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**The Examination of the Effects of a Patient Pre-Surgical Education Class on the Expectations of Patients in Total Knee Arthroplasties**

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1. The participants for this study will be obtained from an Orthopaedic Surgeon’s office in New Braunfels, Texas. Participants will range from 55 to 85 years of age and will include a broad range of socioeconomic classes, formal education levels, and cultural backgrounds. Involvement in this study will be strictly voluntary and will be limited to participants undergoing their first primary total joint replacement. Patients who have undergone another total joint replacement such as a shoulder, hip, or knee will be excluded from the study. Those undergoing surgery for a septic knee, a revision knee, or aspectic loosening of their knee will also excluded. Because the age ranges of patients vary, the overall health of participants will vary. However, the participants will be acceptable surgical candidates, they will be able to independently attend the patient education course, and they will be able to function in an independent or semi-independent manner. Those with a diagnosed of dementia, any other cognitive disorder, as well as those whose primary language in not English will excluded from the study.
2. Recruitment of the participants will take place at a single Orthopaedic Surgeon’s clinic. Because the researcher is a partner in the practice, an employee of Texas Hill Country Orthopaedics, P.A. will present the research to potential participants independently of the primary researcher. This process will be implemented to reduce the concern of the participants felling obligated to participate in the research due to the fact that there is a personal relationship that has been established between the primary researcher and participants. Consent forms will be given to and signed by the participants prior to any interview or collection of data as it relates to the current study is obtained. The consent form will detail the purpose of the study to include specific questions where necessary. Each participant will also be notified verbally and it will be stated in the consent form that the primary research is a partner in the orthopaedic practice as well as the primary researcher. The participants will be made aware that the study is attempting to determine the effects of a pre-surgical patient education course on long-term patient expectations of total knee arthroplasty. The consent form and the instrumentation protocols are attached.
3. The underlying purpose of this study is to determine if the use of a pre-surgical patient education course with an additional educational module that addresses recovery during the first 12 months is more effective in modifying participants’ pre-operative expectations than participants receiving the standard pre-operative educational course alone. This research will include one randomized controlled trial to modify pre-operative expectations for participants undergoing a unilateral total knee arthroplasty as measured by the Hospital for Special Surgery Total Knee Replacement Expectation Survery© (TKR Survey).

An established research protocol has been developed and will continue to be implemented in order for all components of this research to be presented uniformly and all data will be obtained through consistent means. The protocol has been developed and agreed upon by the primary researcher, dissertation committee members, as well as the surgeon involved in this study. Once the participant decides to pursue a total knee arthroplasty, the research protocol as outlined in figure 1.1 will be implemented while the participants are in the office with the researcher.

**Participants**

Participants will include an age range from 55 to 85 years of age; they will include a broad range of socioeconomic classes, variations in formal and informal education levels, and differing cultural backgrounds. Participation in this study is strictly voluntary and will be limited to patients undergoing their first primary total joint replacement. Exclusionary criteria for this study will include participants having received another total joint replacement such as a shoulder, hip, or knee. Surgical treatment for participants undergoing a revision due to septic or aspectic loosening of their total knee components will also excluded. Those with a diagnosis of dementia or a history of other cognitive disorders will be disqualified due to their limited cognitive abilities. Individuals who do not retain autonomy for their medical power of attorney will be excluded due to the fact that they have delegated their medical decisions to a third party. In addition, patients must use English as their primary language in order to participate in this study.

Once patients have decided they would like to pursue total knee arthroplasty, an employee of Texas Hill Country Orthopaedics, P.A. will then present the proposed research and each patient will have the opportunity to participate or decline to take part in this current research study. The employee will then explain and inform each participant about the purpose and requirements of the study. Each participant will sign a Participant Consent Form which will then be scanned into their electronic medical records with the paper copy being shredded in accordance with office policy and procedures. The primary researcher will then approach each participant and begin the administration of each testing instrument.

The following research protocol described in Figure 1.1 will be implemented; in addition, the instruments described below will then be administered during participants’ office visit.

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**Figure 1.1 In office research protocol**

**Testing Instruments**

The testing instruments that will be used during this research are two highly used health surveys and one survey that was developed in 2001 to specifically address long-term expectations of total knee arthroplasty recipients. Therefore the three surveys used will be the Western Ontario and McMasters University Osteoarthritis Index 3.1 (WOMAC, 3.1), the Short-Form-36 (SF-36), and the Hospital for Special Surgery Knee Replacement Expectations Survey (HSS-Knee Replacement Expectations Survey).

The WOMAC 3.1 Index can be described as a tri-dimensional, disease-specific, self-administered, health status measurement tool specifically developed for patients with osteoarthritis of hips and knees (Bellamy, 2008). This instrument is comprised of 24 items which probes clinically-important and patient-relevant symptoms within three dimensions: pain, function, and joint stiffness. Numerous studies in the field of orthopaedics have utilized the WOMAC 3.1 Index for the assessment of patients with osteoarthritis. Two major validation studies have been completed to assess the reliability and validity of this instrument (Bellamy, 2008). Reliability was determined by Cronbach’s alpha pre-operatively, 6 weeks, and 6 months post-operatively. The reliability values for the three abovementioned subscales for the Likert Scale (i.e. LK) were as follows: Pain: LK = 0.08, 0.78, 0.93; Stiffness = 0.88, 0.75, 0.88; Physical Function = 0.93, 0.92, 0.97 (Bellamy, 2008). Therefore, the WOMAC 3.1 Index is an instrument that exhibits excellent reliability and validity when assessing pain, function, and joint stiffness in patients with osteoarthritis of the hip and knees.

The second instrument that will be administered is the Medical Outcomes Study Short Form-36 Health Survey (SF-36). This instrument was designed for the use of clinical practice and research, health policy evaluations, and general population surveys (Ware & Sherbourne, 1992, Tellini, Ciccone, Blonna, Rossi, Marmotti, & Castoldi, 2007, McHorney, Ware, & Raczek, 1993, Stansfeld, Roberts, & Foot, 1997). The SF-36 includes 36 questions divided into eight health concept sections: 1) physical functioning: 2) role limitations because of physical health problems; 3) bodily pain; 4) social functioning; 5) general mental health (psychological distress and psychological well-being); 6) role limitations because of emotional problems; 7) vitality (energy/fatigue); 8) general health perceptions (Ware & Sherbourne, 1992). It consists of the eight-scale profile of functional health and well-being, as well as being psychometrically based in the physical and mental health summaries (Tellini, Ciccone, Blonna, Rossi, Marmotti, & Castoldi, 2007). The SF-36 is a widely accepted and used general health instrument that is often used as a point of reference for other tests. It is also widely used in various specialties and subspecialties of medicine as a valid and reliable general-health survey to measure patients’ overall perception of their health (Ware & Sherbourne, 1992, McHorney, Ware, & Raczek, 1993, Stansfeld, Roberts, & Foot, 1997).

The third instrument that will be administered to patients is the Hospital for Special Surgery Total Knee Replacement Expectations Survey© (TKA© Survey). This survey is a patient driven scale comprised of 17 components that address symptoms, activities of daily living, walking distance, employment, and psychological well-being (Mancuso, 2001). It was originally developed by researched at the Hospital for Special Surgery in New York attempting to address pre-operative patient expectations of knee surgery as well as patient expectations of total knee replacements.

**Course and Long-Term Expectation Module Description**

As standard to the surgeon’s clinical practice, each participant will be signed up for the pre-operative education course per their preference of date. Participants will not be randomly assigned to the control or intervention group; instead a randomization table will be established to determine when the additional module is conducted and when it will not be used. The control group used in this study will receive the standard pre-surgical patient education class and the intervention group will receive the standard pre-operative education class in addition to the supplementary information (ie. module) targeting expectations of recovery for the first 12 months after surgery. Once participants in both groups have completed the pre-education course, all participants will once again complete the TKA: Survey©.

**Standard Pre-Surgical Patient Education Course Description**

Each class addresses preparing for surgery, the surgery, recovery, going home, caregiver education, and discharge planning for participants. Information is presented in a didactic format with implementation and usage of models and equipment such as actual models of a total knee implant, walkers, assistive-device aids for dressing, and continuous passive motion (CPM) machines for post-surgical range of motion. The multidisciplinary team involved in the course includes physical and occupational therapists, pre-admission nurse, registered first assistant operating-room nurse, surgical floor nurse, and a pastor. The facilitator of the course is a licensed physical therapist familiar with the surgical and post-surgical therapeutic care for total joint arthroplasty patients. A registered nurse who is a first assistant to the surgeon in the operating room discusses the surgical procedure to include a generic explanation of the prosthesis used and sterile techniques that are in place to reduce the risk and contraction of an infection in the operating room. The admissions nurse, also a registered nurse discusses the preparation of patients prior to their arrival to the hospital for their surgery as well as for their admission on the day of the surgery. The director of the Surgical Floor, who is a registered nurse, discusses patients’ transfer from the recovery room to the surgical unit as well as informing them of keeping the nursing staff aware of pain levels and needs they may have while on the unit. The Surgical Floor is where all of the total joint arthroplasty patients are cared for in the hospital. The facilitator of the class takes the patients through options for possible placement and care after they are discharged from the hospital. In addition, she discusses advanced directives and durable medical equipment that may be needed once the patients are discharged. She informs them that upon discharge from the hospital all of their immediate needs involving equipment will then be ordered. Finally, the pastor discusses the need and completion for advanced directives, living wills, and do not resuscitate documents if patients do not already have these documents completed.

**Long-Term Expectation Module Intervention Description**

In 2009 the addition of the long-term expectation module was collaboratively developed, reviewed by the multidisciplinary team also including orthopaedic surgeons and implemented to address more of the needs of participants’ long term goals. The need for this additional module was recognized by this researcher during interactions with patients post-operatively. Questions frequently arose from patients such as “What can or should I expect at one year after my knee surgery? I thought I would be pain free and back to jogging.”. Even though the treating physician discusses various long-term goals with patients, they are many times caught up in the pre-surgical phases of the surgery or they fail to ask or do not recall the primary goals of the total knee replacement. Often it is noted that patients are experiencing a significant amount of pain and are not so concerned with long-term outcomes, but they are primarily focused on getting the surgery scheduled, done, and getting other aspects of their personal lives in order prior to their surgery. As a result, many times they fail to remember to ask the physician or staff about long-term goals. Therefore this gap was recognized by this researcher and felt that providing additional education to patients regarding long-term expectations would allow for them to have a clearer understanding about goals after their surgery. As seen in Mancuso et al.’s (2008) study the additional long-term expectation module was collaboratively developed, reviewed, and implemented to address symptoms (ie. pain, limping), functioning (ie. walking, exercising, conducting activities of daily living), and psychosocial (ie. psychological well-being, interaction with others). Presentation of the additional module will be seamlessly presented as the final section of the course and will add an additional 15 minutes to the course. The researcher who was the primary creator of the additional long-term expectation module and who is a practicing clinician in the surgeon’s office participating in the research will be the presenter of the long-term expectation module to the intervention group. Qualifications include advanced degree in health and medical related fields, current practicing clinician in the area of orthopaedics, and a PhD Candidate in the area of Adult, Professional, & Community Education.

All participants will be provided the same high quality standard of care and no education or information that is imperative to their care will be with held. The current standard of care is that all patients undergoing a total knee arthroplasty are advised to attend the standard pre-surgical education course. Often times during the course participants ask questions that relate to long-term outcomes or expectations. Facilitators and providers involved in the course fully and completely disclose all information that is required to answer the patient’s questions. This practice will continue; however, the intervention group will have a structured module that addresses long-term expectations.

1. The potential risks to the participants of this study are assumed to be minimal to none. In general there is no risk anticipated under most circumstances, though it is possible that some participants might find it mildly stressful due to the upcoming surgery and anticipation of post-surgical pain and their function. This risk is not anticipated to be so frequent or so substantial as to require an intervention plan. The current high quality standard of care will be continued and nothing that is imperative or crucial to the participants’ surgery will be with held.
2. To minimize the risks for the subjects, participants will be reminded during each interaction that if they require a rest break that they only need to alert the researcher and a break will be taken. They will also be reminded that participation in the study is strictly voluntary and they are free at any time to be removed from the study. Strict compliance with HIPAA Federal Regulations for a physician’s office will continued to be followed as will the confidentiality of the measurement tool results that will be obtained from the participants.

1. The one likely direct benefit of the study will be that the patients will be able to provide information to the researcher regarding what was beneficial from the pre-surgical education course, what information was excluded and what information they felt would have benefitted them, as well as input regarding the overall effectiveness of the pre-surgical education class. An additional benefit for the participation is the contribution they will potentially offer to education of future patients and to health educators through dissemination of results of this study.
2. There will be no monitory compensation nor any other type of compensation offered to the participants of this study.
3. Risks are assessed to be negligible to none, while benefits are assessed to be more likely. Benefits for the participants will be the contribution of their experience as wells as their surgical outcomes to the field of Orthopaedic patient education. The contribution of the information obtained will benefit future patients as well as contribute to the literature on a needed research study.
4. The review process to obtain access to the patient population at the Orthopaedic Surgeon’s office will be presented to the Surgeon/CEO for his approval for access to the patients. These same patients will be attending the pre-surgical patient education course at Christus-Santa Rosa Hospital – New Braunfels and a post-education evaluation will be administered. Therefore IRB approval will be obtained by the IRB committee at Christus-Santa Rosa – New Braunfels. The purpose of the research project will be described to the Committee as will the process for confidentiality and informed consent.
5. This project is to meet and fulfill the dissertation requirements for a Ph.D. degree in Adult, Professional, and Community Education. The doctoral student is the primary researcher: Natasha Ray HSP # 302937 and one faculty member, Steven Furney HSP# 210103.
6. Approval from Christus-Santa Rosa Hospital New Braunfels and Texas Hill Country Orthopaedics, P.A. is attached to this document.
7. Individuals that will have access to the participants as well as to the research data will be restricted to the primary researcher of Natasha Ray, the supervising faculty member, Steve Furney, Ph.D, other dissertation committee members, Robert Reardon, Ph.D, Clarena Larrotta, Ph.D, and Brenda Boucher, PhD. The consent forms will be kept separately from any and all other documents used in this research project. After the data are analyzed the research project will be submitted for publication to a peer-reviewed journal to assist other professionals. Although the stated faculty members will have access to study related data, only the primary researcher will have access to the participants’ medical history. The reason the primary researcher will have access to the participants’ medical history is due to the fact that she is a practicing clinician in the orthopaedic surgeon’s office participating in the research and she is a partner in the practice. However, none of the medical history that is taken and obtained by the primary researcher for the purposes of medical care will be utilized or shared for the purposes of the proposed research.