Feasibility of a Digital Home-Based Supervised Physical Exercise Training Program Before and After Surgical Hip Replacement

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The primary objective is to investigate the feasibility of a digital home-based supervised physical exercise training program through the TRAK platform (TRAK intervention) before and after surgical hip replacement for both patients and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON56881

Source
ToetsingOnline

Brief title
THP PreRehabApp

Condition

- Joint disorders

Synonym
Coxarthrosis & Hip osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: EIT Health

Intervention

Keyword: Digital, Hip replacement, Home-Based, Physical exercise

Outcome measures

Primary outcome

The primary objective is to investigate the feasibility for both patients and care providers (physiotherapists and orthopaedic surgeons) of a digital home-based supervised physical exercise training program through the TRAK platform (TRAK intervention) before and after surgical hip replacement, which will be assessed on the domains mentioned below.

The main outcome parameter of interest within the feasibility outcomes is adherence to the prescribed TRAK exercise sessions. Adherence is defined as the percentage of exercise sessions patients have started and/or completed in the program.

Acceptability (How individuals involved react to the program):

Patient acceptability of physiotherapy with TRAK will be assessed by the ease of use of the TRAK platform using the system usability scale (SUS), questions about the usefulness of the TRAK intervention on a 5-point Likert scale, satisfaction with the TRAK platform on a 11-point NRS scale, satisfaction of the patients with the physiotherapy activities (NRS), satisfaction of the patients with the surgery (NRS), and the intention to use TRAK on a 5-point Likert scale.

Care providers* satisfaction with the TRAK platform will be measured on a

11-point NRS scale and the ease of use of the TRAK platform for the physiotherapist using the system usability scale (SUS).

Demand (Use and/or need for the intervention):

Patients* demand for physiotherapy with TRAK will be assessed by the number of patients approached to reach 30 included patients. Additionally, adherence to the TRAK intervention will be monitored and when and if patients want to stop the intervention. The demand for use of the TRAK platform will also be evaluated through semi-structured interviews.

Care providers* demand for use of the TRAK platform will be evaluated through semi-structured interviews.

Practicality (the extent to which an intervention can be delivered when resources, time, commitment, or some combination thereof are constrained in some way):

Patients* ability to carry out the intervention activities will be assessed by using questions related to using the TRAK platform. Next to this, patient*s ability to carry out the intervention activities will be assessed by the proportion of and possible reasons for withdrawal. Additionally, we will note down the amount of needed contact with the physiotherapists. We will also investigate the practicality through interviews.

Care providers Weekly journal entries from physiotherapists will provide insight into intervention practicality, such as the barriers they run into, deviations from treatment/intervention protocol, how (fast) questions are resolved and whom was involved. Next to this, we want to look into the time spent compared to usual care and the amount of needed contact with the

patients. We will also investigate these outcomes through interviews.

Implementation & Integration (The extent, likelihood, and manner in which an intervention can be implemented as planned and the level of system change needed to integrate a new program or process into an existing infrastructure):

Care providers* perspectives on implementation and integration of the TRAK intervention will be collected using semi-structured interviews. Weekly journal entries will also provide additional insight into barriers and facilitators for implementation of the intervention.

Limited efficacy (effect of intervention on outcomes in a limited way):

We will explore the effect of the TRAK intervention on pain (NRS, rest and activity), patient specific complaints (PSK, quality of life (EQ-5D-5L), function (Oxford Hip Score (OHS) and Hip disability and Osteoarthritis Outcome Score (HOOS)), adverse events, Physical activity level (IPAQ-SF), and walking capacity and quality (Timed Up and Go test (TUG), 6-minute walk test with sensors), medication use, health care use.

Secondary outcome

In the baseline questionnaire, patient demographic information (educational attainment, employment status and marital status), patient characteristics (age, sex), and comorbidities (cardiovascular disease, kidney disease, diabetes mellitus) will be collected.

Care providers* characteristics including age, sex, work experience and occupation type will be questioned at the start of the interviews.

Another study parameter is physical activities performed without the TRAK

platform.

Study description

Background summary

Hip osteoarthritis is a debilitating joint disease characterized by the degradation of articular cartilage and structural damage to the joint. When conservative interventions such as medications, physical therapy, injections, and lifestyle modifications are no longer effective, and the condition severely impairs daily life, total joint replacement surgery is considered. Total hip arthroplasty (THA) is widely regarded as one of the most effective medical interventions, providing significant relief from pain and enhancing physical function and overall quality of life for individuals suffering from severe hip osteoarthritis [1,2]. In the Netherlands in 2019, 222 per 100.000 inhabitants underwent hip replacement surgery due to osteoarthritis [3]. However, despite the apparent effectiveness, between 7% and 23% of patients undergoing THA experience an unfavourable outcome [4,5].

To enhance the outcomes of total joint replacement, both post-operative and pre-operative rehabilitation strategies have been proposed. Traditionally, physiotherapy is administered as post-surgical rehabilitation to expedite recovery and improve overall outcomes [6,7]. In the Netherlands, the Royal Dutch Society for Physical Therapy (KNGF) recommends post-operative exercise therapy for THA, especially for patients at risk for delayed recovery [8]. In the last decade, preoperative rehabilitation, often referred to as prehabilitation, has gained significant interest. This aligns with the idea of better in, better out (BiBo), meaning the better a patient enters a hospital (*better in*), the better and faster he leaves the hospital (*better out*). In the Netherlands, an advisory BiBo guideline for physical therapists has been developed. KNGF guidelines indicate that pre-operative exercise therapy can be considered before THA [8]. Systematic reviews, although mainly based on small randomized controlled trials (RCTs), have demonstrated low to moderate evidence suggesting that preoperative physiotherapy interventions can reduce pain and enhance functional performance in patients undergoing THA [9-13]. However, evidence is heterogenic and high quality studies are missing.

Several determinants of success of pre- and postoperative exercise therapy have been mentioned in literature. Firstly, it is essential to find the optimal target population, as for example non-participation is high among fragile elderly [14] and most active patients will probably experience less benefit. Screening for risk factors can reduce the amount of complications of the surgery, e.g. function loss, having a delirium or even death. The BiBo guideline therefore proposes a risk model (based on age, sex, BMI, time of the

Timed Up & Go (TUG) test and the Charnley score) to determine if THA patients have an increased risk of delayed recovery and are eligible for prehabilitation [15]. Secondly, the nature of the intervention is a key determinant of effectiveness. Thus far, pre- and postoperative exercise therapies have been diverse and often limited in terms of type of exercises and its dosage. It is essential to ensure an adequate dosage, while simultaneously maintaining high adherence rates [16]. In their systematic review, Punnoose et al. propose a minimum of 4-6 weeks and 2 sessions per week of prehabilitation for patients undergoing orthopedic surgery [11].

Another substantial barrier for pre- and postoperative exercise therapy is travel burden for patients, especially since patients are not allowed to drive their car in the first weeks after surgery. Finally, challenges like shortages in healthcare staff and the general need for reduced healthcare costs, requires new ways of delivering care. To overcome these challenges, tele-rehabilitation or a blended care approach might be preferred over a completely supervised rehabilitation. Home-based or blended care strategies might result in a reduction of healthcare expenditures and improved adherence to home-based exercises by incorporating gamification and remote supervision of a therapist [17-20]. Home-based exercise therapy pre- and postoperatively has shown to be feasible [21] and as effective as supervised approaches[22-25]. Adding up to this, telerehabilitation achieves non-inferior physical and functional outcomes as those receiving equal dosage in-person rehabilitation programmes [26]. At the moment there are new technological developments to enhance dose and adherence like TRAK. TRAK is a web-based platform that facilitates remote information provision, making use of an exercise program with visual feedback and contact with a physiotherapist. A benefit of the platform is that it uses artificial intelligence (AI) providing real-time measurements and feedback during performance of exercises [27]. A feasibility study among 16 patients with knee problems and 15 physiotherapists showed high usability of a web-based application like the TRAK system [28]. The main goals of the TRAK system are to enhance the effectiveness of THA in terms of functional ability and pain in a cost-effective way, speeding up the rehabilitation process and reducing the need for pain medication and face-to-face visits with physiotherapists or other health care providers. In the current study, we aim to enhance outcomes for THA patients at risk for delayed recovery by providing home-based pre- and postoperative exercise therapy through the TRAK platform (TRAK intervention) with remote supervision from a physiotherapist. More information about the use of the TRAK platform is needed to gain a better understanding of how the intervention can suit patients and physiotherapists needs and improve likelihood of successful implementation. Which is why we will investigate the feasibility of the TRAK intervention before and after surgical hip replacement for both patients and care providers.

Study objective

The primary objective is to investigate the feasibility of a digital home-based

supervised physical exercise training program through the TRAK platform (TRAK intervention) before and after surgical hip replacement for both patients and physiotherapist.

Secondary Objective(s):
- To explore the effectiveness of the TRAK intervention on patient outcomes before and after the hip replacement surgery
- To assess feasibility of the TRAK intervention within the different phases (pre- and post-operative therapy)

Study design

The study will investigate the feasibility of the TRAK intervention. We will use Bowen*s feasibility framework to guide data collection in this study, as we aim to assess multiple focus types of feasibility [29]. The included areas are acceptability, demand, implementation, integration, practicality and limited efficacy. Adaptation and expansion were deemed to be not applicable in the current context. Two types of participants are involved; patients (n = 30) that are planned to undergo primary hip arthroplasty and at risk for delayed recovery, and care providers: physiotherapists and orthopedic surgeons. Patients and care providers will be recruited at the Sint Maartenskliniek. Patients will receive 6-8 weeks pre- and 8 weeks post-operative exercise therapy using the TRAK platform (see Figure 1). Usual care mostly consists of no exercise therapy before surgery, and a referral for 6-12 weeks of physiotherapy after surgery.
For the patients receiving within the TRAK intervention group, a first (face-to-face) meeting with the physiotherapist to explain the program and exercises will be planned at baseline. During the pre- and post-rehabilitation, physical rehabilitation exercises will be conducted at the patient's home. Physiotherapists of the Sint Maartenskliniek will monitor the activities of the patients (through information available on the platform) and contact patients when needed, for example when patients do not perform their exercises as scheduled. Therapists will have regular contact moments with patients at least once per two weeks. Next to this, patients can also contact the physiotherapist via the app for support. Measurements will be performed at baseline (at least 6 weeks prior to surgery), pre-surgery (4 days before surgery), 8 weeks and 26 weeks post-surgery. This will be a post-market study with a medical device with CE marking (MDR article 74.1). No other medical devices apply, TRAK is the only investigational product considered, with its independent use being sufficient to conduct the intended study.

Intervention

The TRAK intervention comprises of physiotherapy exercises using the TRAK platform. The TRAK platforms* intended use is to deploy it as a tracking and monitoring tool for the patient, enabling them to perform a physical exercise

routine for therapeutic treatment both before and after hip replacement surgery in a completely digital manner. Patients will be instructed to perform daily exercises for 6-8 weeks pre-surgery and 8 weeks post-surgery. The execution of the exercises will be recorded by the patient, and these recordings will be available for the physiotherapist to conduct monitoring for where help is needed. The training is based on the training program for knee and hip osteoarthritis of the KNGF [33]. This program consists of a minimum of two times a week strength exercises and five times a week at least 30 minutes aerobics exercises. The TRAK intervention concists of four times a week roughly 20 minutes strength exercises. Within TRAK only the strength exercises are possible. To comply to the KNGF program, patients will be asked to perform and write down their aerobics exercises in a journal. The TRAK training program includes the same exercises/sessions for all the patients, although these can be personalized timewise or repetition wise based on the capacities and complaints of the individual patient. Pre-surgery and post-surgery exercises will be partly the same, although there will be also other exercises pre-surgery versus post-surgery due to a difference in aim of the training. The training program is compiled by the physiotherapists of the Sint Maartenskliniek, and personalized based on the participant*s needs to ensure favorable progress.
At baseline patients will receive explanation on the TRAK platform from a researcher. They will also meet the physiotherapist that will walk them through the exercise program. From baseline onwards patients will have phone contact (roughly 10 minutes) with the physiotherapist once every 2 weeks to monitor progress and answer questions.

Study burden and risks

The TRAK-app is a registered computer program designed for remote monitoring and functional assessment by the healthcare professional during the rehabilitation process (self-monitoring) of patients with musculoskeletal injuries. The subjects recruited for this clinical trial will not be exposed to any procedures that could endanger their safety as the training exercises are exercises normally used in usual care. Now patients will do these exercises at home with an AI based app. Those exercises will be recorded during performing, with a potential fall during performance as the only possible risk during the clinical trial. Although this risk is equivalent to performing exercises during usual care. Patients participating in the clinical trial will be asked to only come to the hospital one extra time, for the baseline measurement. Adding up to this, the questionnaires are extra next to the usual surgery standards. This all makes the clinical trial not that burdensome. With the TRAK intervention patients are asked to perform (extra) physiotherapy training prior to their surgery. The gain is that patients will be more fit before the surgery and after the surgery. This all shows that this clinical trial bares small risks for patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 45 year
- Scheduled for surgical intervention for primary hip replacement.
- Osteoarthritis as primary indication for the hip replacement.
- Between 6 and 8 weeks prior to surgery.
- At risk for delayed recovery, defined as having a sumscore of > 51 at the BiBo criteria [15]
o The score is calculated based on the following factors:
* BMI >= 25 kg/m2 = 17 points
* Charnley-score: B/C = 36 points*
* TUG >= 12,5 sec = 27 points
* Sex: male = 1 points
* Age >= 70 year = 6 points

* We will include patients on their Charnley-score, this score is needed to reach the threshold of more than 51 points. The TUG will be performed at baseline, although we won*t exclude patients if they have a TUG of less than 12.5 seconds. BMI, sex and age can also be determined at baseline.
- Patients possessing a tablet, smartphone, or laptop with internet access and camera.
- Must have an active email account.
- Signature on the informed consent form.
- Commitment to undergo prescribed treatments.

Exclusion criteria

- Patients with intellectual disabilities or cognitive impairment.
- Patients not living independently
- Co-morbidities that affect daily life functioning (e.g. stroke, heart and vascular disease).
- Patients unable to use mobile applications, cell phones, tablets, laptops, or email and lacking support from a family member or caregiver who can utilize these technologies.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2024
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	TRAK

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-07-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86111.091.24