smerte, funksjon og livskvalitet. Pasientene vil bli fulgt opp i to år med gjentatte målinger.

Vurdering
Prosjektet er todelt. I studie 1 skal man utvikle et screeningverktøy som identifiserer pasienter med høy risiko for smerte etter TKP. Studie 2 vil teste effekten av fysioterapi og mental trening i kombinasjon, som et tillegg til og som erstatning for TKP i en tre-armet randomisert studie. Det skal innhentes opplysninger fra spørreskjema, pasientjournal, samt fra nasjonale registre (helse- omsorg og sosiale tjenester). Det er utarbeidet informasjon og samtykkeskjemaer tilpasset ulike faser og deltakere i prosjektet.

Komiteen har ingen innvendinger mot at prosjektet gjennomføres som beskrevet i søknad og protokoll.

Vedtak
Med hjemmel i helseforskningsloven § 9 jf. 33 godkjenner komiteen at prosjektet gjennomføres.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder til 30.06.2037. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 30.06.2042. Forskningsfilen skal oppbevares atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal

deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse og omsorgssektoren».

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt.

Komiteens avgjørelse var enstemmig.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn på korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Gjøril Bergva
Rådgiver

Kopi til: Lovisenberg Diakonale Sykehus ved øverste administrative ledelse: post@lds.no

FORNØYDHET OG HELSEKOMPETANSE ETTER HOFTE- OG KNEPROTESEOPERASJON

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Dette er en forespørsel til deg om å delta i et forskningsprosjekt for å undersøke fornøydhet og helsekompetanse etter hofte- og kneproteseoperasjon. Lovisenberg Diakonale Sykehus samarbeider med Nasjonalt Register for Leddproteser for å samle inn data i Norge. Formålet med dette prosjektet er todelt. For det første, å teste et nytt spørreskjema som omhandler fornøydhet og livskvalitet etter hofte- og/eller kneproteseoperasjon. For det andre, å få kunnskap om helsekompetanse, inkludert digital helsekompetanse. Digital helsekompetanse omhandler evnen til å forstå, vurdere og anvende digital helseinformasjon for å kunne ta fornuftige valg relatert til egen helse.

HVA INNEBÆRER PROSJEKTET FOR DEG?

Dersom du velger å delta i prosjektet, vil du bli spurt om å fylle ut et spørreskjema. Spørsmålene omhandler alder, kjønn, bosituasjon, utdanningsnivå, fornøydhet og helsekompetanse etter hofte- og kneproteseoperasjon. I tillegg vil vi innhente data fra Nasjonalt Register for Leddproteser om proteseoperasjonen. Vi forventer at det vil ta om lag 30 minutter å fylle ut spørreskjemaet. Et lite utvalg vil bli bedt om å fylle ut en liten andel av spørreskjemaet ved en anledning til.

MULIGE FORDELER OG ULEMPER

Deltagelse i studien innebærer ingen spesielle fordeler eller ulemper.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst trekke ditt samtykke uten å oppgi noen grunn. Dersom du trekker deg kan du kreve å få slettet innsamlede opplysninger. Du kan kreve innsyn i opplysningene som er lagret om deg og har rett til å korrigere feil. Disse vil da bli utlevert innen 30 dager. Dette gjelder ikke dersom opplysningene er anonymisert eller publisert, og kan begrenses dersom opplysningene er inngått i utførte analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder.

HVA SKJER MED OPPLYSNINGENE OM DEG?

Spørreskjemaet returneres til Lovisenberg Diakonale Sykehus i en ferdig frankert svarkonvolutt og skannes inn på et tilgangsstyrt og passordbeskyttet område på sykehusets forskningsserver. Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 2027. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra Regional komité for medisinsk og helsefaglig forskningsetikk (REK) og andre relevante myndigheter. Du har rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud. Vi vil behandle opplysningene konfidensielt og i samsvar

med personvernregelverket. Du vil ikke kunne gjenkjennes i publikasjoner. Opplysningene anonymiseres når prosjektet avsluttes. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og kan finne tilbake til deg.

Det daglige ansvaret forvaltes av prosjektleder. Hvis du har spørsmål om behandlingen av helse- og personopplysninger i studien kan du kontakte prosjektleder ved kontaktinformasjonen nedenfor, eller personvernombudet på Lovisenberg Diakonale Sykehus: (Erling Moldal, epost: Personvern@lds.no)

GODKJENNINGER

REK har gjort en forskningsetisk vurdering og godkjent prosjektet. (REK: 2017/968) Personvernombudet på Lovisenberg Diakonale Sykehus har vurdert og tilrådet prosjektet.

Lovisenberg Diakonale Sykehus og prosjektleder Anners Lerdal er ansvarlig for personvernet i prosjektet.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte:
Prosjektleder: Anners Lerdal. E-postadresse: Anners.lerdal@medisin.uio.no
Doktorgradsstipendiat: Ingvild Buset Bergvad. E-postadresse: IngvildBuset.Bergvad@lds.no

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER BRUKES SLIK DET ER BESKREVET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

Fysisk aktivitet og mental trening for pasienter med kneartrose, som vurderes for kneproteseoperasjon

Dette er et spørsmål til deg om å delta i et forskningsprosjekt. Målet er få kunnskaper om fysioterapibehandling i kombinasjon med mental trening innvirker på behandlingsresultatet for pasienter som vurderes for kneproteseoperasjon. Forskning viser at pasienter opplever varierende effekt etter kneprotesekirurgi, og at mange kan ha nytte av målrettet trening. Studien er organisert som et samarbeid mellom Lovisenberg Diakonale Sykehus i Oslo, Kysthospitalet i Hagevik, Bergen og Martina Hansens Hospital i Bærum. Lovisenberg Diakonale Sykehus er prosjektansvarlig og har hovedansvaret for gjennomføringen av studien.

HVA INNEBÆRER PROSJEKTET?

Hvis du velger å delta i studien vil du ved loddtrekning bli fordelt i en av tre grupper:

Gruppe A: Trekkes du til denne gruppen vil du bli bedt om å utsette kneproteseoperasjonen i ett år. I stedet vil du gjennomgå en pasientskole om kneartrose, livsstilsfaktorer, fysisk aktivitet og trening, samt selvhjelpsstrategier. Du vil også motta et opplegg med tilpasset fysioterapibehandling to ukentlige timer á 60 minutter over 12 uker. Hver treningstime vil bestå av oppvarming, styrketrening, funksjonell trening og tøying. Du vil også bli oppfordret til å gjøre egentrening hjemme. Parallelt med fysioterapi vil du gjennomføre et kurs med mental trening over internett med ukentlige oppgaver over 10 uker. Internett-kurset skal hjelpe deg til å finne gode strategier for å håndtere smerter, trene og være aktiv. Du kan logge deg inn og gjøre oppgavene fra egen PC, nettbrett eller smarttelefon på tidspunkter som passer best for deg.

Gruppe B: Trekkes du til denne gruppen vil du bli søkt innlagt til kneproteseoperasjon. Før operasjonen vil du gjennomgå en pasientskole om kneartrose, livsstilsfaktorer, fysisk aktivitet og trening, samt selvhjelpsstrategier. Etter operasjonen vil du motta et opplegg med tilpasset fysioterapibehandling to ukentlige timer á 60 minutter. Hver treningstime vil bestå av oppvarming, styrketrening, funksjonell trening og tøying. Du vil også bli oppfordret til å gjøre egentrening hjemme. Parallelt med fysioterapi vil du gjennomføre et kurs med mental trening over internett med ukentlige oppgaver over 10 uker. Internett-kurset skal hjelpe deg til å finne gode strategier for å håndtere smerter, trene og være aktiv. Du kan logge deg inn og gjøre oppgavene fra egen PC, nettbrett eller smarttelefon på tidspunkter som passer best for deg.

Gruppe C: Trekkes du til denne gruppen vil du bli søkt innlagt til kneproteseoperasjon og følger standard behandling inkludert vanlig fysioterapi etter operasjonen.

Hvis du bestemmer deg for å delta vil du bli bedt om å komme til sykehuset for kontroll før du starter å trene eller blir operert, og 3,6,12 og 24 mnd. etterpå. Du vil også bli bedt om å gå med en aktivitetsmåler og å svare på spørreskjema i forbindelse med de 5 kontrollene.

Spørsmålene omhandler bakgrunnsinformasjon om deg, smerter, psykisk helse, tanker om sykdom og kneproblemene dine, og om helsen din. Vi forventer at det vil ta om lag 30 minutter å fylle ut spørreskjemaet. I prosjektet vil vi i tillegg innhente opplysninger fra din journal om undersøkelser, (røntgenbilder, blodprøver) og behandling**,** (medikamentbruk, anestesi, operasjonslengde, liggetid i sykehus) du har vært gjennom.

MULIGE FORDELER OG ULEMPER

Noen av deltakerne vil bli trukket til å delta i spesialtilpasset fysioterapibehandling og et internettbasert kurs i mental trening. Noen kan oppleve det som en ulempe å bli bedt om å utsette eventuell operasjon i ett år, mens andre kan oppleve det som positivt å få prøve ut et alternativ til operasjon. Å delta i studien innebærer ingen spesiell økt risiko sammenliknet med andre pasienter som gjennomgår kneprotesekirurgi. Det forventes at pasientene som ved loddtrekning trekkes til kun fysioterapi og mental trening vil ha færre komplikasjoner enn pasienter som gjennomgår kirurgi. Deltagelse i studien vil ikke påvirke din behandling eller oppfølging etter at studien er over.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektarbeider Maren Falch Lindberg, tlf.: 94815762 marenfalch.lindberg@lds.no eller prosjektleder Anners Lerdal, tlf. 23225000, anners.lerdal@lds.no

HVA SKJER MED INFORMASJONEN OM DEG?

Spørreskjemaene sendes inn til Universitetet i Oslo sin tjeneste for sensitive data ("TSD"). TSD systematiserer og oppbevarer svarene du har gitt i spørreskjemaet før materialet overføres til en forskningsserver ved Lovisenberg Diakonale Sykehus, hvor resultatene kobles sammen med utvalgte opplysninger fra din journal. Det er inngått databehandleravtale med TSD som instruerer TSD om hvordan de skal håndtere opplysningene de mottar.

I tillegg til opplysningene fra journalen vil vi etter en tid innhente opplysninger om ditt bruk av helse-, omsorg og sosiale tjenester fra nasjonale registre (dvs. Forløpsdatabasen Trygd, Kontroll og Utbetaling av Helserefusjoner og Norsk Pasientregister). Disse opplysningene hentes for å studere langtidskonsekvenser av behandlingen.

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til opplysninger om deg gjennom en navneliste. Det betyr at opplysningene er avidentifisert. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

Det vil ikke være mulig å identifisere deg i resultatene fra studien når disse publiseres.

Lovisenberg Diakonale Sykehus og Kysthospitalet Hagevik har et felles dataansvar for helse- og personopplysninger som inngår i studien. Partenes respektive forpliktelser er regulert i en egen avtale, hvor det blant annet fremkommer at Lovisenberg Diakonale Sykehus er ansvarlig for at forskningsdataene oppbevares og forvaltes på en sikker måte, siden forskningsdataene lagres og aksesseres fra Lovisenberg sine IT-løsninger. Avidentifiserte data om helsekompetanse kan bli delt med den norske HLS19-forskergruppen ved Helsedirektoratet.

Det daglige ansvaret forvaltes av prosjektleder. Hvis du har spørsmål om behandlingen av helse- og personopplysninger i studien, kan du kontakte prosjektleder på kontaktinformasjonen som er oppgitt ovenfor eller personvernombudet ved Lovisenberg Diakonale Sykehus Anne Grete Sandbukt, tlf: 47 93 22 24 79, annegrete.sandbukt@lds.no.

OPPFØLGINGSPROSJEKT

Hvis det blir aktuelt med oppfølging utover de to årene som er angitt, vil vi be om nytt samtykke til deltagelse.

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk REK (referansenr.: 2017/968).

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Forespørsel om å delta i forskningsprosjekt

Mai 2022

Til deg som er proteseoperert,

I samarbeid med Nasjonalt Register for Leddproteser er dette et spørsmål til deg om å delta i et forskningsprosjekt som skal undersøke fornøydhet og helsekompetanse etter hofte- og kneproteseoperasjon. Denne studien vil gi oss verdifull kunnskap som vi kan bruke for å forbedre pasientbehandlingen. Vedlagt finner du kort informasjon om prosjektet, samtykkeerklæring og spørreskjema.

Med vennlig hilsen

Prosjektgruppen v/ prosjektansvarlig: Professor Anners Lerdal

Lovisenberg Diakonale Sykehus

multi-knee

Fornøydhet og helsekompetanse etter hofte og kneproteseoperasjon

Veiledning for utfylling av spørreskjema
Dette spørreskjemaet vil ta ca. 20 minutter å fylle ut. Informasjonen vil bli brukt til å få mer kunnskap om fornøydhet og helsekompetanse hos pasienter som har gjennomgått protesekirurgi i hofte og/eller kne.

Det er ikke sikkert du finner svaralternativer som passer akkurat din situasjon, men det er likevel viktig at du svarer på alle spørsmål. Velg i så fall det svaralternativet som kommer nærmest.
De ferdigutfylte spørreskjemaene legges i vedlagt svarkonvolutt og returneres så snart du har anledning. Husk å underskrive det vedlagte samtykket.

Tusen takk for din deltakelse i studien!

Dato for utfyllelse: _____

Med vennlig hilsen

Prosjektgruppen v/ Anners Lerdal

FORNØYDHET OG HELSEKOMPETANSE ETTER HOFTE- OG KNEPROTESEOPERASJON

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Dette er en forespørsel til deg om å delta i et forskningsprosjekt for å undersøke fornøydhet og helsekompetanse etter hofte- og kneproteseoperasjon. Lovisenberg Diakonale Sykehus samarbeider med Nasjonalt Register for Leddproteser for å samle inn data i Norge. Formålet med dette prosjektet er todelt. For det første, å teste et nytt spørreskjema som omhandler fornøydhet og livskvalitet etter hofte- og/eller kneproteseoperasjon. For det andre, å få kunnskap om helsekompetanse, inkludert digital helsekompetanse. Digital helsekompetanse omhandler evnen til å forstå, vurdere og anvende digital helseinformasjon for å kunne ta fornuftige valg relatert til egen helse.

HVA INNEBÆRER PROSJEKTET FOR DEG?

Dersom du velger å delta i prosjektet, vil du bli spurt om å fylle ut et spørreskjema. Spørsmålene omhandler alder, kjønn, bosituasjon, utdanningsnivå, fornøydhet og helsekompetanse etter hofte- og kneproteseoperasjon. I tillegg vil vi innhente data fra Nasjonalt Register for Leddproteser om proteseoperasjonen. Vi forventer at det vil ta om lag 30 minutter å fylle ut spørreskjemaet. Et lite utvalg vil bli bedt om å fylle ut en liten andel av spørreskjemaet ved en anledning til.

MULIGE FORDELER OG ULEMPER

Deltagelse i studien innebærer ingen spesielle fordeler eller ulemper.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst trekke ditt samtykke uten å oppgi noen grunn. Dersom du trekker deg kan du kreve å få slettet innsamlede opplysninger. Du kan kreve innsyn i opplysningene som er lagret om deg og har rett til å korrigere feil. Disse vil da bli utlevert innen 30 dager. Dette gjelder ikke dersom opplysningene er anonymisert eller publisert, og kan begrenses dersom opplysningene er inngått i utførte analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder.

HVA SKJER MED OPPLYSNINGENE OM DEG?

Spørreskjemaet returneres til Lovisenberg Diakonale Sykehus i en ferdig frankert svarkonvolutt og skannes inn på et tilgangsstyrt og passordbeskyttet område på sykehusets forskningsserver. Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 2027. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra Regional komité for medisinsk og helsefaglig forskningsetikk (REK) og andre relevante myndigheter. Du har rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud. Vi vil behandle opplysningene konfidensielt og i samsvar

med personvernregelverket. Du vil ikke kunne gjenkjennes i publikasjoner. Opplysningene anonymiseres når prosjektet avsluttes. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og kan finne tilbake til deg.

Det daglige ansvaret forvaltes av prosjektleder. Hvis du har spørsmål om behandlingen av helse- og personopplysninger i studien kan du kontakte prosjektleder ved kontaktinformasjonen nedenfor, eller personvernombudet på Lovisenberg Diakonale Sykehus: (Erling Moldal, epost: Personvern@lds.no)

GODKJENNINGER

REK har gjort en forskningsetisk vurdering og godkjent prosjektet. (REK: 2017/968) Personvernombudet på Lovisenberg Diakonale Sykehus har vurdert og tilrådet prosjektet.

Lovisenberg Diakonale Sykehus og prosjektleder Anners Lerdal er ansvarlig for personvernet i prosjektet.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte:
Prosjektleder: Anners Lerdal. E-postadresse: Anners.lerdal@medisin.uio.no
Doktorgradsstipendiat: Ingvild Buset Bergvad. E-postadresse: IngvildBuset.Bergvad@lds.no

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER BRUKES SLIK DET ER BESKREVET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

BAKGRUNNSINFORMASJON

1. I hvilket år er du født?:_____

2. Kjønn:

- ☐ Mann
- ☐ Kvinne
- ☐ Annet

3. Hvem bor du sammen med?
(sett ett eller flere kryss)

- ☐ Ektefelle/samboer
- ☐ Barn/svigerbarn
- ☐ Bor alene
- ☐ Søster/bror
- ☐ Annen familie/slekt
- ☐ Bor på institusjon
- ☐ Andre

4. Hva er din sivilstand?

- ☐ Gift/registrert partner
- ☐ Ugift
- ☐ Enke/enkemann
- ☐ Skilt
- ☐ Separert

ARBEID

5. Hva slags arbeidssituasjon har du nå?
(sett ett eller flere kryss)

- ☐ Lønnet arbeid
- ☐ Selvstendig næringsdrivende
- ☐ Heltids husarbeid
- ☐ Utdanning, militærtjeneste
- ☐ Arbeidsledig, permittert
- ☐ Pensjonist/trygdet

GEOGRAFI

6. Hvilket fylke bor du i?

- ☐ Troms og Finnmark
- ☐ Nordland
- ☐ Trøndelag
- ☐ Møre og Romsdal
- ☐ Vestland
- ☐ Rogaland
- ☐ Agder
- ☐ Vestfold og Telemark
- ☐ Viken
- ☐ Oslo
- ☐ Innlandet

UTDANNING

7. Hvilken utdanning er den høyeste du har fullført?

- ☐ Grunnskole 7-10 år, framhaldsskole folkehøgskole
- ☐ Real- eller middelskole, yrkesskole, ett- eller toårig videregående skole
- ☐ Artium, økonomisk gymnas eller allmennfaglig retning i videregående skole
- ☐ Høgskole eller universitet, mindre enn 4 år
- ☐ Høgskole eller universitet, 4 år eller mer

Norwegian

eHLQ e-Health Literacy Questionnaire

Vi vil gjerne be deg om å svare på 35 utsagn om dine meninger og erfaringer om bruk av digitale tilbud og teknologi i helse. For de fleste tar det ca. 10 minutter å fylle ut skjemaet.

Det finnes ingen riktige eller gale svar. Besvar spørsmålene ut fra dine erfaringer og tenk på hvordan du bruker helseteknologi for å styrke og ivareta din helse.

Det er viktig at alle utsagn blir besvart, så hvis det er et utsagn du ikke kan forholde deg til umiddelbart, så prøv likevel å angi et synspunkt. Dersom det er situasjoner som du ikke kan sette deg inn i vil det beste svaret være «uenig».

Litt om hvordan ordene vi bruker i skjemaet kan forstås:

Ordet **"helsearbeider"** dekker de personene du møter i helsevesenet, f.eks. hos din egen lege, på sykehuset eller i kommunehelsetjenesten. Det kan f.eks. være leger, sykepleiere, tannleger, ernæringsfysiologer, fysioterapeuter, helsesøstre eller psykologer.

Med «**helsetilbud»** menes de tjenester du tilbys av både helsepersonell og de personer du har kontakt med som ikke er autorisert helsepersonell, som f.eks. trenere, veiledere og alternative terapeuter.

Betegnelsen **"digitale systemer om helse"** dekker internett-sider, registre og andre kilder til helseopplysninger som er tilgjengelige digitalt, f.eks. elektronisk pasientjournal, helsenettsteder eller tjenestene fra din egen lege.

Ordet**" teknologi"** dekker digitale systemer som kan bli brukt til å finne, vise, registrere eller mestre informasjon på enheter som din mobiltelefon, datamaskin, nettbrett, eller ulike registreringsapparater som pulsklokke, klesplagg eller digitale skala etc. Det kan være et apparat eller flere apparater.

eHLQ

	Angi hvor enig eller uenig du er i følgende påstander	Veldig uenig	Uenig	Enig	Veldig enig
1	Jeg er sikker på at mine helseopplysninger kun brukes av personene de er beregnet for.	❑	❑	❑	❑
2	Teknologi gjør at jeg føler meg engasjert i min egen helse.	❑	❑	❑	❑
3	Mine helseopplysninger er alltid tilgjengelige for dem som har behov for tilgang.	❑	❑	❑	❑
4	Jeg vet hvordan jeg skal bruke teknologi for å få informasjon jeg trenger.	❑	❑	❑	❑
5	Kunnskapen jeg har hjelper meg til å ha gode samtaler med andre om helse.	❑	❑	❑	❑
6	Jeg vet hvordan jeg bruker teknologi til nytte for meg selv .	❑	❑	❑	❑
7	Jeg bruker teknologi til å finne informasjon om helse.	❑	❑	❑	❑
8	Jeg kan taste inn opplysninger i digitale systemer om helse.	❑	❑	❑	❑
9	Helsearbeidere jeg har kontakt med har tjenester jeg kan få tilgang til digitalt.	❑	❑	❑	❑
10	Mine elektroniske helseopplysninger oppbevares på en sikker måte.	❑	❑	❑	❑
11	Jeg bruker ofte teknologi for å forstå spørsmål om min helse.	❑	❑	❑	❑
12	Jeg har nok kunnskap til å delta i samtaler om helsen min.	❑	❑	❑	❑
13	Teknologi hjelper meg til å velge hvilke helsetilbud som er best for meg.	❑	❑	❑	❑
14	Jeg har god forståelse av hvordan helsearbeidere bruker mine helseopplysninger.	❑	❑	❑	❑
15	Jeg forstår undersøkelsesresultater som handler om meg.	❑	❑	❑	❑
16	Jeg får tak i mine helseopplysninger uansett hvor jeg er.	❑	❑	❑	❑

eHLQ

	Angi hvor enig eller uenig du er i følgende påstander	Veldig uenig	Uenig	Enig	Veldig enig
17	Jeg lærer raskt å finne ut av nye digitale muligheter.	❑	❑	❑	❑
18	Jeg opplever at digitale systemer om helse tilpasser seg til mine evner.	❑	❑	❑	❑
19	Jeg syns at teknologi hjelper meg med til å ta vare på helsen min.	❑	❑	❑	❑
20	Jeg bruker teknologi til å dele informasjon om helsen min.	❑	❑	❑	❑
21	I store trekk forstår jeg hvordan kroppen min fungerer.	❑	❑	❑	❑
22	Jeg er sikker på at bare de personene som har rett til det ser mine helseopplysninger.	❑	❑	❑	❑
23	Alle digitale systemer om helse som jeg bruker, kommuniserer med hverandre .	❑	❑	❑	❑
24	Jeg synes jeg får bedre hjelp fra helsearbeidere når jeg bruker teknologi.	❑	❑	❑	❑
25	Jeg bruker teknologi til å holde orden på helseopplysningene mine.	❑	❑	❑	❑
26	Jeg bruker målinger i forhold til min kropp til å forstå min helse.	❑	❑	❑	❑
27	Teknologi forbedrer kommunikasjonen min med helsearbeidere.	❑	❑	❑	❑
28	Digitale systemer om helse ser ut til å tilpasse seg mine behov .	❑	❑	❑	❑
29	Jeg kan nå de fleste av mine kontakter i helsevesenet digitalt.	❑	❑	❑	❑
30	Jeg har tillit til at helsearbeidere benytter helseopplysningene mine på en passende måte.	❑	❑	❑	❑
31	Jeg synes at mine digitale tjenester stilles til rådighet i en form som passer meg.	❑	❑	❑	❑
32	Det er enkelt for meg å lære å bruke ny helseteknologi.	❑	❑	❑	❑
33	Digitale systemer om helse gir meg lett tilgang til det jeg har bruk for.	❑	❑	❑	❑

	Angi hvor enig eller uenig du er i følgende påstander	Veldig uenig	Uenig	Enig	Veldig enig
34	Jeg har tilgang til digitale helsetilbud som fungerer godt.	❑	❑	❑	❑
35	Jeg synes at teknologi er nyttig for å få følge med på helsetilstanden min.	❑	❑	❑	❑

Takk for hjelpen. ☺

T1

Spørreskjema

Dato:……..

BAKGRUNNSINFORMASJON

1. I hvilket år er du født?:_____

2. Kjønn:

☐ Mann
☐ Kvinne

3. Hvem bor du sammen med?
(sett ett eller flere kryss)

☐ Ektefelle samboer
☐ Barn/svigerbarn
☐ Bor alene
☐ Søster/bror
☐ Annen familie/slekt
☐ Bor på institusjon
☐ Andre

4. Hva er din sivilstand?

☐ Gift/registrert partner
☐ Ugift
☐ Enke/enkemann
☐ Skilt
☐ Separert

5. Har du barn?

Ja ☐ Nei ☐

6. Hvis du har barn, hvor mange barn har du daglig ansvar for innenfor følgende aldersgrupper:

0-5 år	6-10 år	11-15 år
_____ (antall)	_____ (antall)	_____ (antall)

UTDANNING

7. Hvilken utdanning er den høyeste du har fullført?

☐ Grunnskole 7-10 år, framhaldsskole folkehøgskole

☐ Real- eller middelskole, yrkesskole, ett- eller toårig videregående skole

☐ Artium, økonomisk gymnas eller allmennfaglig retning i videregående skole

☐ Høgskole eller universitet, mindre enn 4 år

☐ Høgskole eller universitet, 4 år eller mer

ARBEID

8. Hva slags arbeidssituasjon har du nå?
(sett ett eller flere kryss)

☐ Lønnet arbeid
☐ Selvstendig næringsdrivende
☐ Heltids husarbeid
☐ Utdanning, militærtjeneste
☐ Arbeidsledig, permittert
☐ Pensjonist/trygdet

ARBEID forts.

9. Hvis du er eller har vært i inntekts-givende arbeid, kan du angi hvilken av disse yrkeskategoriene ditt yrke faller innenfor?

(Hvis du ikke er i arbeid nå, svarer du ut fra det yrket du hadde sist.)

- ☐ Administrativ leder, politiker
- ☐ Akademisk yrke (minst 4 års høyskole- eller universitetsutdanning
- ☐ Yrke med kortere høyskole- eller universitetsutdanning (1-3 år) og teknikere
- ☐ Kontor- og kundeserviceyrker
- ☐ Salgs-, service- og omsorgsyrker
- ☐ Jordbruks-, skogbruks- og fiskeryrker
- ☐ Håndverker, bygningsarbeider, fagarbeider og lignende
- ☐ Yrke uten formelt krav til utdanning
- ☐ Har ikke hatt inntektsgivende arbeid (f.eks. pga. heltids husarbeid, studier, trygd)

10. Har du noen sykdom eller lidelse av mer varig natur, noen medfødt sykdom eller virkninger av skade?
Vi tenker på vanskeligheter/begrensninger av mer varig karakter. Med varig karakter menes at de har vart eller forventes å vare i 6 måneder eller mer.

Ja ☐ Nei ☐

11. Er du ofte syk? Ja ☐ Nei ☐

12. Er du sykemeldt pga kneproblemene dine nå?

Ja ☐ Nei ☐

13. Er du sykemeldt pga andre årsaker?

Ja ☐ Nei ☐

ANDRE HENDELSER I LIVET

14. Sett kryss hvis du i den senere tiden (de siste 4 uker) har opplevd noen av følgende hendelser:

- ☐ Giftet deg/flyttet sammen med samboer
- ☐ Fått barn
- ☐ Dødsfall familie/nære venner
- ☐ Alvorlig bomessige eller økonomiske problemer

Andre sykdommer

Det følgende er en liste over vanlige medisinske problemer. Avmerk i den grå kolonnen med ja eller nei. Hvis JA, svar på spørsmålene i de blå og grønne kolonnene. Hvis NEI, gå videre til neste linje.

	Har du problemet?		Får du behand-ling for det?		Begrenser det dine aktiviteter?	
Problem	Ja	Nei	Ja	Nei	Ja	Nei
1. Hjertesykdom						
2. Høyt blodtrykk						
3. Lungesykdom						
4. Diabetes						
5. Magesår/ magesykdom						
6. Tarmsykdom						
7. Nyresykdom						
8. Leversykdom						
9. Anemi eller annen blodsykdom						
10. Hodepine						
11. Depresjon						
12.Slitasjegikt/artrose						
13. Rygg/ nakkesmerter						
14. Leddgikt/ revmatoid artritt						
15. Sykdom i bindevev eller muskulatur						
16. Hudlidelser						
17. Kreft						
18. Andre medisinske problemer (angi) ----------						

Spørreskjema om helse

Norsk versjon, for Norge

(Norwegian version for Norway)

Under hver overskrift ber vi deg krysse av den ENE boksen som best beskriver helsen din I DAG.

GANGE

Jeg har ingen problemer med å gå omkring ❑
Jeg har litt problemer med å gå omkring ❑
Jeg har middels store problemer med å gå omkring ❑
Jeg har store problemer med å gå omkring ❑
Jeg er ute av stand til å gå omkring ❑

PERSONLIG STELL

Jeg har ingen problemer med å vaske meg eller kle meg ❑
Jeg har litt problemer med å vaske meg eller kle meg ❑
Jeg har middels store problemer med å vaske meg eller kle meg ❑
Jeg har store problemer med å vaske meg eller kle meg ❑
Jeg er ute av stand til å vaske meg eller kle meg ❑

VANLIGE GJØREMÅL *(f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)*

Jeg har ingen problemer med å utføre mine vanlige gjøremål ❑
Jeg har litt problemer med å utføre mine vanlige gjøremål ❑
Jeg har middels store problemer med å utføre mine vanlige gjøremål ❑
Jeg har store problemer med å utføre mine vanlige gjøremål ❑
Jeg er ute av stand til å utføre mine vanlige gjøremål ❑

SMERTER/UBEHAG

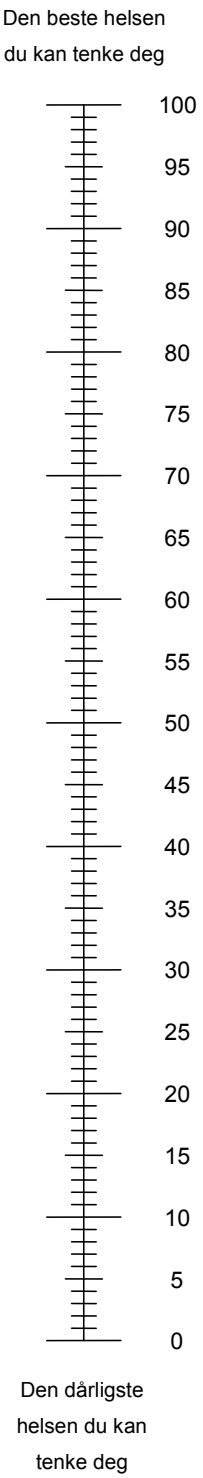
Jeg har verken smerter eller ubehag ❑
Jeg har litt smerter eller ubehag ❑
Jeg har middels sterke smerter eller ubehag ❑
Jeg har sterke smerter eller ubehag ❑
Jeg har svært sterke smerter eller ubehag ❑

ANGST/DEPRESJON

Jeg er verken engstelig eller deprimert ❑
Jeg er litt engstelig eller deprimert ❑
Jeg er middels engstelig eller deprimert ❑
Jeg er svært engstelig eller deprimert ❑
Jeg er ekstremt engstelig eller deprimert ❑

- Vi vil gjerne vite hvor god eller dårlig helsen din er I DAG.
- Denne skalaen er nummerert fra 0 til 100.
- 100 betyr den beste helsen du kan tenke deg.
  0 betyr den dårligste helsen du kan tenke deg.
- Sett en X på skalaen for å angi hvordan helsen din er I DAG.
- Skriv deretter tallet du merket av på skalaen
  inn i boksen nedenfor.

HELSEN DIN I DAG = ☐



40857

Brief Pain Inventory

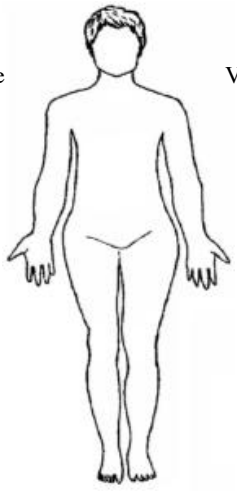
Pasientnr. ☐☐☐ Dato ☐☐.☐☐.☐☐☐☐

1. Gjennom livet har de fleste av oss hatt smerter (som lett hodepine, forstuelser eller tannpine). Har du i dag smerter av et annet slag enn slike dagligdagse smerter.

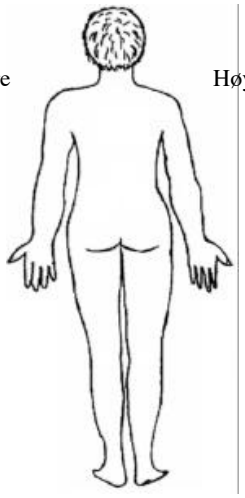
☐ Ja ☐ Nei

2. Vil du skravere de områdene på kroppen hvor du har smerter. Marker med et kryss der du har mest vondt.

Høyre Venstre



Venstre Høyre



3. Vennligst sett ring rundt det tallet som best beskriver de sterkeste smertene du har hatt i løpet av de siste 24 timer.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

4. Vennligst sett ring rundt det tallet som best beskriver de svakeste smertene du har hatt i løpet av de siste 24 timer.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

5. Vennligst sett ring rundt det tallet som best angir hvor sterke smerter du har i gjennomsnitt.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

6. Vennligst sett ring rundt det tallet som best angir hvor sterke smerter du har akkurat nå.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

Vennligst snu arket

40857

7. Hvilken behandling eller medisiner får du for å lindre smertene dine?

8. I hvor stor grad har behandling eller medisiner lindret smertene dine de siste 24 timene?
Vennligst sett en ring rundt det prosenttallet som viser hvor stor smertelindring du har fått.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Ingen lindring **Fullstendig lindring**

Sett en ring rundt det tallet som for de siste 24 timene best beskriver hvor mye smertene har virket inn på :

9. Daglig aktivitet

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket **Fullstendig påvirket**

10. Humør

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket **Fullstendig påvirket**

11. Evne til å gå

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket **Fullstendig påvirket**

12. Vanlig arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket **Fullstendig påvirket**

13. Forhold til andre mennesker

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket **Fullstendig påvirket**

14. Søvn

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket **Fullstendig påvirket**

15. Livsglede

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket **Fullstendig påvirket**

Tusen takk for hjelpen!

Bergen 15 May 2007

Norwegian KOOS, version LK1.0

The KOOS form was translated into Norwegian in the following way.

Translation done at The Norwegian Arthroplasty Register (NAR)

- KOOS was translated from the Swedish version by two researchers in orthopedics. The choice of using the Swedish version was based on the assumption that cultural differences between the two neighbour countries would be minimal due to similarities in language and lifestyle.
- The translation was checked by two bilingual orthopedic surgeons (Swedes with permanent address in Norway).
- The form was tested on knee arthroplasty patients to clarify potential misinterpretations.

Translation done by The Norwegian National Knee Ligament Registry (NKLR)

- A translation from the English version was done by an orthopedic researcher.
- Another translation from the Swedish version was done by a former researcher at the Norwegian School of Sport Sciences who is bilingual in Norwegian and Swedish.
- The translations were compared, and due to only minor differences in the use of synonyms, the NKLR chose a wording as close to the Swedish translation as possible. This is due to the fact that the creators of the KOOS form are Swedish, even though the first form was made in English.

Finally the NAR and the NKLR versions were compared, minor adjustments were done, and the translators agreed upon a common translation. The final validated Norwegian version is named KOOS Norwegian version LK1.0

Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
5021 Bergen

The Norwegian Arthroplasty Register
Department of Orthopaedic Surgery
Haukeland University Hospital
N-5021 Bergen, Norway

☎ +47 -5597 6454/3742
+47 -5597 3749
http://www.haukeland.no/nrl/

KOOS SP RRESKJEMA FOR KNEPASIENTER

DATO: _____/_____/_____ FØDELSENR (11 siffer): _____

NAVN: _____

Veiledning: Dette spørreskjemaet inneholder spørsmål om hvordan du opplever kneet ditt. Informasjonen vil hjelpe oss til å følge med i hvordan du har det og fungerer i ditt daglige liv. Besvar spørsmålene ved å krysse av for det alternativ du synes passer best for deg (kun ett kryss ved hvert spørsmål). Hvis du er usikker, kryss likevel av for det alternativet som føles mest riktig.

Symptom

Tenk på de **symptomene** du har hatt fra kneet ditt den **siste uken** når du besvarer disse spørsmålene**.**

S1. Har kneet vært hovent?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

S2. Har du følt knirking, hørt klikking eller andre lyder fra kneet?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

S3. Har kneet haket seg opp eller låst seg?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

S4. Har du kunnet rette kneet helt ut?

Alltid	Ofte	Iblant	Sjelden	Aldri
☐	☐	☐	☐	☐

S5. Har du kunnet bøye kneet helt?

Alltid	Ofte	I blant	Sjelden	Aldri
☐	☐	☐	☐	☐

Stivhet

De neste spørsmålene handler om **leddstivhet**. Leddstivhet innebærer vanskeligheter med å komme i gang eller økt motstand når du bøyer eller strekker kneet. Marker graden av leddstivhet du har opplevd i kneet ditt den **siste uken**.

S6. Hvor stivt er kneet ditt når du nettopp har våknet om morgenen?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐	☐	☐	☐	☐

S7. Hvor stivt er kneet ditt **senere på dagen** etter å ha sittet, ligget eller hvilt?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐	☐	☐	☐	☐

Smerte

P1. Hvor ofte har du vondt i kneet?

Aldri	Månedlig	Ukentlig	Daglig	Hele tiden
☐	☐	☐	☐	☐

Hvilken grad av smerte har du hatt i kneet ditt den **siste uken** ved følgende aktiviteter?

P2. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P3. Rette kneet helt ut

Ingen	Lett	Moderate	Betydelig	Svært stor
☐	☐	☐	☐	☐

P4. Bøye kneet helt

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P5. Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P6. Gå opp eller ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P7. Om natten i sengen (smerter som forstyrrer søvnen)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P8. Sittende eller liggende

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P9. Stående

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Funksjon I hverdagen

De neste spørsmål handler om din fysiske funksjon. **Angi graden av vanskeligheter du har opplevd den siste uken ved f lgende aktiviteter p grunn av dine kneproblemer**.

A1. Gå ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A2. Gå opp trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Angi graden av **vanskeligheter** du har opplevd ved hver aktivitet den **siste uken**.

A3. Reise deg fra sittende stilling

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A4. Stå stille

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A5. Bøye deg, f.eks. for å plukke opp en gjenstand fra gulvet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A6. Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A7. Gå inn/ut av bil

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A8. Handle/gjøre innkjøp

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A9. Ta på sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A10. Stå opp fra sengen

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A11. Ta av sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A12. Ligge i sengen (snu deg, holde kneet i samme stilling i lengre tid)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A13. Gå inn og ut av badekar/dusj

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A14. Sitte

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A15. Sette deg og reise deg fra toalettet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Angi graden av **vanskeligheter** du har opplevd ved hver aktivitet den **siste uken.**

A16. Gjøre tungt husarbeid (måke snø, vaske gulv, støvsuge osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A17. Gjøre lett husarbeid (lage mat, tørke støv osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Funksjon, sport og fritid

De neste spørsmålene handler om din fysiske funksjon. Angi graden av vanskeligheter du har opplevd **den siste uken** ved følgende aktiviteter på grunn av dine kneproblemer.

SP1. Sitte på huk

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP2. Løpe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP3. Hoppe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP4. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP5. Stå på kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Livskvalitet

Q1. Hvor ofte gjør ditt kneproblem seg bemerket?

Aldri	Månedlig	Ukentlig	Daglig	Alltid
☐	☐	☐	☐	☐

Q2. Har du forandret levesett for å unngå å overbelaste kneet?

Ingenting	Noe	Moderat	Betydelig	Fullstendig
☐	☐	☐	☐	☐

Q3. I hvor stor grad kan du stole på kneet ditt?

Fullstendigl	I stor grad	Moderat	Til en viss grad	Ikke i det hele tatt
☐	☐	☐	☐	☐

Q4. Generelt sett, hvor store problemer har du med kneet ditt?

Ingen	Lette	Moderate	Betydelige	Svært store
☐	☐	☐	☐	☐

Takk for at du tok deg tid og besvarte samtlige sp rsm l!

Until otherwise is decided it is recommended that future revisions of the Norwegian KOOS form are done by The Norwegian Arthroplasty Register. If someone find that any questions from the questionnaire is difficult to understand or difficult to answer, we will be thankful to receive information on this.

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Spørreskjema for knepasienter (Forgotten Joint Score - 12)

Pasient: _____ Dato: ___.___._____

Et friskt ledd er man ikke bevisst i hverdagen. Men selv små plager kan gjøre at man blir oppmerksom på et ledd. Dette innebærer at man tenker på leddet eller blir oppmerksom på det. De følgende spørsmålene handler om **hvor ofte du i hverdagen er oppmerksom på ditt affiserte kneledd.**

Vennligst velg det mest passende svaret på hvert spørsmål.

	Legger du merke til ditt kneledd…	**Aldri**	**Nesten aldri**	**Sjelden**	**Noen ganger**	**Som oftest**
1.	… i sengen om natten?	O	O	O	O	O
2.	… når du sitter i en stol i mer enn en time?	O	O	O	O	O
3.	… når du går mer enn 15 minutter?	O	O	O	O	O
4.	… når du tar et bad/dusjer?	O	O	O	O	O
5.	… når du kjører i bil?	O	O	O	O	O
6.	… når du går opp trapper?	O	O	O	O	O
7.	… når du går i ulendt terreng?	O	O	O	O	O
8.	… når du reiser deg opp fra en lavtsittende stilling?	O	O	O	O	O
9.	… når du står oppreist i lang tid?	O	O	O	O	O
10.	… når du gjør husarbeid eller arbeider i hagen?	O	O	O	O	O
11.	… når du går på tur/vandretur?	O	O	O	O	O
12.	… når du driver med din favorittsport?	O	O	O	O	O

SMERTE, FYSISK AKTIVITET OG JOBB (Fear-Avoidance Beliefs Questionnaire, Waddell et al 1993)

Her er noe av det som andre har fortalt oss om ryggsmertene sine. Kryss av for ett tall fra 0 *(helt uenig)* til 6 *(helt enig)* for hvert utsagn for å si hvor mye fysiske aktiviteter som å bøye seg, løfte, gå eller kjøre vil påvirke ryggen *din*.

		HELT UENIG 0	1	USIKKER 2	3	4	5	HELT ENIG 6
1	Smertene mine ble forårsaket av fysisk aktivitet							
2	Fysisk aktivitet forverrer smertene mine							
3	Fysisk aktivitet kan skade ryggen min							
4	Jeg burde ikke utføre fysiske aktiviteter som (kan) forverre smertene mine							
5	Jeg kan ikke utføre fysiske aktiviter som (kan) forverre smertene mine							

Følgende utsagn handler om hvordan det vanlige arbeidet ditt påvirker eller kan påvirke ryggsmertene dine

		HELT UENIG 0	1	USIKKER 2	3	4	5	HELT ENIG 6
6	Smertene mine ble forårsaket av arbeidet mitt eller et uhell på jobben							
7	Arbeidet mitt forverret smertene mine							
8	Jeg har framsatt erstatningskrav for smertene mine							
9	Arbeidet mitt er for tungt for meg							
10	Arbeidet mitt forverrer eller kan forverre smertene mine							
11	Arbeidet mitt kan skade ryggen min							
12	Jeg burde ikke utføre det vanlige arbeidet mitt med mine nåværende smerter							
13	Jeg kan ikke utføre det vanlige arbeidet mitt med mine nåværende smerter							
14	Jeg kan ikke utføre det vanlige arbeidet mitt før smertene er behandlet							
15	Jeg tror ikke jeg vil være tilbake på det vanlige arbeidet mitt innen tre måneder							
16	Jeg tror ikke jeg noen gang vil være i stand til å komme tilbake til det arbeidet							

The Fear-Avoidance Beliefs Questionnaire (FABQ) (Waddell et al 1993)
Oversatt av Margreth Grotle og Nina K:Vøllestad 2001,
Seksjon for Helsefag, Universitetet i Oslo,

Scoringsprosedyre

- Man skårer de to skalaene – FABQ for fysisk aktivitet (den øverste delen) og for arbeid (den nederste delen) hver for seg
- FABQ for fysisk aktivitet består av summen av sps 2, 3, 4 og 5
- FABQ for arbeid består av summen av sps 6, 7, 9, 10, 11, 12 og 15.

Pain Catastrophizing Scale (PCS)

Alle opplever smerter på et aller annet tidspunkt i livet. Slike smerteopplevelser kan være hodepine, tannverk, ledd- og muskelsmerter. Folk er ofte utsatt for situasjoner som kan forårsake smerter, slik som sykdom, skade, tannbehandling og kirurgi.
Vi er interessert i hva slags tanker og følelser du har når du har smerter. Nedenfor står det 13 utsagn som beskriver ulike tanker og følelser som kan være forbundet med smerte. Bruk følgende skala og indiker i hvilken grad du har slike tanker og følelser når du opplever smerte.

	Når jeg har smerter ...	**Ikke i det hele tatt**	**Litt**	**I moderat grad**	**I stor grad**	**Hele tiden**
1	jeg er hele tiden bekymret for at smertene ikke vil gi seg	0	1	2	3	4
2	jeg føler at jeg ikke klarer å fortsette	0	1	2	3	4
3	det er forferdelig og jeg tror at det aldri vil bli bedre	0	1	2	3	4
4	det er fryktelig, og jeg føler at det overvelder meg	0	1	2	3	4
5	jeg føler at jeg ikke holder det ut lenger	0	1	2	3	4
6	jeg blir redd for at smertene skal bli verre	0	1	2	3	4
7	jeg tenker stadig på andre smertefulle opplevelser	0	1	2	3	4
8	jeg ønsker desperat at smertene skal forsvinne	0	1	2	3	4
9	det virker som jeg ikke klarer å få det ut av hodet	0	1	2	3	4
10	jeg tenker stadig på hvor vondt det er	0	1	2	3	4
11	jeg tenker stadig på hvor inderlig jeg vil at smertene skal gi seg	0	1	2	3	4
12	det er ingenting jeg kan gjøre for å redusere smertenes intensitet	0	1	2	3	4
13	jeg lurer på om noe alvorlig kan komme til å skje	0	1	2	3	4

…….…Sum

(PCS Michael JL Sullivan 1995, translated by M Grotle et al 2008)

87%

Alt i alt, hvordan er dine knæproblemer nu i forhold til før du startede din behandling i studiet?

- ○ Bedre, en vigtig forbedring
- ◉ Lidt bedre, nok til at det er en vigtig forbedring
- ○ Meget lille forbedring, ikke nok til at det er en vigtig forbedring
- ○ Uændret
- ○ Meget lillet forværring, ikke nok til at det er en vigtigt forværring
- ○ Lidt værre, nok til at det er en vigtig forværring
- ○ Værre, en vigtig forværring

‹ › Næste

89%

Når du tænker på din knæfunktion, vil du så vurdere din nuværende tilstand som tilfredsstillende?

Ved knæfunktion skal du tage højde for dine daglige gøremål, sport og fritidsaktiviteter, dine smerter og andre symptomer, samt din livskvalitet.

- ◉ Ja
- ○ Nej

‹ › Næste

Danish **R**ct on **E**xercise versus **A**rthroscopic **M**eniscal surgery for young adults – The **DREAM** study

90%

Vil du vurdere din egen tilstand som så utilfredsstillende, at du syntes behandlingen har fejlet?

- (•) Ja
- ( ) Nej

‹ › Næste

Health Locus of Control I

Locus of control is an important component of individual wellness. This activity will assist you in identifying your locus of control and its ability to affect your health. This rating scale is an adaptation of the Multidimensional Health Locus of Control Scales. The test is composed of three subscales:

1. The **Internal Health Locus of Control Scale (I)** measures whether you feel that you have control over your own health.
2. The **Powerful Others Health Locus of Control Scale (P)** measures whether you feel that powerful individuals, such as physicians or other health professionals, control your health.
3. The **Chance Health Locus of Control Scale (C)** measures whether you feel your health is due to luck, fate, or chance.

Directions: For each answer, choose a number from 1 to 5 that best describes your feelings.

5 = Strongly agree
4 = Agree 3 = Neither agree nor disagree
2 = Disagree
1 = Strongly disagree

Subscale 1: Internal Health Locus of Control

_____ If I get sick, my behavior determines how soon I get well.

_____ I am in control of my health.

_____ When I get sick, I am to blame.

_____ If I take care of myself, I can avoid illness.

_____ If I take the right actions, I can stay healthy.

_____ **Total**

Subscale 2: Powerful Others Health Locus of Control

_____ Having regular contact with my physician is the best way for me to avoid illness.

_____ Whenever I don't feel well, I should consult a medically trained professional.

_____ My family has a lot to do with my becoming sick or staying healthy.

_____ Health professionals control my health.

_____ When I recover from an illness, it's usually because other people such as doctors, nurses, family, and friends, have been taking good care of me.

_____ Regarding my health, I can only do what my doctor tells me to do.

_____ **Total**

Subscale 3: Chance Health Locus of Control

_____ No matter what I do, if I am going to get sick, I will get sick.

_____ Most things that affect my health happen to me accidentally.

_____ Luck plays a big part in determining how soon I will recover from an illness.

_____ My good health is largely a matter of good fortune.

_____ No matter what I do, I am likely to get sick.

_____ If it is meant to be, I will stay healthy.

_____ **Total**

To obtain your score for a subscale, add the numbers you chose.

A score of 23 to 30 on any subscale means you have a strong inclination toward that particular subscale. For example, a high C score indicates you hold strong beliefs that your health is a matter of chance.

A score of 15 to 22 means you are moderate on that particular subscale. For example, a moderate P score indicates you have moderate belief that your health is due to powerful others.

A score of 6 to 14 means you are low on that particular subscale. For example, a low 1 score means you generally do not believe that you control your own health.

Spørsmål om søvn

Instruksjoner: Følgende spørsmål har med ditt vanlige søvnmønster **den siste måneden** å gjøre. Du skal svare på hva som er mest riktig for **de fleste** dager og netter den siste måneden. Vennligst svar på alle spørsmål.

1. I løpet av den siste måneden, når har du vanligvis lagt deg om kvelden?

VANLIG LEGGETID _____

2. I løpet av den siste måneden, hvor lang tid (i minutter) har det vanligvis tatt deg å sovne om kvelden?

ANTALL MINUTTER _____

3. I løpet av den siste måneden, når har du vanligvis stått opp om morgenen?

VANLIGVIS STÅTT OPP KL _____

4. I løpet av den siste måneden, hvor mange timer søvn har du faktisk fått om natten? (Dette kan være forskjellig fra hvor mange timer du oppholdt deg i sengen)

ANTALL TIMER SØVN HVER NATT_____

For hvert av de følgende spørsmål, kryss av for det beste svar. Vennligst svar på alle spørsmålene.

5. I løpet av den siste måneden, hvor ofte har du hatt problemer med søvnen fordi du….

	Ikke i løpet av den siste måneden	Mindre enn en gang i uken	En eller flere ganger i uken	Tre eller flere ganger i uken
Ikke klarer å sovne i løpet av 30 minutter	☐	☐	☐	☐
Våkner opp midt på natten eller tidlig om morgenen	☐	☐	☐	☐
Må opp for å gå på toalettet	☐	☐	☐	☐
Ikke klarer å puste ordentlig	☐	☐	☐	☐
Hoster eller snorker høyt	☐	☐	☐	☐
Føler deg for kald	☐	☐	☐	☐
Føler deg for varm	☐	☐	☐	☐
Har vonde drømmer	☐	☐	☐	☐
Har smerter	☐	☐	☐	☐
Andre grunner, vennligst beskriv: _____				
6. Hvor ofte, i løpet av den siste måneden, har du hatt problemer med søvnen på grunn av dette	☐	☐	☐	☐

7. I løpet av den siste måneden, hvordan vil du bedømme søvnkvaliteten din totalt sett?

☐ Veldig bra

☐ Ganske bra

☐ Ganske dårlig

☐ Veldig dårlig

	Ikke i løpet av den siste måneden	Mindre enn en gang i uken	En eller flere ganger i uken	Tre eller flere ganger i uken
8. I løpet av den siste måneden, hvor ofte har du tatt medisin (med eller uten resept) som hjelp til å sove?	☐	☐	☐	☐
9. I løpet av den siste måneden, hvor ofte har du hatt problemer med å holde deg våken under bilkjøring, måltider eller når du holder på med sosiale aktiviteter?	☐	☐	☐	☐

10. I løpet av den siste måneden, hvor stort problem har det vært for deg å ha overskudd nok til å få ting gjort?

☐ Ikke noe problem i det hele tatt

☐ Bare et lite problem

☐ Et visst problem

☐ Et stort problem

11. Deler du seng eller rom med noen?

☐ Deler ikke seng eller rom med noen

☐ Partner/romkamerat i annet rom

☐ Partner i samme rom, men ikke i samme seng

☐ Partner i samme seng

T1

Din fysiske aktivitet generelt

Vennligst les alle alternativene nedenfor.
Sett kryss for det alternativet som best beskriver ditt nåværende nivå av fysisk aktivitet eller din interesse for fysisk aktivitet. Tenk på all fysisk aktivitet unntatt aktivitet som er en del av jobben din.

☐ For tiden er jeg ikke fysisk aktiv, og har ingen planer om å bli fysisk aktiv i løpet av de neste 6 måneder.

☐ For tiden er jeg ikke fysisk aktiv, men jeg tenker på å bli mer fysisk aktiv i løpet av de neste 6 måneder.

☐ For tiden er jeg noe fysisk aktiv, men det er ikke regelmessig.

☐ For tiden er jeg regelmessig fysisk aktiv, men det er først i løpet av de siste 6 måneder at jeg har begynt med det.

☐ For tiden er jeg regelmessig fysisk aktiv, og jeg har vært det lengre enn de siste 6 måneder.

Hvordan er din fysiske aktivitet i fritiden?

Arbeidsvei regnes som fritid. Oppgi omtrent hvor mange timer pr. uke du er fysisk aktiv. Sett et antall timer som kan gjelde for en vanlig uke siste måned.

Lett aktivitet (ikke svett/andpusten)	**Hard aktivitet** (svett/andpusten)
☐ Ikke aktiv	☐ Ikke aktiv
☐ Under 1 time pr. uke	☐ Under 1 time pr. uke
☐ 1-2 timer pr. uke	☐ 1-2 timer pr. uke
☐ 3 timer eller mer	☐ 3 timer eller mer

HAD

Hospital Anxiety & Depression Scale (januar 1999)

Navn: _____ Fødselsdato: _____

Dato for utfylling: _____ Pasient nr.: _____

Behandler: _____

Rettledning

Legen er klar over at følelser spiller en stor rolle ved de fleste sykdommer. Hvis legen vet mer om følelser, vil han/hun bli bedre i stand til å hjelpe deg.

Her kommer noen spørsmål om hvorledes du føler deg. For hvert spørsmål setter du kryss for ett av de fire svarene som best beskriver dine følelser den siste uken. Ikke tenk for lenge på svaret – de spontane svarene er best.

1. Jeg føler meg nervøs og urolig

- ❑ 3 Mesteparten av tiden
- ❑ 2 Mye av tiden
- ❑ 1 Fra tid til annen
- ❑ 0 Ikke i det hele tatt

2. Jeg gleder meg fortsatt over tingene slik jeg pleide før

- ❑ 0 Avgjort like mye
- ❑ 1 Ikke fullt så mye
- ❑ 2 Bare lite grann
- ❑ 3 Ikke i det hele tatt

3. Jeg har en urofølelse som om noe forferdelig vil skje

- ❑ 3 Ja, og noe svært ille
- ❑ 2 Ja, ikke så veldig ille
- ❑ 1 Litt, bekymrer meg lite
- ❑ 0 Ikke i det hele tatt

4. Jeg kan le og se det morsomme i situasjoner

- ❑ 0 Like mye nå som før
- ❑ 1 Ikke like mye nå som før
- ❑ 2 Avgjort ikke som før
- ❑ 3 Ikke i det hele tatt

5. Jeg har hodet fullt av bekymringer

- ❑ 3 Veldig ofte
- ❑ 2 Ganske ofte
- ❑ 1 Av og til
- ❑ 0 En gang i blant

6. Jeg er i godt humør

- ❑ 3 Aldri
- ❑ 2 Noen ganger
- ❑ 1 Ganske ofte
- ❑ 0 For det meste

7. Jeg kan sitte i fred og ro og kjenne meg avslappet

- ❑ 0 Ja, helt klart
- ❑ 1 Vanligvis
- ❑ 2 Ikke så ofte
- ❑ 3 Ikke i det hele tatt

8. Jeg føler meg som om alt går langsommere

- ❑ 3 Nesten hele tiden
- ❑ 2 Svært ofte
- ❑ 1 Fra tid til annen
- ❑ 0 Ikke i det hele tatt

9. Jeg føler meg urolig som om jeg har sommerfugler i magen

- ❑ 0 Ikke i det hele tatt
- ❑ 1 Fra tid til annen
- ❑ 2 Ganske ofte
- ❑ 3 Svært ofte

10. Jeg bryr meg ikke lenger om hvordan jeg ser ut

- ❑ 3 Ja, jeg har sluttet å bry meg
- ❑ 2 Ikke som jeg burde
- ❑ 1 Kan hende ikke nok
- ❑ 0 Bryr meg som før

11. Jeg er rastløs som om jeg stadig må være aktiv

- ❑ 3 Uten tvil svært mye
- ❑ 2 Ganske mye
- ❑ 1 Ikke så veldig mye
- ❑ 0 Ikke i det hele tatt

12. Jeg ser med glede frem til hendelser og ting

- ❑ 0 Like mye som før
- ❑ 1 Heller mindre enn før
- ❑ 2 Avgjort mindre enn før
- ❑ 3 Nesten ikke i det hele tatt

13. Jeg kan plutselig få en følelse av panikk

- ❑ 3 Uten tvil svært ofte
- ❑ 2 Ganske ofte
- ❑ 1 Ikke så veldig ofte
- ❑ 0 Ikke i det hele tatt

14. Jeg kan glede meg over gode bøker, radio og TV

- ❑ 0 Ofte
- ❑ 1 Fra tid til annen
- ❑ 2 Ikke så ofte
- ❑ 3 Svært sjelden

Takk for utfyllingen!

Sum A:

1+3+5+7+9+11+13= _____

Sum D:

2+4+6+8+10+12+14= _____

Sum A + D: _____

Skåringsveiledning til HAD

(Hospital Anxiety and Depression Scale)

Selvutfylling på sju angst- og depresjonsspørsmål.

Sum A eller Sum D:
En skår på 11 eller mer regnes for å være et tilfelle av angst eller depresjon som vil trenge nærmere utredning (med SPIFA for eksempel) og eventuelt behandling. En skår på 8-10 anses som et mulig tilfelle, og lavere skår uttrykker en viss symptombelastning, som kan ha betydning samlet sett, men som i seg selv ikke krever spesifikk behandling av angst eller depresjon.

Sum A + Sum D:
Det er også mulig å legge sammen angst- og depresjonsskåren til en totalskår fordi en del pasienter har en blanding av angst og depresjon. Et tilfelle vil da ha en totalskår på 19 eller mer. Et mulig tilfelle vil ha en skår på 15-18. Skår på over 15 vil trenge oppfølging og eventuelt behandling.

Dersom inntil to spørsmål på HAD er ubesvart, vil det være mulig å beregne totalskår. Sumskåren deles med antallet besvarte spørsmål og svaret ganges med 14. Dette gir estimert totalskår.

Referanser:

Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361-70.

Herrmann C. International experiences with the hospital anxiety and depression scale – a review of validation data and clinical results. J Psychosom Res 1997; 42:17-41.

Prosedyre 12-trinns trappetest

Kort beskrivelse av testen:
Trappetesten tar tiden på hvor raskt deltakeren kommer seg opp og ned en trappeavsats. Testen er også en test på benstyrke og balanse.

Utstyr:
Trapp med god belysning og uten forstyrrelser. En trappeavsats på 12 trinn med trinnhøyde 16-20cm. Samme trapp brukes ved alle målepunkt for samme pasient.
Stoppeklokke.

Utgangsstilling:
I bunnen av trappeavstatsen. Gode, stødige sko bør brukes.
Ganghjelpemiddel deltakeren vanligvis bruker er tillatt, dette registreres. Bruk av gelender (èn side) er også tillatt om nødvendig, dette skal registreres.

Instruksjon og gjennomføring av testen:
Deltakeren instrueres i å ta seg så fort som mulig opp og ned de 12 trinnene. Farten skal ikke gå på bekostning av tryggheten. Det anbefales en testrunde for å vurdere om deltakeren kan gå trygt i trapp.
Ved tvil om deltakerens sikkerhet ved trappetesten, bør tester følge bak deltakeren opp trappen og foran/ved siden av ned trappen.

Instruksjon: «Nå skal du ta deg opp og ned denne trappeavsatsen så fort du kan, men ikke så fort at du blir utrygg. Klar og START!»
Det gis ingen oppmuntring underveis.
Deltakeren kan stoppe og hvile underveis, men tiden skal ikke stoppes.

Tidtaking begynner ved startsignal, og stoppes når begge føtter er nede på grunnflaten. Tiden rundes av til nærmeste 100dels sekund.

Ressurser:

OARSI manual: https://www.oarsi.org/sites/default/files/docs/2013/manual.pdf

OARSI video: : https://www.oarsi.org/research/physical-performance-measures

Prosedyre 40 meter gangtest

Kort beskrivelse av testen:
40 meter gangtest måler gangtempo og evne til å snu/endre retning over korte distanser. Deltakeren skal gå så raskt som mulig en 10 meters oppmålt distanse, 4 ganger.

Utstyr:
En 10 meter lang oppmålt distanse, markeres med teip på gulvet i hver ende.
2 kjegler. Èn kjegle plasseres ca.2 meter før første teip, den andre ca. 2 meter etter siste teip, disse skal deltakeren snu rundt. Det må være tilstrekkelig med plass til å snu rundt kjeglene.
Stoppeklokke. Kalkulator for å regne ut hastighet.

Utgangsstilling:
Deltakeren starter med tærne ved den ene teipbiten. Gode, stødige sko bør brukes.
Ganghjelpemiddel deltakeren vanligvis bruker er tillatt, dette registreres.

Instruksjon og gjennomføring av testen:
Deltakeren instrueres i å gå så raskt (og trygt) som mulig. Det anbefales at deltakeren går 1-2 lengder med vending rundt kjegle før testen startes, for å være sikker på at testen er forstått. Deltakeren skal så gå frem og tilbake rundt kjeglene totalt 4 ganger (40 meter).

Instruksjon: «Gå så fort du kan, trygt og uten å løpe. Gå til den første kjeglen, snu ved å gå rundt den, gå tilbake rundt den andre kjeglen og fortsett slik til du har gått distansen 4 ganger. Klar og START».
Det gis ingen oppmuntring underveis.

Ganghjelpemidler er tillatt, men skal registreres. Deltakeren bør bruke det ganghjelpemiddelet de er vant til å bruke når testen gjennomføres.
Om deltakeren vurderes å ha nedsatt gangevne/være ustø, bør tester følge noe bak og til side for deltakeren. Er det ikke fare for deltakerens sikkerhet før tester stå godt til siden og ha god oversikt over begge vendepunkter.

Tiden tas kun når pasienten går mellom de to teipbitene, slik: tidtakingen starter på startsignalet ved første teip, og pauses når pasienten har krysset neste teip med begge føtter. Deltakeren snur så rundt kjeglen og tidtakingen starter ved kryssing av teipen igjen. Tiden det tar å vende rundt kjeglene skal altså ikke tas med. Tiden stoppes når deltakeren har krysset startlinjen med begge føtter for siste gang.

Tiden rundes av til nærmeste 100dels sekund. Testen uttrykkes som hastighet (m/s) ved å dele distanse (40 meter) på tid (sekunder).

Ressurser:

OARSI manual: https://www.oarsi.org/sites/default/files/docs/2013/manual.pdf

OARSI video: https://www.oarsi.org/research/physical-performance-measures

NKRR video: https://diakonhjemmetsykehus.no/nkrr/klinisk-verktoykasse/a-til-a/40-meter-gangtest-4-x-10-m

Prosedyre 30 sekunder sette og reise seg-test

Kort beskrivelse av testen:
30 sekunder sette og reise seg-test er en fysisk test som undersøker styrke i bena. Deltakeren skal i løpet av 30 sekunder reise og sette seg på en stol så mange ganger vedkommende greier. Antall repetisjoner man klarer gir et tall på funksjon.

Utstyr:
Stol med setehøyde 45 cm. Det er viktig at samme type stol brukes på alle pasienter og alle måletidspunkter.
Stoppeklokke.

Utgangsstilling:
Stolen plasseres inntil vegg slik at den ikke kan skli bakover. Velg et sted uten for mye forstyrrelser. Utgangsstilling er sittende. Deltakeren skal holde hendene i kryss over brystet og knærne bør være i 90° fleksjon eller rett i overkant. Deltakeren bør ha vanlig, komfortable sko på.

Instruksjon og gjennomføring av testen:
«Nå skal vi teste hvor mange ganger du klarer å reise og sette deg i løpet av 30 sekunder. Du skal reise deg helt opp – med strake knær – og sette deg helt ned igjen. Du trenger ikke lene deg mot rygglenet, men du skal sette deg helt ned for hver gang (ikke bare touche nedpå). Hendene skal holdes i kryss over brystet gjennom hele testen».

Vis pasienten øvelsen mens du snakker og la deretter deltakeren gjennomføre 1-2 prøveforsøk.

«Jeg sier ifra når du kan begynne. Husk at det er om å gjøre å reise og sette seg flest mulig ganger i løpet av 30 sekunder. Klar, ferdig, START!»

Tell antall repetisjoner høyt (tell når deltakeren reiser seg opp).
Deltakeren skal strekke helt ut i knærne og være tydelig ned på setet for at repetisjonen skal telle. Ikke gi noen form for oppmuntring underveis. Dersom deltakeren er helt oppe, eller på vei ned igjen når det er gått 30 sekunder telles dette som en repetisjon.
Testpersonen kan stoppe og hvile underveis, men tiden skal ikke stoppes.

Tilrettelegging: dersom deltakeren ikke greier å reise seg med armene i kryss over brystet, kan testen tilrettelegges. Tillat at personen støtter hendene på lårene eller bruker sine vanlige ganghjelpemidler. Hvis personen klarer å reise og sette seg med tilrettelegginger, skal antall en notere antall som en tilrettelagt score (se scoringsskjema). Merk av hvilken tilrettelegging som er gjort.

Ressurser:

OARSI manual: https://www.oarsi.org/sites/default/files/docs/2013/manual.pdf

OARSI video: https://www.oarsi.org/research/physical-performance-measures

Original prosedyre fra FYSIOPRIM:
https://www.med.uio.no/helsam/forskning/prosjekter/fysisk-form/prosedyre-30-sekunder-sette-og-reise-seg.pdf

Video, FYSIOPRIM: https://www.med.uio.no/helsam/forskning/prosjekter/fysisk-form/evaluering-fysisk-form.html

Manual for måling av bevegelighet i MultiKnee

Bevegelighet som skal måles:

- Aktiv fleksjon
- Passiv fleksjon
- Aktiv ekstensjon
- Passiv ekstensjon

Aktiv fleksjon

Utgangsstilling: rygliggende på benk. Hevet hodeende/pute slik det er komfortabelt for pasienten.

Instruksjon til pasienten: bøy kneet ditt ved å la hælen følge underlaget til du ikke greier lenger.

Bevegelighet måles så snart pasienten forteller at maks bevegelighet er nådd.

Passiv fleksjon

Utgangsstilling: måling av passiv fleksjon tar utgangspunkt i maks aktiv fleksjon. Hvis smerter kan måling av aktiv og passiv fleksjon deles i to.

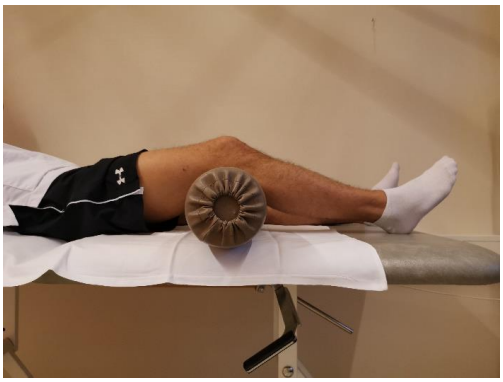
Instruksjon til pasienten: slapp av så godt du greier.

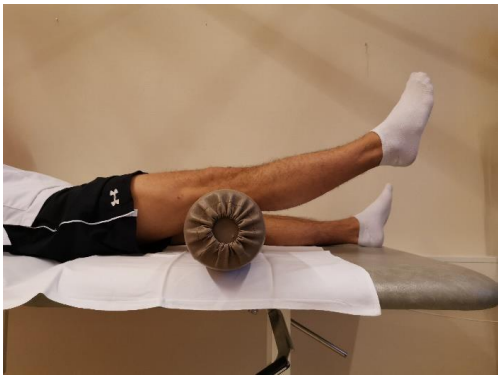
Bildet viser hvordan goniometeret holdes samtidig som høyre hånd øker bevegeligheten til pasienten sier stopp/aktuell stopp.

Aktiv ekstensjon

Utgangsstilling: ryggliggende på benk. Hevet hodeende/pute slik det er komfortabelt for pasienten. Pølle under kne.

Instruksjon til pasienten: strekk ut kneet ditt så langt du greier. Låret skal være i ro, og baksiden av kneet i kontakt med pøllen.



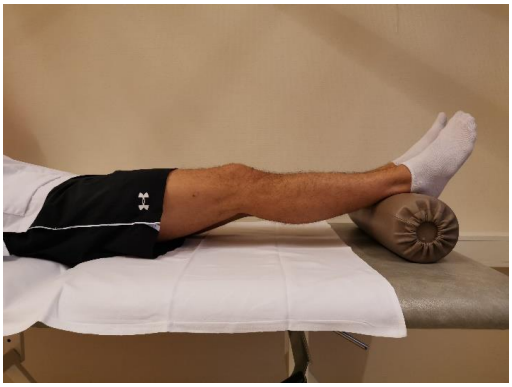


Bevegeligheten måles når pasienten forteller at maksimal strekk er oppnådd.

Passiv ekstensjon

Utgangsstilling: ryggliggende på benk. Hevet hodeende/pute slik det er komfortabelt for pasienten.

Instruksjon til pasienten: slapp av i beinet.



Bevegeligheten måles så snart pasienten er avslappet i beinet.

Obs: ved uttalt utrotasjon i hoften (som på bildet under) kan det være nødvendig å støtte opp beinet litt.

ID:
Dato: Test nummer:

Skåringsskjema Multi Knee

Høyde: Vekt:

Testene utføres i denne rekkefølgen:
Trappetest: Trapp mellom 4. og 5. etasje
40 m gangtest: Korridor sengepost 4. etg
30 sek «Sette og reise seg»-test: Treningsrom 4. etg
Måle bevegelighet: Treningsrom 4. etg
Actigraf settes på testdagen, gå med den en uke, sende tilbake i frankert konvolutt

1. Trappetest

Tid (sekunder 00.00):	Tilpasning:
	☐ Bruker rekkverk opp/ned/begge ☐ Bruker ganghjelpemiddel ☐ Ikke testet – ikke mulig ☐ Ikke testet – ikke villig

2. 40 m gangtest:

Ganghjelpemiddel:	Tid (sekunder 0.00)	Hastighet (40/tid i sekunder) (0.00 m/sek)	Tilpasset:
			☐ Støtter hendene på lårene ☐ Bruker ganghjelpemiddel ☐ Ikke testet – ikke mulig ☐ Ikke testet – ikke villig

3. 30 sek «reise og sette seg»-test:

Antall repetisjoner:	Tilpasning:	Tilpasset score:
	☐ Støtter hendene på lårene ☐ Bruker ganghjelpemiddel ☐ Ikke testet – ikke mulig ☐ Ikke testet – ikke villig	

4. Bevegelighet

Aktiv fleksjon	Passiv fleksjon	Aktiv ekstensjon	Passiv ekstensjon	Tilpasninger
		Minus -	Minus -	

ID:
Dato: Test nummer:

Skåringsskjema Multi Knee

Høyde: Vekt:

Testene utføres i denne rekkefølgen:
Trappetest: Trapp mellom 4. og 5. etasje
40 m gangtest: Korridor sengepost 4. etg
30 sek «Sette og reise seg»-test: Treningsrom 4. etg
Måle bevegelighet: Treningsrom 4. etg
Actigraf settes på testdagen, gå med den en uke, sende tilbake i frankert konvolutt

1. Trappetest

Tid (sekunder 00.00):	Tilpasning:
	☐ Bruker rekkverk opp/ned/begge ☐ Bruker ganghjelpemiddel ☐ Ikke testet – ikke mulig ☐ Ikke testet – ikke villig

2. 40 m gangtest:

Ganghjelpemiddel:	Tid (sekunder 0.00)	Hastighet (40/tid i sekunder) (0.00 m/sek)	Tilpasset:
			☐ Støtter hendene på lårene ☐ Bruker ganghjelpemiddel ☐ Ikke testet – ikke mulig ☐ Ikke testet – ikke villig

3. 30 sek «reise og sette seg»-test:

Antall repetisjoner:	Tilpasning:	Tilpasset score:
	☐ Støtter hendene på lårene ☐ Bruker ganghjelpemiddel ☐ Ikke testet – ikke mulig ☐ Ikke testet – ikke villig	

4. Bevegelighet

Aktiv fleksjon	Passiv fleksjon	Aktiv ekstensjon	Passiv ekstensjon	Tilpasninger
		Minus -	Minus -	

Informasjon til deg som skal behandle pasienter i MultiKnee-studien

Informasjon om studien

MultiKnee-studien er en forskningsstudie som undersøker effekten av et nytt behandlingsopplegg ved kneartrose. Omtrent 20 % av pasienter som gjennomgår en kneproteseoperasjon opplever liten eller ingen bedring i etterkant [1, 2]. Det er per nå ikke konsensus om hva som er den beste behandlingen for denne pasientgruppen.
Denne studien er en randomisert kontrollert multisenterstudie. Formålet med studien er å teste ut en behandling bestående av fysioterapi etter AktivA-modellen og nettbasert kognitiv atferdsterapi (CBT) som et alternativ til, eller i kombinasjon med operasjon. Effekt vil bli målt på blant annet smerte, livskvalitet og fysisk aktivitet med spørreskjemaer og fysiske tester.

Studien er et samarbeid mellom Lovisenberg Diakonale Sykehus, Martina Hansens Hospital og Kysthospitalet i Hagevik.

Det skal inkluderes 282 pasienter som randomiseres til tre grupper:

Gruppe A, ikke-kirurgisk gruppe: Gjennomgår MultiKnee treningsprogram med mulighet for operasjon senere ved behov. Ved behov kan pasienten fortsette med fysioterapi utover intervensjonstiden.

Gruppe B, kombinert gruppe: Blir operert med innsetting av kneprotese, gjennomgår deretter MultiKnee treningsprogram. Ved behov kan pasienten fortsette med fysioterapi utover intervensjonstiden.

Gruppe C, kontrollgruppe: Gjennomgår operasjon med innsetting av kneprotese, og får vanlig opptrening med fysioterapeut i etterkant.

MultiKnee treningsprogram består av tre deler:

1. Artroseskole
2. Et 12 ukers treningsopplegg med personlig oppfølging av fysioterapeut
3. Et 10-ukers e-terapikurs i kognitiv terapi (iCBT)

Hva innebærer dette for deg?

For at studien skal ha en god vitenskapelig kvalitet, er det viktig at treningsprinsippene i AktivA-modellen blir fulgt. Vi ønsker primært at fysioterapeuter som behandler pasienter i gruppe A og B skal være sertifiserte AktivA-terapeuter. Hvis du ikke har gjennomført AktivA-kurset, finner du veiledning i vedlagte PDF-fil. Annen behandling skal normalt ikke gis parallelt med denne treningen. Unntak kan være hvis det for eksempel skulle oppstå akutte smerter som kan behandles med akutt smertelindring som kuldepakninger.
Vi i prosjektgruppen vil holde kontakt med deg i løpet av behandlingsperioden, og vi tar gjerne imot spørsmål på telefon eller mail.

Hvis du får pasienter som er i kontrollgruppen (gruppe C), skal du gi den behandlingen du ellers ville ha gitt denne pasientgruppen.

Nærmere beskrivelse av MultiKnee treningsprogram:

AktivA er et program hvor hensikten er å implementere internasjonale retningslinjer for pasienter med artrose i klinisk fysioterapipraksis. Tilsvarende program i Sverige (BOA)[3] og Danmark (GLA:D)[4], har vist gode resultater med hensyn til livskvalitet, fysisk funksjon og smerte. Programmet består av tre deler – et strukturert utdanningsprogram for fysioterapeuter, et kunnskapsbasert informasjons- og treningsopplegg for pasienter med kne- og/eller hofteartrose og elektronisk registrering av data inn i en sentral database ved Oslo universitetssykehus.

Behandlingsprogrammet i AktivA-modellen består av to deler:

- Artroseskole
    - Gjennomføres som gruppeundervisning på et av de tre sykehusene som deltar i studien, eller på et institutt som arrangerer artroseskole etter AktivA-modellen
- Veiledet trening
    - Individuelt tilpasset trening individuelt eller i gruppe. Treningen skal basere seg på prinsippene i AktivA-modellen. Øvelsene skal være tilpasset den enkelte pasient og progresjonen styres av fysioterapeuten gjennom treningsperioden. Mer informasjon om treningsprinsippene og øvelser med progresjon i vedlagt PDF fil.

(mer informasjon på www.aktivmedartrose.no)

I tillegg til artroseskole og trening gjennomfører pasienten et e-terapikurs i kognitiv terapi (iCBT). Programmet gir pasienten en innføring i mental trening for håndtering av symptomer med vekt på smerter. Det består av 10 moduler som skal gjennomføres parallelt med treningen. Modulene inneholder en blanding av tekst, videoer og forskjellige oppgaver som sammen vil gi pasienten teknikker og strategier for å håndtere fysiske og mentale utfordringer. Medarbeidere i prosjektet følger pasientene tett i gjennomføringen av dette programmet.

Vi oppfordring alle fysioterapeuter som deltar i studien til å delta på AktivA kurs for å få sertifisering. Vi kan tilby dekking av kursavgift for et begrenset antall fysioterapeuter, så ta kontakt med oss i studien hvis du er interessert. Det er prinsippet om «førstemann til mølla» som gjelder.

Oppfølging

Pasientene blir fulgt opp med kontroller på sykehuset etter 3, 6, 12 og 24 måneder for utfylling av spørreskjema og gjennomføring av fysiske tester.
Vi vil ha jevnlig telefonkontakt både med behandlende fysioterapeut og pasient for å følge progresjonen, registrere oppmøte og eventuelle komplikasjoner som oppstår underveis. Vi er også tilgjengelig på telefon og e-post ved spørsmål.

Kontaktpersoner:

Lovisenberg Diakonale Sykehus/Martina Hansens Hospital: Ingvild Buset Bergvad, tlf. 901 66 433, e-post: beib@lds.no
Kysthospitalet i Hagevik: Turid Rognsvåg, tlf. 56565964, e-post: turid.rognsvag@helse-bergen.no

Vedlegg:

- **Treningsprogram AktivA.pdf (Prinsippene for trening og øvelser med progresjon)**

Du finner mer informasjon om studien her:

https://www.facebook.com/Multi-Knee-trial-590024504832255/
https://lovisenbergsykehus.no/fag-og-forskning/forskningsprosjekter/multiknee

Referanser:

[1] A.D. Beswick, V. Wylde, R. Gooberman-Hill, A. Blom, P. Dieppe, What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients, BMJ Open 2(1) (2012) e000435.
[2] M.F. Lindberg, C. Miaskowski, T. RustoEn, L.A. Rosseland, B.A. Cooper, A. Lerdal, Factors that can predict pain with walking, 12 months after total knee arthroplasty, Acta Orthop 87(6) (2016) 600-606.

[3] C.A. Thorstensson, G. Garellick, H. Rystedt, L.E. Dahlberg, Better Management of Patients with Osteoarthritis: Development and Nationwide Implementation of an Evidence-Based Supported Osteoarthritis Self-Management Programme, Musculoskeletal care 13(2) (2015) 67-75.
[4] S.T. Skou, E.M. Roos, Good Life with osteoArthritis in Denmark (GLA:D): evidence-based education and supervised neuromuscular exercise delivered by certified physiotherapists nationwide, BMC Musculoskelet Disord 18(1) (2017) 72.

Treningsprogram AktivA

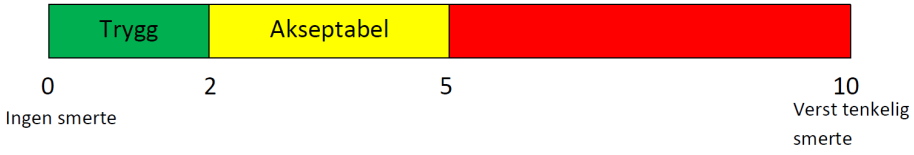
Treningsprinsippene og basisøvelsene som gjennomgås i AktivA bygger på grunnleggende treningsanbefalinger for pasienter med kne- og hofteartrose og inneholder øvelser basert på prinsipper for nevromuskulær trening og styrketrening. I tillegg presenteres forslag til øvelser for bevegelighetstrening og aerob utholdenhetstrening som kan egne seg for pasienter med kne- eller hofteartrose.

Det vil være opp til hver enkelt fysioterapeut å tilpasse det optimale treningsprogrammet for den enkelte pasient. Øvelsene som presenteres her er ment som et utvalg basisøvelser som vil passe for de fleste pasienter med kne- eller hofteartrose. Andre øvelser kan også benyttes.

For de fleste pasienter vil det være hensiktsmessig å gjennomføre treningen i gruppe ledet av fysioterapeut. Deltagerne følger sine individuelt tilpassede treningsprogram og progresjon styres av fysioterapeuten gjennom treningsperioden. Vi anbefaler at en gruppetreningstime består av tre deler: Oppvarming, øvelsestrening og nedtrapping (bevegelighetstrening). En treningstime kan vare i 45-60 minutter og hver deltager bør helst trene i gruppen 2 ganger i uken i minimum 6 uker. I tillegg bør deltagerne oppfordres til å gjennomføre en tredje ukentlig treningsøkt på egenhånd der målet bør være å vedlikeholde/øke den aerobe kapasiteten.

Smerte

En numerisk skala (NRS) kan anvendes til overvåkning av smerter under og etter trening. Skalaen er gradert fra 0 til 10 der 0 er ingen smerte og 10 er verst tenkelig smerte (figur 1). Selvrapportert smerte opp til 2 på NRS betraktes som «trygg». Smerte opp til 5 betraktes som «akseptabel», mens smerte over 5 kan betraktes som «ikke akseptabel». Dagen etter trening bør smertene ha avtatt til normalt nivå, og smertenivået bør ikke stige over tid. Smerte på normalt nivå defineres som slik smerten var før treningen. Dersom man smerten er for høy eller pasienten får økt inflammasjon/hevelse, bør treningen doseres ned neste gang, før man igjen forsøker å gradvis øke dosering.



Figur 1. NRS for overvåkning av smerter under og etter trening.

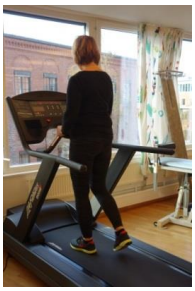
Dosering

Treningsdosering må tilpasses den individuelle pasient og må baseres på faktorer som smerte og hevelse i affisert ledd, tilleggssykdommer, fysisk form og tidligere erfaring med trening. Likevel bør noen generelle prinsipper om dosering legges til grunn for vurderingen. Disse vil bli presentert under hver av delene i treningsprogrammet.

Progresjon

Det er veldig viktig å progrediere treningen. Få inn nevromuskulær kontroll og deretter øke vanskelighetsgrad og motstand/belastning. Bruk gjerne «2+ prinsippet» - etter en til to uker med en gitt belastning ser man om pasienten kan klare 2 ekstra repetisjoner på siste serie. Hvis så er tilfelle, økes motstand/belastning.

Del 1 – Oppvarming




10-15 min oppvarming på tredemølle, ergometersykkel e.l.

Del 2 – Nevromuskulær trening / styrketrening

Retningslinjer i forhold til dosering av styrketrening:

Belastning:

- 40-50 % av 1RM (svært lett / lett belastning) for eldre og svært utrente personer som nettopp har begynt med trening.
- 60-70 % av 1 RM (moderat / hard belastning) for nybegynnere til lett trente personer.
- ≥80 % av 1 RM (hard /svært hard belastning) for personer med mye erfaring fra styrketrening.

Repetisjoner og sett:

- 8-12 repetisjoner anbefales for å øke styrke hos de fleste voksne.
- 10-15 repetisjoner er effektivt for å forbedre styrke hos eldre som nettopp har begynt med trening.
- 2-4 sett anbefales for de fleste voksne.

Kne over tå – viktig for alle øvelser!


Føttene skal plasseres med tilnærmet hoftebreddes avstand, føttene skal peke forover, og bevegelsen skal utføres med knær over tær.

Øvelse A – Tyngdeforskyvning/Utfall sideveis


Utførelse

- Forflytte tyngden fra side til side («skøyteøvelse»)
- Kne over tå, husk hoftestabilitet
- Kontrollerte bevegelser


Utførelse

- Stående utgangsstilling, utfall sideveis
- Stabilisere hofte og kne
- Kontrollerte bevegelser
- Kne over tå

Progresjon

- Øke vanskelighetsgrad ved å øke avstanden ut til siden ved utfall
- Øke fleksjonsvinkel i kne
- Øke belastningen ved å bruke håndvekter, ryggsekk, vektstang

Øvelse B – Step/trapp


Utførelse

- Kne over tå
- Kontrollerte bevegelser
- Opp og ned på samme ben
- Få inn hoftemuskulaturen
- Start på lavt trappetrinn for å sikre god stabilitet i hofte/kne og tyngdeoverføring

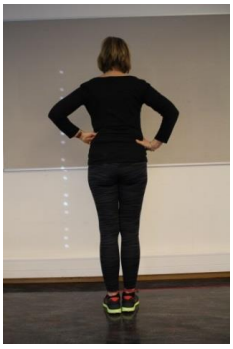
Progresjon

- Øke høyde på step/trappetrinn
- Øke belastningen ved å bruke håndvekter, sekk, vektstang

Øvelse C – Hofteabduksjon med strikk


Utførelse (uten veggfeste)

- Strikk rundt fot
- Stabilisere i hofte og kne på standbeinet
- Holde overkroppen oppreist og i ro
- Bevege motsatt bein i abduksjon og ekstensjon



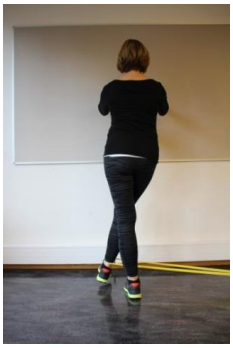

Utførelse (med veggfeste)

- Strikk rundt fot (strikken skal gå bak stambeinet)
- Stabilisere i hofte og kne på standbeinet
- Hold overkroppen oppreist og i ro
- Abdusere motsatt bein (husk abduksjon og ekstensjon for å unngå bruk av hoftefleksorer)

Progresjon

- Øke belastningen ved å bruke hardere strikk/større motstand eller stå lengre unna veggen

Øvelse D – Hofteadduksjon med strikk

Utførelse

- Stabilisere i hofte og kne på stambeinet
- Hold overkroppen oppreist og i ro
- Addusere motsatt bein

Progresjon

- Øke belastningen ved å bruke strikk med større motstand eller stå lengre unna veggen

Øvelse E – Knebøy


Utførelse

- Kontrollerte bevegelser
- Knær over tær og stabilisering i hofte
- Evt. planke under hælen hvis man mister holdningen eller ikke klarer å bøye seg dypt nok ned


Progresjon

- Balanseputer
- Øke fleksjonsvinkel i knær
- Øke motstand med strikk
- Ett ben




Progresjon

- Øke belastningen (også med strikk og på balansepute) ved å bruke håndvekter, ryggsekk eller vektstang
- Bruk av gymball

Øvelse F – Utfall/fremfall


Utførelse

- Starte i utfallsstilling og senke og reise opp kroppen fra denne stillingen
- Tyngden på fremre ben
- Kne over tå
- Få tak i hoftemuskulaturen
- Viktig med kontroll og kvalitet over bevegelsene


Progresjon

- Øke fleksjonsvinkel i kne
- Øke vanskelighetsgraden ved å starte i stående stilling og falle fremover og skyve seg opp igjen
- Øke tempoet når man skyver seg opp
- Pass på vinkel i kne




Progresjon

- Øke belastningen ved bruk av håndvekter, vektstang, ryggsekk
- Balansepute/bosu
- Bakre ben på stol/krakk

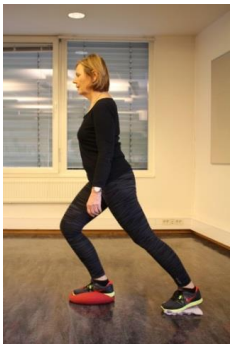
Øvelse G – Skliøvelse sideveis og bakover


Utførelse sideveis

- Klut/teppeflis e.l. under den ene skoen
- Stabilitet og kontroll i hofte og kne på standbeinet
- Skyv det andre benet ut til siden og trekk det tilbake igjen med full tyngde på standbeinet


Utførelse bakover

- Klut/teppeflis e.l. under den ene foten
- Stabilitet og kontroll i hofte og kne på standbeinet
- Skyv benet bakover og trekk det frem igjen med full tyngde på standbeinet

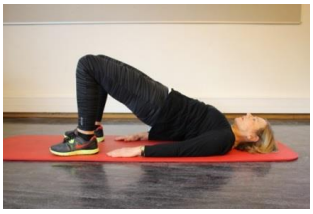
Progresjon

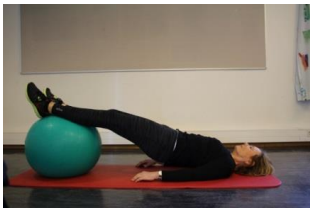
- Øke vanskelighetsgrad ved å stå på balansepute
- Øke fleksjonsvinkel i kne og hofte
- Bruke håndvekter, ryggsekk, vektstang

Øvelse H - Bekkenløft


Utførelse

- Løfte bekkenet opp, holde det stabilt og hofteleddet mest mulig ekstendert
- Kontrollerte bevegelser – stabilitet, ikke «falle ned» med bekkenet




Progresjon

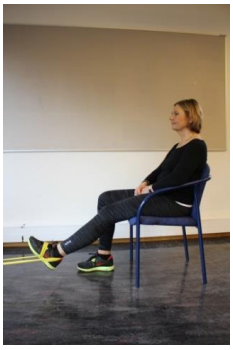
- Øke vanskelighetsgrad ved å legge armene langs siden eller i kryss over brystet
- Løfte ett ben
- Bruke balansepute eller gymball

Øvelse I – Knefleksjon/ekstensjon med strikk

Forslag til øvelse dersom man ikke har annet utstyr tilgjengelig.


Utførelse

- Sittende utgangsstilling, strikk rundt fot
- Ekstendere i kne – stramme quadriceps godt
- Kontrollerte bevegelser




Utførelse

- Sittende utgangsstilling, strikk rundt fot
- Flektere i kne
- Kontrollerte bevegelser

Progresjon

- Strikk med større motstand eller strammere strikk

Øvelse J – Leg curl på ball


Utførelse

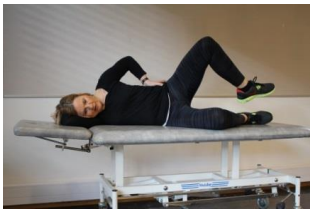
- Hælene på gymball
- Løfte opp bekkenet og trekke ballen inn mot setet – stabilitet, ikke «falle ned» med bekkenet
- Starte med armene ut til siden fra kroppen

Progresjon

- Plassering av armene (langs siden, i kryss over brystet)

Øvelse K – Hofterotatorer og abduktorer






Utførelse

- Sideliggende utgangsstilling, ligge stabilt med bekkenet
- Føtter sammen
- Løfte kneet opp
- Pass på at ikke bekkenet tipper bakover
- Få pasienten til å kjenne at riktig muskulatur brukes

Progresjon

- Litt avstand mellom føttene når man løfter opp kneet
- Løfte benet med strakt kne, tærne skal peke rett fremover (ikke bruke hoftefleksorer)

Øvelser L – Legg press i apparat



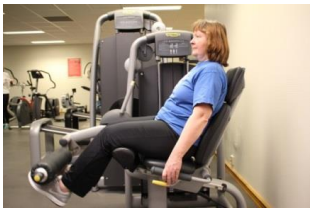
Utførelse

- Føttene plasseres i hoftebreddes avstand, knær over tær
- Kontrollerte bevegelser både konsentrisk og eksentrisk
- Stabilisere med mage/ryggmuskulatur

Progresjon

- Fleksjonsvinkel i knær og hofte
- Trene konsentrisk på to ben, eksentrisk på ett ben
- Trene ett ben om gangen
- Justere belastning (kg), sjekke 1RM eller tilsvarende

Øvelse M – Kneekstensjon i apparat



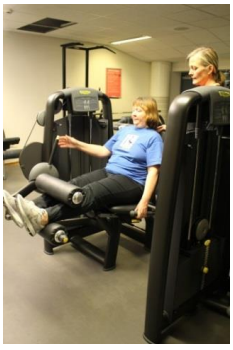
Utførelse

- Tilpass apparatet
- Kontrollerte bevegelser både konsentrisk og eksentrisk, fokus på sluttekstensjonen
- Stabilisere med mage/ryggmuskulatur

Progresjon

- Vinkel i kne
- Trene konsentrisk på to ben og eksentrisk på ett ben
- Trene ett ben om gangen
- Justere belastning (kg), sjekk 1RM eller tilsvarende

Øvelse N – Knefleksjon i apparat




Utførelse

- Tilpass apparat
- Kontrollerte bevegelser både konsentrisk og eksentrisk
- Stabilisere med mage/ryggmuskulatur

Progresjon

- Vinkel i kne
- Trene ett ben om gangen
- Justere belastning (kg), sjekk 1RM eller tilsvarende

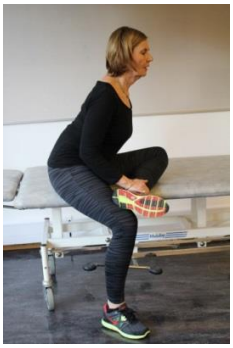
Del 3 Bevegelighetstrening

Retningslinjer i forhold til dosering for bevegelighetstrening

- ≥ 2-3 ukentlige treningsøkter er anbefalt for å øke leddbevegelighet. Best effekt oppnås ved daglig trening.

Øvelse A – Hofterotatorer

Forskjellige utgangsstillinger for samme øvelser



Utførelse

- Sittende utgangsstilling med det ene benet på benk
- Støtte hælen med det andre benet
- Bøye fremover med svai i ryggen

Utførelse

- Starte i firefotsstående, flytte det ene benet på utsiden av det andre kneet
- Flytte tyngden bakover
- Holde armene strake og svai i ryggen

Utførelse

- Stående utgangsstilling, benken justeres slik at den rekker ca på øvre del av låret
- Legg det ene benet oppå benken (fleksjon, abduksjon, rotasjon)
- Holde armene strake og rett/svai i ryggen

Øvelse B – Hofteekstensjon

Forskjellige utgangsstillinger for samme øvelse

Utførelse

- Stående utgangsstilling med begge bena i gulvet
- Presse hoften fremover

Utførelse

- Knestående utgangsstilling
- Bruk støtte hvis ustødig
- Presse hoften fremover

Utførelse

- Stående utgangsstilling med det ene benet på benk, stol e.l
- Evt kan samme øvelse gjøres i knestående
- Bruk støtte hvis ustødig
- Presse hoften fremover

Øvelse C – Ekstensjon i kne

Forskjellige utgangsstillinger for samme øvelse

- Sittende på gulvet med pølle e.l. under ankelen
- Kneet skal henge fritt
- Evt presse i ekstensjon

- Sittende med andre benet på stol e.l.
- Kneet skal henge fritt
- Evt presse i ekstensjon

Del 4 Aerob utholdenhetstrening

Retningslinjer i forhold til dosering av aerob utholdenhetstrening

- Moderat til hard intensitet anbefales for de fleste voksne.
- 30-60 min daglig (150 min ukentlig) moderat intensiv aktivitet ELLER 20-60 min daglig (75 min ukentlig) hard intensiv aktivitet ELLER en daglig kombinasjon av moderat og hard aktivitet er anbefalt for de fleste voksne.
- For svært utrente personer kan < 20 min daglig (< 150 min ukentlig) aktivitet være gunstig.

Innholdet i denne treningen bør ta utgangspunkt i pasientens muligheter, ønsker og erfaringer med å drive fysisk aktivitet hjemme eller i sitt nærområde organisert på en slik måte at det er gjennomførbart for pasienten på egenhånd. Eksempler på treningsformer kan være sykling, trening i sal, ski, svømming/bassengtrening, dans o.l.

Table 1 Overview of the content of each of the 10 sessions in the cognitive-behavioral intervention

Session	Theme	Content	Exercise	Theory and goal
1.	Getting started	Gate control theory (video) Learn to know Kathrine (video) The relation between thoughts, feelings and behavior (video) Relaxation technique	Try the relaxation technique Writing exercise: Life Story	Knowledge about pain mechanisms and the interaction of thoughts, emotions and behavior form the basis of change Learn relaxation technique to reduces muscle tension and autonomic arousal
2.	Goals for the recovery	Five key elements important for coping with pain (medical, mental wellbeing, lifestyle, life story, physical activity) (video) FAQ physical activity Follow Kathrine Goals for recovery	Make a pie chart; important areas to focus on My goal for recovery Writing exercise: Affirmative Writing Reminder: relaxation technique	Awareness of how it is possible to cope with pain form the basis of changing unhelpful behavior Knowledge about physical activity reduce fear-avoidance behavior Goalsetting increase motivation and adherence to the program
3.	Stress and pain	How to change habits (video) Understanding and managing stress (video) Identifying main stressors Locus of control (video)	Identifying main stressors Writing exercise: How has pain affected you? Update goals for recovery Reminder: relaxation technique	Understanding stress, how to change habits and locus of control promotes changing processes Reflective practice to increase awareness of own stressors
4.	Lifestyle	How different kind of lifestyle can contribute to the symptoms (training and restitution) (video) How worry and anxiety influence behavior (video) Safety behavior (video)	Identify and challenge safety behavior Writing exercise: Safety behavior and lifestyle Update goals for recovery Reminder: relaxation technique	Knowledge about how lifestyle factors, worry and anxiety influence behavior, can motivate to change behavior Be aware of own safety behavior and challenge it to start the process of changing behavior
5.	Identifying automatic thoughts	Thinking errors (video) How challenging situations can be perceived as threat, loss or challenge (video)	Exploration of internal dialogue Writing exercise: Pain triggers and alternative thoughts	Education about thinking errors and internal dialogue to start reflecting on own thoughts

		The inner dialogue (video)	Update goals for recovery Reminder: relaxation technique	Use the writing exercise to raise awareness about pain triggers and generate alternative thoughts
6.	Creating alternative thoughts	Common thinking errors (video)	Identify thinking errors and generate alternative thoughts Writing exercise: Emotional expression Update goals for recovery Reminder: relaxation technique	Practice in identifying thinking errors and generating alternative thoughts to continue the process of changing thoughts and behavior
7.	Be more mindful	Default Mode Network (DNM) and mental habits (video) Focused attention (video) Conscious refocusing (audio file)	Practice conscious refocusing Writing exercise: Going Deeper Update goals for recovery Reminder: relaxation technique	Practice focused attention and conscious refocusing to reduce DNM activity
8.	Selective attention	Unhelpful assumptions Becoming more mindful (video) Selective attention (video)	Mindfulness exercise: "Floating leaves" (audio file) Writing exercise: Choose perspective Update goals for recovery Reminder: relaxation technique	Education to increase awareness of unhelpful assumptions. Guided imagery and practice selective attention to reduce muscle tension and autonomic arousal
9.	Postponing worry and rumination	Worry and rumination Why worry escalates Postponing worry and rumination Postponement log	Make worry postponement log Writing exercise: Living with loss and changes Update goals for recovery Reminder: relaxation technique	Learn about worry and rumination. Practice making a worry postponement log Reflecting on how loss and changes in life affect you, and how to live with it
10.	What next?	What have I learned? What next?	Writing exercise: What have I learned	Reflection on what that has been learned and future plans

Table 2 PT Manual

Week	Theme	Topics to address	Learning goals
1	Get started	Help patient to get started and Ask if they have tried the relaxation technique Ask if they have completed diary exercise.	Learn about the relation between thoughts, feelings and behaviour Learn a relaxation technique
2	Goals for the recovery	Ask if the patient has started to fill in pie chart and the Goal podium. Remind on relaxation technique and writing exercise:	Be able to support patient in setting goals and using strategies to cope with pain
3	Stress and pain	Discuss what they consider as main stressors Help to fill in the goal podium and remind on relaxation techniques and writing exercise:	Learn about stress and pain, and be able to support patients to change habits
4	Lifestyle	Ask if the patient has completed the exercise about “safety behaviour” Help to revise the goal podium Remind on relaxation techniques and writing exercise:	Learn about safety behaviour and be able to help patient to be aware of how different kind of lifestyle can contribute to the symptoms
5	Identifying automatic thoughts	Discuss how it was to do the exercise about “Inner dialogue” Remind on writing exercise: Pain triggers and alternative thoughts. Remind on relaxation techniques	Be able to help patient to be aware of own thinking errors and automatic thoughts
6	Creating new thoughts	Ask about -what he/she gets out of the information about thinking errors -what experience he/she had when identified own thinking errors Remind on writing exercise: Emotional expression Remind on relaxation techniques	Be able to support patient to identify own thinking errors and create alternative thoughts
7	Becoming more mindful	Ask if: -patient experience having selective attention directed against threat and loss in relation to their OA -what experience he/she has in relation to the exercise “conscious refocusing” Remind on the writing exercise: Going deeper Remind on relaxation techniques	Learn about Default Mode Network (DNM) and mental habits to be able to support the patient to become more mindful
8	Selective attention	Ask patient: -what they think about the exercise “Floating leaves” Remind on the writing exercise: Choose Perspective Remind on relaxation techniques	Learn about selective attention and be able to support the patient to be more mindful

9	Postponing worry and rumination	Ask patient if: -he/she can distinguish between worry and rumination -he/she can postpone the worry and rumination by creating a “Postponement log” Remind on writing exercise: Living with loss and changes In life Remind on relaxation techniques	Learn about worry, rumination and why worry escalates. Be able to support patient to postpone worry and rumination and make a postponement log
10	What next?	Discuss what the patient has learned, what he/she has achieved and what remains. Encourage the patient to look back on previous exercises. Remind on writing exercise: What have I learned Discuss what to do next	Be able to support the patient to use what they have learned and to create new goals in life.
11	Specialization for physiotherapists	Understanding the concept The learning model Key elements in CBT Home exercises	Increase physiotherapists knowledge about the elements of the intervention
12	Conversation with the participants	Motivating interview (MI) (video) MI techniques (video) Resistance When users experience challenges To get stuck in unhelpful thoughts – encourage meta-perspective Pitfalls in building alliances Unhelpful assumptions	Improve the quality of the interaction between the physiotherapist and the participant

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