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Effects of a tele-prehabilitation program or an in-person prehabilitation program in surgical candidates awaiting total hip or knee arthroplasty: Protocol of a pilot single blind randomized controlled trial

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ABSTRACT

Background: The accessibility for total joint arthroplasty often comes up against long wait lists, and may lead to deleterious effects for the awaiting patients. This pilot single blind randomized controlled trial aims to evaluate the impact of a telerehabilitation prehabilitation program before a hip or knee arthroplasty compared to in-person prehabilitation or to usual wait for surgery.

Methods/design: Thirty-six patients on a wait list for a total hip or knee arthroplasty will be recruited and randomly assigned to one of three groups. The in-person prehabilitation group (n = 12) will receive a 12-week rehabilitation program (2 sessions/week) including education, exercises of the lower limb and cardiovascular training. Patients in the tele-prehabilitation group (n = 12) will receive the same intervention using a telecommunication software. The control group (n = 12) will be provided with the hospital's usual documentation before surgery. The Lower Extremity Functional Scale (LEFS) will be the primary outcome measure taken at baseline and at 12 weeks. Secondary measures will include self-reported function and quality of life as well as performance tests. A mixed-model, 2-way repeated-measure ANOVA will be used to analyse the effects of the rehabilitation programs.

Discussion: This pilot study is the first to evaluate the feasibility and the impact of a telerehabilitation prehabilitation program for patients awaiting a total joint arthroplasty. The results of this pilot-RCT will set the foundations for further research in the fields of rehabilitation and tele-medicine for patients suffering from lower limb osteoarthritis.

Trial registration: ClinicalTrials.gov: NCT02636751.

1. Introduction

Osteoarthritis (OA) is a very common disorder that affects 1 in 8 Canadians among which more than half of the population over 65 years of age [1,2]. Future estimations indicate that the incidence of OA will increase by at least 26% over the next 30 years in Canada because of inactivity, obesity and aging [2]. Hip and knee are the joints most affected by OA, incuring important disability [3]. Lower limb OA is initially treated conservatively with therapeutic interventions such as physical activity modification, exercise, weight

Abbreviations: TJA, Total joint arthroplasty; TKA, Total knee arthroplasty; THA, Total hip arthroplasty; LEFS, Lower Extremity Functional Scale; WOMAC, Western Ontario & McMaster Universities Osteoarthritis Index; SF-36, The Short Form (36) Health Survey; GRS, Global Rating Scale; TUG, Timed Up and Go; SPW, Self-paced Walk; ST, Stair Test; FRSQ, Fonds de recherche du Québec – Santé; ANOVA, Analysis of variance; ICC, Intraclass correlation coefficient; RCT, Randomized clinical trial.

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control, and medication [4,5]. Surgical interventions such as total joint arthroplasty (TJA) have been proven a treatment of choice for the most severe cases. However, the accessibility to such surgeries often come up against long wait lists, and prolonged wait times may lead to deleterious effects on the health status and quality of life of the awaiting patients [6].

Prehabilitation refers to education and exercising before a surgery. Attention to prehabilitation has increased in the last decade and a growing body of evidence suggests that it could have a positive effect on postoperative outcomes and may reduce disabilities before and after surgery for a number of conditions [7–9]. In the context of prehabilitation for TJA, trials have already shown that a rehabilitation exercise program before a TJA could lead to a shorter hospitalisation length of stay [10], in addition to increased muscle strength [11,12] and range of motion following a total hip or knee arthroplasty [11,13].

As the aging population and the constant increase in chronic diseases keep pressuring healthcare systems worldwide [14], lack of resources tends to lengthen wait time for surgery like TJA. Policymakers have therefore been searching for a care optimisation strategy to improve healthcare accessibility.

Among the solutions stands the use of technology to help improve accessibility to rehabilitation services. Telerehabilitation has gained increased recognition and is defined as the provision of rehabilitation services at a distance, using information and communication technologies [15]. Previous studies have already shown that telerehabilitation programs are feasible in a home-care setting [16–18].

Tousignant et al. demonstrated that a telerehabilitation program after a total knee arthroplasty (TKA) was as effective and less expensive than conventional physiotherapy [19–21]. Bedra et al. qualified as viable a home-based telerehabilitation program after a hip fracture [16], while Anton et al. demonstrated that a Kinect™-based system can be an adjuvant to physiotherapy after a total hip replacement [22,23]. Such programs can optimise the delivery of care in community rehabilitation, especially by increasing the number of patients seen in a single day, by reducing health care costs and travel time, and by providing access to medical care otherwise unavailable in rural or remote areas [24]. However, no study, to our knowledge, analysed the outcome of telerehabilitation prior to a total joint replacement.

This pilot single blind randomized controlled trial therefore aims to evaluate the feasibility and impact on pain and disability of a telerehabilitation prehabilitation program for patients awaiting a total joint (hip or knee) arthroplasty compared to in-person prehabilitation or usual care. Our hypothesis is that a 12-week in-person or telerehabilitation prehabilitation program will significantly increase functional mobility and quality of life before the surgery, for the subjects in the experimental groups as compared to those in the control group.

2. Material and methods

2.1. Study design

Patients will be randomly assigned to one of three groups. The in-person prehabilitation group will receive a 12-week rehabilitation program including education, cardiovascular training using low-impact activities, as well as range of motion, strengthening and proprioceptive exercises of the lower limb, in addition to walking aid adjustment. General information about pain control, such as ice application and medication usage will also be provided. Patients in the tele-prehabilitation group will receive the same exercise program and advice through an Internet-based telecommunication software. The control group will be provided with the hospital's usual documentation before total joint arthroplasties, consisting of information regarding the pre- and post-surgery course and medication. The exercise components of the prehabilitation program are those commonly used with patients suffering from lower limb osteoarthritis or after TJA. The particularity lies in the timeframe when they will be held, i.e. the pre-operative phase of a TJA. All the prehabilitation sessions will we provided by licensed physiotherapists, members of the *Ordre professionnel de la physiothérapie du Québec*.

For all participants, evaluations will be performed at the inclusion in the study (baseline) and after the completion of the 12-week rehabilitation program. The study will be approved by the *Center intégré universitaire de santé et de services sociaux de l'Est de l'île de Montréal, site Maisonneuve-Rosemont (HMR)* ethic committee and all study participants will sign an informed consent form. The study protocol will also be published on the https://clinicaltrials.gov website.

2.2. Participants

Thirty-six (36) patients on a wait list for a total arthroplasty of hip (18) or knee (18) at the *Center intégré universitaire de santé et de services sociaux de l'est de l'île de Montréal*, site Maisonneuve-Rosemont (HMR) and site Santa-Cabrini will be recruited. Maisonneuve-Rosemont is a tertiary care hospital with an orthopaedic department while Santa-Cabrini is a community hospital. Participants will need to fulfill the following eligibility criteria: 1- Age greater than 18 years; 2- Waiting for a TKA or a THA; 3- Suffering from severe OA of hip or knee; 4- Quebec resident covered by the *Régie de l'assurance maladie du Québec* (Quebec public healthcare insurance); 5- Speaks French; 6- Has access to a high-speed internet connection. The following exclusion criteria will be used: 1- Suffering from inflammatory arthritis; 2- Scheduled for a bilateral surgery; 3- Has had a lower limb surgery in the past 6 months; 4- Scheduled for a revision of a previous TKA or THA; 5- Planned for a wide acetabular head hip prosthesis or a hip articular resurfacing; 6- Receiving compensation from the Quebec Workers' Compensation Board *(Commission des normes, de l'équité, de la santé et de la sécurité du travail)*; 7- Suffering from a severe psychiatric, neurologic or cardiac disorder, or other types of disorders that could interfere with the rehabilitation program.

Patients will be identified by the treating surgeons or by a research professional once patients are scheduled for surgery. Patients will be contacted by a research assistant by phone to receive further information about the trial and perform a preliminary screening. After obtaining preliminary consent, participants will be given an appointment at the Maisonneuve-Rosemont Research Center in order to validate their eligibility and a baseline evaluation and formal written consent will be sought. In case of refusal, sociodemographic data, such as age, sex and reason for refusal will be collected for further selection bias analysis.

Patients will then be randomly assigned to the control group or to one of the two experimental groups. An independent research assistant will open the sealed opaque randomization envelope indicating the participant's assignment to a group. A random number generator will be used to establish randomization lists prior to the initiation of the study. A member of the research team, not involved with data collection, will generate the randomization list. Blocked randomization of 6 will be used to make sure that three equal groups of 12 subjects participants are obtained.

2.3. Participant evaluation

Evaluations will take place at two points in time: at baseline and at the end of the 12 week intervention (or 12 weeks after baseline