EFFECT OF PREOPERATIVE PATIENT EDUCATION PROGRAM ON FUNCTIONAL OUTCOMES AFTER TOTAL KNEE ARTHROPLASTY

STUDY PROTOCOL

FLORIANÓPOLIS
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ABSTRACT

The knee is one of the joints most affected by osteoarthritis (OA), causing individuals to present joint stiffness, muscle weakness and proprioceptive deficit limiting the performance of daily activities. Total knee arthroplasty (TKA) presents good results in reducing the pain and stiffness of individuals in the final phase of OA. However, changes in gait and strength may persist postoperatively. Preoperative guidance for TKA were efficient in reducing pain and functional deficits and improving quality of life, however the functionality was measured by scales. Thus, this study aims to evaluate the effect of preoperative guidance on three-dimensional gait analysis, functional mobility, postural control and kinesiophobia level in subjects with TKA. Will be recruited patients of both sexes undergo unilaterally TKA in the city of Florianópolis and referred by an orthopedist to the Physiotherapy Clinic of UDESC. These will be divided into two groups: one that will receive verbal guidance and a leaflet with information related to their physical condition as well as signs and symptoms in the postoperative period and a group that will receive only verbal guidance. Both groups will be evaluated by a blind evaluator in the preoperative and postoperative periods (6 weeks and 6 months). The evaluations will be divided into five stages. Anthropometric measurements of the individual will be made and then the WOMAC functionality questionnaire and the Tampa Scale of Kinesiophobia will be applied. Then the individual will walk by 5 meters for three-dimensional gait analysis through the Vicon System, AMTI Force Platforms and Noraxon electromyograph. A functional mobility assessment will also be performed by Timed Up And Go. Finally, evaluation of the postural control with Neurocom Equilibrium Platform will be performed. Statistical data will be analyzed by analysis of variance 3x2 considering time factor (pre, post 6 weeks and post 6 months) and groups (with and without information leaflet). The p-value used will be 0.05.

Palavras-chave: osteoarthritis, total knee arthroplasty, physiotherapy, gait analysis, guidance
1 INTRODUCTION

1.1 CONTEXTUALIZATION OF THE PROBLEM

The current extension of life expectancy leads to an increase in the elderly population, commonly affected by degenerative diseases such as osteoarthritis (OA) (MILNER, 2009; YAARI et al, 2015). OA is the chronic-degenerative disease that most affects the elderly. In Brazil there is a lack of consistent data, but a prevalence of 26.5% is inferred. The knee is especially affected, between 23% and 40% of the elderly population, being more prevalent in women and over 74 years (SALVATO et al, 2015). Its onset and progression may be related to age, changes in metabolism, genetic and hormonal factors, biomechanical changes and inflammatory joint processes. The symptomatology goes from pain and joint stiffness to deformities and progressive loss of function (SANTOS et al, 2011). Thus, the treatment of this population should seek to reestablish independence and quality of life, where the resource commonly used in the final stages of OA is total knee arthroplasty (TKA) (HIYAMA et al, 2015).

The articular surface replacements began in the 1940s, undergoing continuous advances (VASCONCELOS et al, 2013), and are today the most effective surgery interventions in terminal phases of OA for success in reducing pain and joint stiffness (CASARTELLI et al, 2013). However, changes in strength, joint mobility, and gait may remain or worsen after joint (HIYAMA et al, 2015).

The recovery of gait function is one of the main objectives after TKA (CASARTELLI et al, 2013), because this activity is related to the independence of the individual besides being one of the activities that presents a higher incidence of fall in the elderly (HALLAL et al, 2013). Abnormal gait patterns may predispose to new degenerative processes or early deterioration of the prosthesis. Thus, identifying abnormalities makes it possible to trace treatment strategies for its correction (MILNER, 2009).

The use of scales and questionnaires is highly used in the evaluation of pain and post-TKA functionality. However, the subjectivity of these evaluations interferes in the quantification of the functional framework and, therefore, in the therapeutic direction. Evidence suggests that measures based on performance are more likely to characterize changes in function than self-reports (YUKSEL et al, 2016).

Investigations of the kinematics in the TKA showed lower flexion in the initial contact phase and less flexion in the oscillation phase. These individuals also had greater varus in
response to the load when compared in asymptomatic individuals (VASCONCELOS et al, 2013). Research associating three-dimensional gait assessment with electromyography (EMG) found patterns that differed from normal, but no preoperative data were collected from individuals in order to quantify the changes that occurred (VILLARDI et al, 2005; LEE et al, 2015).

He knows that the variability of step time depends on the sum of factors physical function, ability to balance and mental state, such as the confidence of the individual in his ability to perform the activity (HYIAMA et al, 2015). There is evidence that persistence of pain can not be based solely on clinical findings, making a purely clinical intervention inefficient (SIQUEIRA et al, 2007). Pain education can alter beliefs about pain, such as the fact that it is related to tissue damage and disability (LOUW et al, 2013), Showing reduction of pain, functional deficits and improvement of the quality of life in patients who received guidance for the postoperative period (MONTICONE et al, 2013).

A review study has shown that preoperative guidance themselves can not modify the patient's physical condition but improve the ability to cope with pain and feel prepared for surgery by reducing anxiety and increasing postoperative comfort (AYDIN et al, 2015). Fear of movement pain characterizes kinesiophobia, where the individual ceases to perform activities inducing a vicious cycle, which results in decreased joint mobility, muscular strength and proprioception, thus increasing the pain experience (MONTICONE et al, 2013).

Although there were studies on the effect of preoperative guidance on patients with TKA, mobility was assessed only through functional questionnaires, with no objective information on the behavior of the spatial-temporal and kinetic parameters of gait, postural control and functionality. Thus, this study aims to evaluate the effect of preoperative guidances on functional gait recovery and kinesiophobia level in subjects post TKA.

1.2 OBJECTIVE

The study was designed to evaluate the effect of preoperative patient education program on functional outcomes after total knee arthroplasty.

1.3 HYPOTHESES OF RESEARCH
• H0: There is no difference on functional outcomes after TKA in patients that received preoperative information and those who did not.
• H1: There is difference on functional outcomes after TKA in patients that received preoperative information and those who did not.

3 METHODOLOGY

3.1 STUDY DESIGN

This study is a single-center, prospective, parallel-group, randomized clinical trial (HULLEY et al, 2015).

3.2 PARTICIPANTS

Sample size estimation calculations were performed taking into consideration the primary outcome measure - Timed up and Go (TUG) test score. These calculations were based on the study published by Mizner et al (2005), and considering a Minimal Clinically Important Change of 2.27 seconds in the TUG score (Yuksel et al, 2016). Considering a power of 80% and a two-sided 0.05 significance level, 28 patients would be necessary to detect a 2.27 second difference between the two arms (14 patients in each arm). Considering a dropout rate of 10%, the total sample size would be 31 patients. We have decided to extend the sample size to 40 patients (20 patients in each arm), assuming small variations on the baseline TUG scores and standard deviation in the study population.

The sample will be recruited between patients of both sexes with indication for total unilateral knee arthroplasty in the city of Florianópolis and referred by orthopedic physicians. The collection will take place in the period between July 2017 and April 2018. Participants will be divided into two groups of equal size: intervention group (GI) who will receive preoperative oral guidance and a leaflet with information related to their physical condition as well as signs and symptoms in the postoperative period (APPENDIX A); Control group (GC) who will receive only verbal guidance in the preoperative period.

The evaluations will occur in three moments (preoperative, 6 weeks and 6 months after the arthroplasty). On the day of the first collection, the participants will be allocated to each
group according to the draw made by a team member who will not participate in the evaluations. This same member will deliver the package leaflet to the GI participants. Evaluators will be blinded to individuals participating in IG and GC. All participants will receive information about the objectives and procedures of the study through the Informed Consent Form (APPENDIX B) prior to the collection.

3.2.1 Inclusion and exclusion criteria

The following criteria will be used:

Inclusion:
- Age above 55 years;
- Literate;
- Elective submission of total unilateral knee arthroplasty (TKA) due to osteoarthrosis;
- Que não tenham realizado substituição unicompartmental anterior ou osteotomia de tibia no mesmo joelho;
- Who have not had knee infection or other serious complications after TKA;
- Body mass index less than 40 kg / m2;
- That he has not performed other arthroplasties on the lower limb in the last 6 months;
- Movement arc greater than 90º in the operated or contralateral knee.

Exclusion
- Associated condition that impedes performance in gait tests, including significant osteoarthrosis in the contralateral knee or hips (defined as pain greater than or equal to 5 in VAS);
- Absence or abandonment in the study follow-up sessions.

Blinding

The nature of the study will allow blinding of the patients regarding study arms. Participants will be blinded to the primary and secondary outcomes being measured. Baseline patient assessment, as well as outcomes assessment at 6 weeks and 6 months will be performed by one investigator blinded for experimental or active comparator arms. Statistical analysis will be performed blinded for experimental or active comparator arms.
Patient assessment

Patients will be assessed at baseline (pre-operatively), in 6 weeks after surgery and 6 months after surgery.

Baseline assessment
Participant characterization will consist of:

a) Demographics (gender, date of birth);
b) Educational level (years);
c) Diagnosis
d) Affected side
e) Date of surgery
f) Gait analysis
g) Timed Up and Go test
h) Knee Osteoarthritis Score - WOMAC
i) EMG muscle activity
j) Kinesiophobia
l) Postural control

3.3 OPERATIONAL AND CONCEPTUAL DESCRIPTION OF THE VARIABLES

3.3.1 Simple support and double support time

Simple support is characterized by contact with the ground with only one foot. When the two feet are in contact with the ground, the double support is characterized. (VILLARDI et al, 2005). Variables will be expressed in seconds.

3.3.2 Stride and step length

Step is the range of gait between the initial contact of one foot and the initial contact of the other foot. Past is based on the actions of a member, it lasts the interval between two
sequential contacts of the same member in the ground (PERRY, 2005). Both will be expressed in centimeters.

3.3.3 Adductor moment in gait

The external adductor moment is the biomechanical measurement for medial load of the knee, the larger the external adductor moment the greater the load in the medial compartment of the knee. Thus, this shows a large incidence in OA, being a better predictor of OA progression. The frontal evaluation of the knee can elucidate the effect of the prosthesis on the response of the medial load in the knee and eventual compensations in the contralateral knee that can contribute to the progression of OA. (ALNAHDI et al, 2011). The variable will be expressed in N/m.

3.3.4 Knee flexion angle in gait

The knee flexion joint angle is measured between the longitudinal axis of the thigh and the longitudinal axis of the leg, knowing that in the anatomical reference position all articular angles are equal to zero (HALL, 2013). The knee flexion in the load response will be measured using the Vicon MX system. The variable will be expressed in degrees.

3.3.5 Electromyographic activity

The electromyographic signal is expressed in root mean square (RMS), obtained through the mean and median frequency of the signal and temporal analysis of the signal. The RMS indicates the chronological activation of the motor units and the amplitude of the muscular activation before the applied exercise (GONÇALVES e SILVA, 2007).

The variable will be expressed as a percentage by normalizing the maximum voluntary contraction. It will be evaluated by the Telemyo DTS electromyograph (Noraxon™).

3.3.6 Self-reported functionality by WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)
The WOMAC questionnaire has 24 items distributed in the dimensions pain, stiffness and function with scores from 0 to 100, being 0 = none, 25 = few, 50 = moderate, 75 = intense and 100 = very intense. The higher the final score, the greater the functional impairment of the individual (GIESINGER et al, 2015). In this study the validated version for the Portuguese language will be used (Fernandes et al, 2003).

3.3.7 Kinesiophobia

Excessive, irrational and debilitating fear of movement and physical activity that results in feelings of vulnerability to pain or fear of injury recurrence is classified as kinesiophobia and can be assessed by the Tampa Scale of Kinesiophobia (SIQUEIRA et al, 2007). This variable is dimensionless and will be evaluated by the TAMPA scale.

3.3.8. Functional mobility by TUG *(Timed Up And Go)*

The TUG assesses the functional capacity of individuals by means of temporal analysis to perform lifting, walking, turning and sitting (PODSIADLO e RICHARDS, 1991). It is a temporal variable that will be measured in seconds.

3.3.9 Center of gravity oscillation speed

Center of gravity is the point at which the torques produced by the weights of the body segments are equal to zero, this measure oscillates in the direction of the largest mass of a moving body (HALL, 2013). This variable is measured in seconds and will be evaluated through the VSR Equilibrium Platform.

3.3.10 Displacement and velocity of pressure center

Pressure center (COP) is the point and application of ground reaction force in response to forces generated by a body in contact with the surface. The COP indicates the trajectory displacement of the soil reaction force vector (HAMILL e KNUTZEN, 2012). The parameters
of the COP will be obtained from the displacement and velocity of the center of gravity by routine elaborated in MATLAB. The displacement of the COP will be expressed in centimeters and the speed of oscillation in centimeters per second.

3.4 INSTRUMENTS

3.4.1 *Vicon MX System*

The Vicon MX system is a passive system that measures reflected light through markers placed on the surface of the human body. This integrated system is indicated for the analysis and measurement of human movement, among them the clinical evaluation of gait (VICON MX, 2006).

For the acquisition of the kinematics data of the gait will be used the system Vicon Bonita 10 MX Giganet (Oxford Metrics Group; UK) Consisting of 10 beautiful cameras with LED emitting component (Light Emitting Diode) that surrounds the lens of each camera, maximum frequency of 250 frames per second (fps), 720p and 4-12mm lenses, 11 cables for Connect the beautiful cameras to giganet unit.

All cameras are connected to the Giganet unit, which feeds the cameras and serves as an instrument for synchronization and integration with other biomechanical laboratory instruments (force platform and electromyography). Once in the video memory, the data is transferred to the computer named Nexus® that will perform the processing and reconstruction of the three-dimensional image of the markers by means of a biomechanical model and mathematical algorithms.

3.4.2 *AMTI OR6-7 Force Platform*

For the study, two AMTI OR6-7 Force Platforms will be used, placed side by side in the center of the course where the individual will gait. Each power platform consists of two rigid surfaces (top and bottom) interconnected by load cell force sensors. This type of platform is a device that has its electrical resistance varied as a function of the mechanical deformation of the same (BARELA e DUARTE, 2011).

The AMTI OR6-7 Force Platform uses four precision-mounted tension gauges to measure forces at any given moment. The measurement of the orthogonal force occurs along
the X, Y, Z axes and the momentum on these axes, producing a total of six outputs. It has vertical capacity to evaluate 4500, 8900 or 17800 Newtons (AMTI, 2010).

Data sampling will occur at 100Hz. The extended signal will be synchronized with the Vicon gait analysis system.

3.4.3 Noraxon Electromyograph

The electromyographic activation of the lower limb muscles will be measured using the Noraxon MyoMuscle v. 3.8. The standard system has EMG preamplifiers, but can be synchronized with other biomechanical sensors. In addition it can operate with up to 16 channels in wireless system, making it easier to capture the signal during the movement. The double electrodes are self-adhesive and attached to the sensor, which is attached to the skin with double-sided tape. The data collected by the electrode is transmitted immediately to the receiver (NORAXON, 2015). The electromyographic data collection will be synchronized to the gait collection performed with the Vicon MX System.

3.4.4 Timed up and Go Test (TUG)

The TUG was developed to evaluate the functional mobility of the elderly. The classification of the elderly is performed according to the time required to complete the task as follows: up to 10 seconds is the time considered normal for healthy, independent adults without risk of falls; Between 11-20 seconds is expected for frail or disabled elderly, with partial independence and with low risk of falls; Above 20 seconds indicates significant deficit of physical mobility and risk of falls (PODSIADLO e RICHARDS, 1991).

This instrument shows excellent intra-observer and inter-observer reliability (ICC = 0.99). The concurrent validity was evaluated by comparing it with the Berb Balance Scale (r = -0.81), walking speed (Pearson r = -0.61) and the Barthel Index (r = -0.51), presenting a Moderate to good correlation between the tests. (PODSIADLO e RICHARDS, 1991). High TUG times were significant in predicting the occurrence of falls and decline in ADLs, identifying individuals with impaired functional capacity (LIN e WOLLACOTT, 2005).
3.4.5 Neurocom Balance Platform

The data will be collected using the SMART EquiTest CRS platform and the NeuroCom Balance Manager software (NeuroCom International, Inc., Clakamas, OR), which is a computerized tool for assessing and managing balance and mobility disorders.

The SMART EquiTest CRS platform consists of dual force platform, visual environment, upper bar with support for the patient harness, LCD monitor for the participant and a computer for system operation.

NeuroCom Balance Manager software measures postural control based on oscillation speed, recorded in degrees / second. The calculation used to determine the oscillation speed in the SET protocol is not publicly available. According to the interpretation suggested by NeuroCom, higher score represents a potential deficit in the balance (NEUROCON, 2010).

3.4.6 Womac Scale (Western Ontario and McMaster Universities Osteoarthritis Index)

The Womac score (ANNEX A) for osteoarthrosis is a valid and reliable instrument, specific for knee OA. Evaluates pain, stiffness and physical functions. This questionnaire consists of three domains - pain, stiffness and function - and must be answered in relation to the intensity of pain, joint stiffness and level of functionality perceived by the individual in the last 72 hours. The questions are presented in Likert scale, where each one has a score ranging from 0 to 100, thus distributed: 0 = none; 25 = few; 50 = moderate; 75 = intense; 100 = very intense. The final score will be obtained by summing the values of all the subjects in each question, the average is obtained, and the values are presented for each section or domain (IVANOVITH, 2002).

3.4.7 Tampa Scale of Kinesiophobia

Kinesiophobia is defined as excessive, irrational and debilitating fear of movement and physical activity, with consequent feeling of vulnerability to pain or fear of relapse of the problem. The cover scale for kinesiophobia (APPENDIX B) will be used to quantify fear of movement. The validated Brazilian version of the scale will be used (SIQUEIRA et al, 2007). Each instruction is scored on a 4-point Likert scale with scores ranging from 1 "totally disagree"
to 4 "strongly agree". It presents as possible results the maximum score of 68 points and the minimum score of 17 points. The higher the score, the higher the kinesiophobia.

3.5 DATA COLLECTION

The study will be developed in the dependencies of the Laboratory of Biomechanics of the Center for Health Sciences and Sports of UDESC. In the preoperative period the subjects will be informed about their physical conditions as well as signs and symptoms of the postoperative period. One group (GI) will receive this information verbally and one leaflet while the other group (GC) will receive only verbal information. The allocation in these groups will be through a lottery, carried out by a member of the team who will not participate in the evaluation stages.

This staff member will read the booklet individually for each GI participant, in a reserved room, before handing out the leaflet to take home. GI participants will be encouraged to reread the information in the home environment and will be asked about the completion of this in the following steps by the staff member responsible for the blinding.

All participants included in the study will perform the kinematic, kinetic and electromyographic gait analysis as well as evaluation of fear of movement, functional mobility and self-perceived functionality in the pre (baseline)-and postoperative period (6 weeks and after 6 months).

The total duration of each evaluation will be approximately 2 (two) hours and 30 (thirty) minutes and all collections will be carried out by the same team. The participant will be allowed to stop the test if they feel pain or become fatigued. The procedures for collecting the data will be performed in 5 steps, described below.

3.5.1 Stage 1 - Anthropometric measurements

Body mass and stature will be measured by means of a mechanical scale of up to 150 kg Filizola® brand, with a resolution of 0.1 kg, and by means of a portable Wiso stadiometer, with a resolution of 0.1 cm. The diameters and lengths required for insertion into the anthropometric model of kinematic analysis will be measured by a pachymeter and a tape measure, both with resolution of 0.1 cm.
3.5.2 Stage 2 – Self-referenced functionality and kinesiophobia

The Brazilian version of the kinesiophobia cover scale and the WOMAC scale will be applied before each gait evaluation in the three periods (pre, post 6 weeks and post 6 months).

3.5.3 Stage 3 – gait analysis

The subjects will be previously instructed to wear swimsuits in order to allow the placement of the markers in the anatomical points and the reading of the same ones by the cameras. All patients will be procedurally oriented and instructed on the tasks to be performed.

Before each collection, the calibration of the Vicon system will be performed. A T-shaped metal structure composed of two rods (containing a total of 5 14 mm reflective markers) will be used to determine the reference coordinates of the laboratory (X, Y and Z). The dynamic calibration will be performed, where the rod will be moved in all planes, generating location and orientation data of the cameras inside one. In static calibration the stem will be placed in the center of the collection area. Standard deviation errors less than 1 mm between known distances between markers.

Afterwards, thirty-two reflective spherical markers (14 mm in diameter) with double faces in specific anatomical points will be fixed in the subject, which will serve as reference for the motion analysis capture system. The markers will be placed in the manubrium, xiphoid process, seventh cervical vertebra, tenth thoracic vertebra, and bilaterally in the following points: acromion, anterior superior iliac spine, posterior superior iliac spine, major femoral tuberosity, lateral thigh region, condyle Lateral femoral, medial femoral condyle, fibular head, anterior tibial tuberosity, lateral malleolus, medial malleolus, first metatarsal head, fifth metatarsal head, and calcaneus.

Also, the electrodes and WiFi sensors of the Noraxon Electromyograph will be glued with double-sided tape on clean skin with cotton soaked in alcohol. The electrodes will be positioned on the long head of the femoral biceps, rectus femoris, vastus lateralis and vastus medialis following the position recommended by the SENIAM (2016).

You will be asked to walk on a 5-meter walkway, performing four trials. During the course of the gait, the participant must step on each of the lower limbs on one of the AMTI force platforms without being aware of this. After the collection, the data will be transported to the Visual 3D System, for measurement and analysis.
3.5.4 Stage 4 – functional mobility assessment

Functional mobility will be evaluated by the timed up and go protocol. A seat with a back and without lateral support, a cone and a stopwatch will be used.

In this protocol the subject will rise from a chair with the backrest resting on the backrest, will walk three meters in a straight line, make a 180 ° turn, return to the chair and sit propping the backrest on the chair. This course will be timed in seconds and the performance of the subject will be graded according to the time spent. The protocol allows you to check the total time spent on the task. The subject will perform 3 attempts. The average number of attempts will be.

3.5.5 Stage 5 – postural control

The NeuroCom SMART EquiTest CRS balancing platform will be used, with a sampling rate of 100 Hz. The equipment will be calibrated according to the manufacturer's standards. The collections will be made with three dynamic protocols pre-established by the system: Sensory Organization Test (SOT), which verifies the sensory motor control; Motor Control Test (MCT), which verifies the automatic motor control; And Adaptation Test (ADT), which verifies adaptive motor control.

All protocols will be performed in the bipodal position, where the individual will position their feet together, parallel, hands along the body and face facing forward. The tests performed will evaluate the posture control of the participant in static posture with open and closed eyes, without and with movement of the support surface and / or visual environment. The order of the three protocols (SOT, MCT and ADP) will be chosen by lot.

During collection the individual should stand at the base of the platform looking forward. He will wear harness (available in small, medium and large size) connected to safety cables throughout the test. During the test only the presence of the evaluator and one other member of the collection team will be allowed to assist the assessor in case of loss of balance. Both should be close to the individual, but should not interfere with the test.

You will be prompted to look at the screen in front of you and center the puppet (corresponding to the alignment of the participant). Before starting the tests the individual will be informed that the platform and the environment can move during the evaluation, but will not be informed about when this will occur. Afterwards, the researcher will start collecting the data,
guiding the participant to keep the doll as centralized as possible without flexing the knees or changing the position of the feet. In cases where the participant uses these or other artifacts to maintain postural control (eg, hold in the environment), the test will be considered a "failure" and the test will continue for the next test.

Figura 1 – Data collection procedure diagram

Inclusion criteria: age over 55 years; Literate; Elective submission of total unilateral knee arthroplasty (TKA) due to osteoarthritis; Who have not performed anterior unicompartamental replacement or tibial osteotomy in the same knee; Who have not had a knee infection or other serious complications after TKA; Body mass index less than 40 kg / m²; Who has not had other arthroplasties in the lower limb in the last 6 months; Bow of movement greater than 90° in the operated or contralateral knee. (n = )

Excluded (n =): associated condition that impedes gait tests performance, lack or abandonment in the study follow-up sessions.

Inclusion

Randomized (n= )

After the draw, they were allocated to the intervention group (n= )

Loss of follow-up (give reasons) (n =)
Discontinued intervention(give reasons) (n= )

Analysis

After the draw, they were allocated to the control group (n= )

Loss of follow-up (give reasons) (n =)
Discontinued intervention(give reasons) (n= )

Excluded from analysis (give reasons) (n= )

Follow-up

Allocation

Analyzed (n =)
Excluded from analysis (give reasons) (n= )

Allokation

After the draw, they were allocated to the intervention group (n= )

Inclusion

Excluded (n =): associated condition that impedes gait tests performance, lack or abandonment in the study follow-up sessions.

Follow-up

Allocation

Analyzed (n =)
Excluded from analysis (give reasons) (n= )

Inclusion
The data collected in the preoperative period will be used as a comparative baseline to determine changes in gait parameters (spatio-temporal, kinetic, electromyographic), postural control and functionality associated with the presence or absence of information in the preoperative.

Self-perceived functionality, fear of movement and TUG time will be exported to spreadsheet in EXCEL software for further statistical analysis.

The gait analysis data will be analyzed in the Vicon-Nexus software, version 2.1.1, through a processing routine that will include filtering and application of the algorithms. In this analysis, frontal (adduction / abduction of the knee) and sagittal (knee flexion / extension) planes will be considered. In addition, the following space-time parameters will be recorded during the run: (1) step length in centimeters; (2) stride length in centimeters; (3) symmetry of the foot; (4) step and step time in seconds; (5) single and double support time in seconds and (6) the knee adductor moment in response to the load.

The coefficient of variation (CV = standard deviation of pitch duration / average pitch duration x 100%) will be calculated to indicate the individual variability in pitch duration.

The raw electromyographic signals will be processed to obtain the linear envelope following the steps of full wave rectification, filter smoothing with 4th order Butterworth and cutoff frequency of 5Hz. The amplitudes of the linear envelopes will be normalized by the maximum voluntary contraction in each muscle (YANG e WINTER, 1984).

The total time to perform the functional mobility task (TUG) will be set in excel for further analysis.

In the evaluation of postural control, the velocity of oscillation of the center of gravity (in degrees per second) in the six conditions, bipodal support, unipodal support and tandem, both on stable and unstable surfaces will be evaluated. The center of gravity velocity data will be processed in a Matlab routine, where the displacement data (cm) and velocity (ms) of the pressure center (COP) will be extracted in the anteroposterior and mediolateral directions.

3.8 MAIN SCIENTIFIC CONTRIBUTIONS OF THE PROPOSAL

It is hoped that, once the hypothesis of the benefit of preoperative guidance in the form of a leaflet on the level of kinesiophobia and functionality of individuals submitted to knee arthroplasty is confirmed, health professionals can use this resource in order to promote Better results for these individuals.
In addition, in the case of a null hypothesis, the cross-evaluation of the data collected at the different moments of the study and between the participants may lead to the formulation of new guidance and / or approaches that may benefit such variables in this public (level of kinesiophobia and functionality).

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APPENDICES

APPENDIX A - Guidance for Patients with Total Knee Arthroplasty

The knee is a joint composed of three bones: femur, tibia and patella. Between the femur and the tibia there is a kind of cushion, the cartilage. In a healthy knee, these structures also distribute body weight and allow the movements needed to walk.

Aging can result in wear and tear on this joint, it is osteoarthritis. When the knee becomes very sore and does not move more, it is necessary to change the joint to relieve pain and return the movements to perform daily activities (sitting, walking, climbing and descending stairs). This exchange is done by surgery, called ARTHROPLASTY.

In knee arthroplasty, the bones (tibia and femur) are replaced with very resistant metal. The patella is replaced by a kind of sturdy plastic.

This surgery is performed by a specialized and well trained team and requires special care in the postoperative period. Adequate observation and care also prolong the use of the prosthesis as much as possible. Thus, this guide will present some clarifications in order to enable a faster and better recovery for you as well as better use of surgery.

BEFORE SURGERY

If you have crutches or walkers, do not forget to take them. Will be useful after surgery.

Also remember to take your preoperative exams, including x-rays. The surgery time varies with each case and will be informed by the doctor, but may suffer increases for various reasons without the need for concern of family members.

DURING THE SURGERY

The best anesthesia for you will be chosen by your anesthesiologist.

The surgery cut is done in front of the knee, after removing the damaged bone part and placing the prosthesis. At the end of surgery may be placed drain and dressing that remain for 48 hours.
AFTER SURGERY

Once the anesthetic effect has passed, you will go to the hospital bed and the pain will be controlled with medication.

The physiotherapy team will guide you on how to move in bed and when to start walking.

On the day of discharge we hope that you can already sit, walk with the help of crutches or walker and leave the hospital sitting in the passenger seat with the stretched operated leg.

POSTOPERATIVE GUIDANCE

In the postoperative the objective is to improve the strength, to minimize swelling and to obtain total movement of the operated leg.

DOUBLE AND STRETCH the leg throughout the day. Please follow correctly the recommendations and exercises passed by the team (doctors, nurses and physiotherapists).

- In the first 12 hours after surgery you CAN NOT support the operated limb on the floor, so when sitting on the bed they should be loose.
- You may have PAIN after surgery, even so let the team know.
- BLEEDING and HEMATOMA may occur after surgery, but do not worry, they slowly disappear.
- AVOID lying on the operated leg NÃO COLOQUE TRAVESSEIRO embaixo do joelho operado. Tente deixar-lo esticado quando estiver deitado.
- When standing, divide the weight of the operated leg with the crutches and the other leg.
- PLACE ICE on the knee with the leg elevated. Do this at least 3 TIMES a day.
- REMOVE THE CARPETS from the house. LOOK WHERE IT PISA! USE shoes with non-slip sole.
- You CAN HAVE SLEEP AND Stiffness in the knee, especially when folding your knee a lot, for example when sitting and getting up from a low chair or car seat.
- ATTENTION IN THE BATH in the first few days. TAKE INTO THE SEATING POSITION for added safety.
- In the first month, AVOID POSITION SITTING FOR MORE THAN 45 MINUTES. Alternate sitting with walking.
• When sitting, it is important to bend the knee and remember not to leave the limb hard to walk. This will make it easier to move and give you more comfort.
• Kneeling is not harmful but may cause noise due to the material of the prosthesis.
• To UP STAIRS use FIRST NON-OPERATED MEMBER after limb operated and lastly the crutch.
• To lower LADDERS, place FIRST BALL, then MEMBER OPERATED and last member not last operated.
• SPORTS ACTIVITIES only after TOTAL KNEE RECOVERY.
• The intercourse is safe between 4 and 6 weeks, but its beginning depends on care as well as other daily activities.
• To drive you should no longer be taking medication for pain and need to have the release of your doctor.
• Over the weeks the possible distance of walking gradually increases as well as the improvement of the other symptoms. The total benefits of joint replacement usually occur between 6 and 8 months postoperatively.
APPENDIX C - Personal data and follow-up of participants

MASTER IN PHYSIOTHERAPY
Preoperative guidance and repercussion in gait after knee arthroplasty

Name: ___________________________ Sex: ( )F ( ) M
Date of birth / age: _________________ Telefone: ( ) ____________
Address: ____________________________________________
Date of surgery: ________ Weight: ________ Height: ________
Anterior surgeries in the operated or contralateral knee: ____________________________

Physiotherapeutic Treatment

PREOPERATIVE - Allocation ( ) GI ( ) GC
Do you do physiotherapy for your knee pain? If yes, how many times in the week? ____
What treatment time (weeks, months, years)? ________________________________
Check the type of procedures you perform in the sessions:
( ) warmth ( ) cold ( ) TENS ( ) US ( ) stretches ( ) strengthening exercises ( ) balancing
exercises ( ) Others, which ones? _______________________________________

6 WEEKS AFTER SURGERY - Booklet reading ( ) Yes ( ) No ( ) GC
Are you doing physiotherapy? If yes, how many times in the week? ________________
How long after the surgery did you start the sessions? ____________________________
If completed, how many sessions and for how long? ____________________________
Check the type of procedures you perform in the sessions:
( ) warmth ( ) cold ( ) TENS ( ) US ( ) stretches ( ) strengthening exercises ( ) balancing
exercises ( ) Others, which ones? _______________________________________

6 MONTHS AFTER SURGERY - Booklet reading ( ) Yes ( ) No ( ) GC
Are you doing physiotherapy? If yes, how many times in the week? ________________
How long after the surgery did you start the sessions? ____________________________
If completed, how many sessions and for how long? ____________________________
Check the type of procedures you perform in the sessions:
( ) warmth ( ) cold ( ) TENS ( ) US ( ) stretches ( ) strengthening exercises ( ) balancing
exercises ( ) Others, which ones? _______________________________________

ATTACHMENTS

ATTACHMENT A – WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)

### WOMAC INDEX

**SECTION A**

**INSTRUCTIONS:**

Answer each question with an “X” in the appropriate box, based on fatigue or the amount of pain you experienced in your muscles. For each situation, enter the amount of pain experienced during the last 48 hours.

**QUESTION:** How much pain do you have?

<table>
<thead>
<tr>
<th>Question</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Walking on a flat surface.</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
</tr>
<tr>
<td>2. Going up or down stairs.</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
</tr>
<tr>
<td>3. At night while in bed.</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
</tr>
<tr>
<td>4. Sitting or lying.</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
</tr>
<tr>
<td>5. Standing upright.</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
</tr>
</tbody>
</table>

**SECTION B**

**INSTRUCTIONS:**

Answer each question with an “X” in the appropriate box, based on the amount of muscle pain you experienced during the last 48 hours.

1. How severe is your pain after first awakening?

<table>
<thead>
<tr>
<th>Question</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How severe is your pain after first awakening?</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
</tr>
</tbody>
</table>

2. How severe is your pain after sitting, lying or resting later in the day?

<table>
<thead>
<tr>
<th>Question</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. How severe is your pain after sitting, lying or resting later in the day?</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
<td>[]</td>
</tr>
</tbody>
</table>
SECTION C

INSTRUCTIONS:
The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please answer each question with an “X” in the appropriate box to indicate the degree of difficulty you have experienced during the last 48 hours due to pain or fatigue.

QUESTION: What degree of difficulty did you have with...

<table>
<thead>
<tr>
<th>Activity</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Descending stairs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Ascending stairs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Rising from sitting.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Standing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Bending to floor.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Walking on flat surface.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Getting in/out of car.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Going shopping.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Rising from bed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Taking off sock/stocking.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Lying in bed:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Getting on/off toilet.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Light domestic duties.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Here are some things other patients told us about their pain. For each statement, please, provide a score from 1 to 4 in case you agree or disagree with the statement. First, you must think if you agree or disagree and then say you agree/disagree entirely or partially.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Entirely disagree</th>
<th>Partially disagree</th>
<th>Partially agree</th>
<th>Entirely agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I’m afraid of getting hurt if I exercise.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. If I tried to overcome this fear, my pain would increase.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. My body is telling me there is something very wrong happening with me.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. My pain would probably be relieved if I made some exercises.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. People are not taking my medical condition seriously.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. The injury put my body at risk for the rest of my life.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Pain always means that my body is hurt.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Just because something worsens my pain, it doesn’t mean it is dangerous.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. I’m afraid of getting hurt by accident.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. The safest attitude I can take in order to prevent my pain from getting worse is just to be careful to not to make any unnecessary movement.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11. I wouldn’t feel so much pain if something really dangerous was not happening with my body.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12. Although I feel pain, I would be better if I was physically active.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13. Pain warns me when to stop exercising in order to not getting hurt.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14. It is not really safe for a person with problems similar to mine to be physically active.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>15. I cannot do all the things normal people do, because I easily get hurt.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>16. Although something causes me a lot of pain, I don’t think it is really dangerous.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17. Nobody should make exercises when in pain.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

*Table 1 - Tampa Scale for Kinesiophobia - Brazil.*