PETKO: Pilates Exercise Training before Knee arthroplasty in patients with Osteoarthritis. A two-arm, randomized, open-label assessor blinded phase II clinical trial

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Abstract:

Background and Aim: *Osteoarthritis (OA) is a degenerative inflammatory disease of the hyaline cartilage of the synovial joints; currently it is the most common joint disease in the world and mainly affects the knee. Total knee arthroplasty (TKA) is one of the treatment choices in the management of severe cases of OA. Pilates is a fitness system that combines different exercises with the aim of increasing flexibility, joint and core strength. There is data that has shown that a Pilates intervention has an effect in the increase of muscle mass, flexibility, dynamic balance and that it also helps to improve mental and psychological status. There are no reports in the literature of the effects of a pre-surgical Pilates intervention in the quality of life of patients after TKA. Therefore, we present a study protocol designed to evaluate the effects, on the activities of daily living (ADL), of a Pilates routine done prior to a TKA, in patients over 60 years of age with severe OA; compared to a pre-surgical intervention of educational sessions.*

Methods: *The PETKO trial is designed to be a single center, two-arm, open-label assessor blinded, randomized controlled trial. A total of 88 patients with an indication for TKA will be randomized in a 1:1 allocation ratio. The experimental arm will receive 18 preoperative sessions of Pilates and educational sessions in a six-week period, while the comparator arm will only receive the educational sessions during the same period. The primary outcome will be the ADL measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) ADL subscale at the 90th day post-surgery. For secondary outcomes we will evaluate the rest of the KOOS subscales, functional exercise capacity, range of motion, leg strength (with the 30-second chair stand test) and hospital length of stay.*

Discussion: *There is a direct relationship between functional status, morbidity and mortality in geriatric patients. The effect of Pilates has been studied in elderly patients and has shown improvements in flexibility, balance, strength, physical, social, spiritual and emotional wellness. This is why we hypothesized that an improvement in the baseline condition of the patients with knee OA, prior to the surgical intervention, may have a direct benefit in the recovery time and on their quality of life, in the long term. The PETKO trial has the advantage of being a well-designed RCT that will evaluate a non-common intervention in a way that has not yet been evaluated.*

INTRODUCTION

Osteoarthritis (OA) is the most common joint disease around the world. It is responsible for considerable disability in millions of patients, even at young ages, and

Abbreviations
OA: Osteoarthritis
TKA: Total knee arhtoplastie
ADL: Activities of daily living
KOOS: Knee Injury and Osteoarthirits Outcome Score
QoL: Quality of life
6MWT: six.minute walk test
30-s CST: 30-second chair stand test
ITT: Intention to treat
RCT: Randomized controlled trial

its costs are estimated to be over $100 billion a year in the United States (Jeffries et al., 2014).

The prevalence of disease increases after 50 years of age, probably due to age-related diminished blood supply and cartilage matrix alterations. Women are more affected than men, having up to 70% of higher prevalence (Jordan et al., 2009; Sharma, 2016; Varady & Grodzinsky, 2016; Weiss & Jurmain, 2007).

In 2012, over 670,000 total knee arthroplasties (TKA) were performed in the United States with a cost of $36.1 billion (Skou et al., 2015) and the number of total knee replacements is expected to grow by 3.48 million procedures by 2030 (Kurtz, Ong, Lau, Mowat, & Halpern, 2007). Modern TKA is performed by means of the resection of the diseased articular surfaces of the knee and later resurfacing with metal and polyethylene prosthetic components, and if the patient is well selected, significant pain relief, improved function and quality of life (QoL) are seen (Loughlin, 2001).

It is known that Pilates is a fitness system that combines different exercises with the aim of increasing flexibility, joint and core strength; it also helps to improve coordination and stability. The routines involved have the versatility that can be individualized according to the patient specific needs or requirements (Levine, Kaplanek, & Jaffe, 2009; Levine, Kaplanek, Scafura, & Jaffe, 2007).

There is evidence about the benefits of Pilates even in short-term interventions. Patients that were exposed to a Pilates routine once a week had an increase in muscle mass, flexibility, balance, core and abdominal muscle strength, body awareness and improvement of their psychological status (Kibar et al., 2015; Nóra, Zsófia, Ferenc, & Attila, 2016).

Cruz-Ferreira et al, evaluated Pilates in a systematic review of randomized controlled trials (RCT) or quasi-RCT performed in healthy people, that had inactive and/or exercise control groups, and that included Pilates routines in at least one of the study arms. They concluded that there was strong evidence to support the use of Pilates with the goal of improving flexibility and dynamic balance and that there was also moderate evidence for an improvement in muscular endurance (Cruz-Ferreira, Fernandes, Laranjo, Bernardo, & Silva, 2011).

Levine reported results in a retrospective analysis of 38 patients that followed specific Pilates protocols based on a post-operative rehabilitation regimen of 2-6 weeks. He showed improved compliance among female joint replacement patients, with 73% of them maintaining an active role in Pilates at one year of follow up (Levine et al., 2009, 2007).

However, to our knowledge at this moment, there are no reports in the literature of the effects of a pre-surgical Pilates intervention in the QoL of patients after TKA. Therefore, we present a study protocol designed to evaluate the effects in the activities of daily living of a Pilates routine done prior to a TKA in patients over 60 years with severe OA; compared to a pre-surgical intervention of educational sessions.

METHODS

Trial Design

The PETKO trial is designed to be a single center, two-arm, open-label assessor blinded, randomized controlled trial. The experimental arm will receive 18 preoperative sessions of Pilates and educational sessions in a six-week period, while the comparator arm will only receive the educational sessions during the same period.

The protocol will be presented to an institutional review board for approval. All subjects must give consent in order to participate in the trial.

Outcome Measures

Baseline and follow-up evaluations will be performed by experienced physiatrists blinded to group assignments when subjects are recruited, after the 6- week intervention period and at the 30th, 60th and 90th day post-surgery.

Primary Outcome Measure

The primary outcome will be the activities of daily living (ADL) measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) ADL subscale at the 90th day post-surgery. The KOOS is a patient- administered, self-explanatory, no licensed required scale, recommended for short and long-term intervals knee OA evaluation. It consists of five subscales that include: pain, other symptoms, ADL, sports and recreation function and knee-related QoL. A normalized score, where 100 indicates no symptoms and 0 shows extreme symptoms, is obtained for each subscale. KOOS has been used in patients from 13 to 79 years of age, and has high test-retest reliability for each of its subscales. Also, KOOS is responsive to changes following surgical and non-surgical interventions (Collins & Misra, 2011).

Secondary Outcome

For secondary outcomes we will evaluate the rest of the KOOS subscales. We will also evaluate functional exercise capacity with the six-minute walk test (6MWT). This test measures the distance (in meters) an individual is able to walk, on a hard flat surface, over a total of six minutes. The 6MWT has a high reproducibility and is easy to

administer, compared to longer time tests (Butland, Pang, Gross, Woodcock, & Geddes, 1982). It has been studied in patients with knee or hip OA, following interventions to improve exercise tolerance (Focht, Rejeski, Ambrosius, Katula, & Messier, 2005). A lower score reflects less distance covered in six minutes, indicating a worse patient function. Test-retest reliability has been reported as high with an ICC between 0.80 and 0.91 according to time of testing (Demers, McKelvie, Negassa, & Yusuf, 2001).

We will also use the 30-second Chair Stand Test (30-s CST) for assessing leg strength in our subjects. The 30-s CST is a modified chair-stand protocol that measures lower body strength by recording the number of stands a person can complete in 30 seconds. It has good test-retest reliability (0.84 and 0.92, respectively) that provides for a valid indicator of lower body strength in generally active, older adults. It has also shown to have good power for discriminating between differences in age categories and also within different physical activity level groups (Jones, Rikli, & Beam, 1999). This test has been validated in different types of older populations (Macfarlane, Chou, Cheng, & Chi, 2006; Millor, Lecumberri, Gomez, Martinez-Ramirez, & Izquierdo, 2013).

Subjects will be assessed for changes in range of motion measured with a goniometer during each of the evaluations. Also we will collect hospital length of stay, in days, for each individual.

Sample Size

Concerning our primary outcome measure, KOOS ADL subscale, we considered as a minimal clinical important difference a value of 10 points with an SD of 15 points. Sample size was estimated with a power of 0.8, an alpha level of 0.05, and a two-sided p-value, giving an approximate number of 36 patients and 36 controls. In addition, a 20% was added to the sample size in order to compensate for study dropouts. Thus a total sample of 88 patients was obtained and distributed in 44 patients for the intervention and 44 controls.

Recruitment

Recruitment will be done in a third level hospital with experience in TKA procedure. Patients will be recruited through convenience sampling in a prospective consecutive way, following inclusion and exclusion criteria, until the calculated sample size is reached. Written informed consent will be signed at the time of recruitment.

Participants

Patients who are candidates for a TKA and are eligible to be enrolled in the study must follow all of the inclusion criteria cited below:
1) Diagnosis of primary knee OA
2) Grade 3 or 4 in Kellgren and Lawrence Radiological classification (Petersson, Boegård, Saxne, Silman, & Svensson, 1997)
3) Age over 60 years
4) Pre-surgical assessment and approval by a Physiatrist and a Geriatrist
5) Surgical indication for TKA
6) Availability for scheduled visits

Patients with any of the following criteria will be excluded from the study:
1) Previous surgical intervention of the affected knee
2) Patients taking Pilates sessions at the time of recruitment
3) Indication for TKA on both knees

Randomization

Patients who meet the inclusion and exclusion criteria will be randomized and assigned to either the experimental or control group with a 1:1 ratio allocation after a pre-surgical standard evaluation from a, blinded to the allocation, Physiatrist and also a Geriatrist. We will use sealed and opaque envelopes to randomize the patients who give the consent.

Furthermore, we will use a blocked randomization process, with random 4 and 6-size blocks, in order to maintain an adequate balance in the number of subjects allocated to both groups.

Intervention

During the pre-surgical evaluation, the patients' basal physical activity will be assessed using the Yale Physical Activity Survey. This survey has been validated for its use in the elder population (DiPietro, Caspersen, Ostfeld, & Nadel, 1993) and will allow us to adjust later in the analysis of the results obtained, for baseline physical status of each subject, as a possible confounding factor.

Control Group

The control group will have weekly educational sessions of 30 minutes each, during the six weeks of the intervention period. The following topics will be addressed: basic concepts of OA, pain management techniques, prevention of falls, basic description of the TKA surgical procedure, postsurgical rehabilitation recommendations and advices for healthy aging.

Experimental Group

Weekly educational sessions will also be offered to patients in the experimental group. The active intervention will consist of a pre-operative Pilates routine over a six-week period, three times per week under guidance of a Pilates certified physical therapist.

The physical therapist will perform a pre-Pilates physical capacity assessment in every patient. According to the performance of the subject, the therapist will individualize their protocol's routine. At week 3, the therapist will perform the same assessment and will be allowed to modify the amount of workload for every patient within the designed routine.

The intervention consists of an individual Pilates routine given 3 times a week, over six weeks (18 sessions in total) (Table 1). The materials needed for the exercises will include: resistance bands, physioballs, a mat and foams. In order to be included in the per protocol analysis, patients must have completed, at least 13 (70%) of the 18 programmed Pilates sessions.

In both groups, surgery will be scheduled exactly one week after the last intervention received (Pilates session or educational session). All patients will receive the same medical follow-up and standard physical therapy for the post-operative period of the TKA procedure.

Statistical Analysis

The primary and secondary outcomes will be compared in both groups. Data distribution will be evaluated by visual (histograms) and statistical normality tests (Shapiro-Wilk and Kolmogorov- Smirnov). For continuous variables we will use unpaired T-test when data is normally distributed and the Wilcoxon rank-sum

Table 1. Routine of Pilates exercises designed for the intervention of PETKO Trial

Step	Pilates Exercise	Repetitions/time
1.	Modified Hundred	50 repetitions
2.	Rest	3 minutes
3.	Modified Hundred	50 repetitions
4.	Roll-Down	8 repetitions
5.	Single Leg Circle Left clockwise	8 repetitions
6.	Single Leg Circle Right clockwise	8 repetitions
7.	Single Leg Circle Left counterclockwise	8 repetitions
8.	Single Leg Circle Right counterclockwise	8 repetitions
9.	Single Leg Stretch	8 repetitions (4 repetitions each leg)
10.	Double Leg Stretch	8 repetitions
11.	Rest	5 minutes
12.	Single Straight Leg Stretch Right	8 repetitions
13.	Single Straight Leg Stretch Left	8 repetitions
14.	Spine Stretch Forward	5 repetitions
15.	Rest	5 minutes
16.	The Saw	16 repetitions (8 repetitions each side)
17.	The Swan Prep	4 repetitions
18.	Single Leg Kick	10 repetitions (5 each leg)
19.	Side Kick Left side	6 repetitions
20.	Side Kick Right side	6 repetitions
21.	Teaser Prep 1	6 repetitions
22.	Single Leg Stretch (with resistance band)	8 repetitions (4 repetitions each leg)
23.	End of the session	

(Adapted from: Levine B, Kaplanek B, Scafura D, Jaffe WL. Rehabilitation after total hip and knee arthroplasty: a new regimen using Pilates training. Bull NYU Hosp Jt Dis. 2007;65(2):120-125)

(Mann-Whitney) test in the setting of non-parametric distribution. For categorical variables, Chi-square test or Fisher's exact test will be performed when appropriate.

For missing data management, the last observation carried forward method was chosen as an intention-to-treat (ITT) analysis. We will also perform a per- protocol approach as a sensitivity analysis for the comparison of the results.

In exploratory analyses we will conduct longitudinal analysis with the individual scores obtained from each subject, at the trial visits, in order to document the direction and magnitude of the change over time. This may allow us to establish the pattern and possible trends in the change of functionality in the study participants. Also we will perform a mixed regression analysis accounting for correlation between longitudinal data adjusting for group, time and age effect modification.

Ethical

The principal investigator, the research coordinator or the research assistant will be responsible for conducting the informed consent process with all the study participants. Any relevant changes in the study protocol and/or the informed consent will be sent to the independent review board as a protocol amendment. All the subjects' identities will be protected with an individual code which only the principal investigator will have access to. The protocol will be registered in an online clinical trial database before starting with the trial.

DISCUSSION

Knee OA has a negative impact in the QoL and it is a leading cause of disability particularly in elderly patients (Farr II, Miller, & Block, 2013). There is a known direct relationship between functional status, morbidity and mortality in geriatric patients, justifying that RCTs done in this population, must be aimed to assess functional status rather than any other outcome as primary endpoint (Bhasin et al., 2008). For these reasons we decided to choose KOOS ADL subscale as the main outcome in this protocol.

As stated before, TKA is a very frequent surgical procedure used for the management of severe knee OA. However, there are very few clinical trials in this field, and to our knowledge their main outcomes have always been evaluated after the surgical interventions were performed (Jogi, Overend, Spaulding, Zecevic, & Kramer, 2015; Skou et al., 2015).

The effect of Pilates has been studied in elderly patients has shown improvements in flexibility and in physical strength (Geremia, Iskiewicz, Marschner, Lehnen, & Lehnen, 2015). Also it has shown to significantly improve the Wellness Scale in elderly people, particularly in the physical, social, spiritual and emotional wellness items of the scale (Roh, 2016).

A group of 30 elderly adults were part of an investigation that assessed the effects of a 5-week Pilates intervention in postural sway and dynamic balance. The results obtained in this trial, showed that even after this short intervention, there were significant differences in balance and leg strength in the participants and that these benefits were sustained up to 12 months. Moreover, data subgroup-analysis proved that those patients that kept doing Pilates after the initial intervention had even a better performance status than those who ceased to continue performing the exercises (Bird & Fell, 2014).

Mokhtari et al conducted a case-control study with 30 patients that evaluated the effect of a 12-week Pilates routine on depression and balance associated with falling in the elderly. In this interesting study subjects exposed to the Pilates routine reported a significant reduction of 19.8% in the Geriatric Depression Scale and up to 16.7% in the balance tests (Mokhtari, Nezakatalhossaini, & Esfarjani, 2013).

Two systematic reviews have analyzed results obtained from studies that evaluated Pilates interventions in elderly populations. Both of these reviews showed evidence of a benefit in static and dynamic balance, and some added improvements in physical and motor status in these types of patients. However, both systematic reviews concluded that the evidence available has poor methodological quality and that further studies are needed to validate all the observed effects of Pilates in aged patients (de Oliveira Francisco, de Almeida Fagundes, & Gorges, 2015; Engers, Rombaldi, Portella, & Cozzensa Da Silva, 2016).

We have found observational reports only done by Levine (Levine et al., 2009, 2007) involving the use of Pilates in patients after TKA, and we are unaware of its benefits if used in a pre-surgical setting. Even though, the data of Pilates interventions shown in the literature, in general, is not as solid as we would have wanted, there is a trend that suggests a physical and QoL improvement of the elderly patients exposed to this type of exercise. This is why we hypothesize, that improving the baseline condition of the patients with knee OA, through a Pilates routine prior to the surgical intervention, may have a direct benefit in the recovery time and in the QoL of these patients, in a long term.

There is a clear gap that demonstrates the lack of controlled Pilates trials to provide solid evidence of its benefit in different populations and settings. The PETKO trial has been designed to be a randomized trial with a proper sample size. It will also have exploratory analysis

on secondary outcomes that could add information about disease patterns, as well as the prediction of long-term outcomes based on the pre-operative response to the intervention.

The topic of adherence has been thought of as a potential pitfall in this protocol, however, by adding costs of transportation and food for all included patients and their companions to the study budget, we plan to ameliorate this situation. Also, the study coordinator will remind and reschedule all of the patients' visits as needed. Besides, we expect that a gradual improvement in the baseline condition of the patients will encourage compliance during the rest of the intervention.

We believe that the PETKO trial is a well-designed RCT that will evaluate a non-common intervention in a way that has not been evaluated yet. Even if the results do not prove our hypothesis, the gathered data will contribute to a field of study that, although very common in the clinical setting, has not been widely studied.

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Conflict of interest and financial disclosure

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