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Implementing an Integrative Pre and Post-Operative Educational Intervention for Older Adults Undergoing Total Hip and Knee Replacement

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IMPLEMENTING AN INTEGRATIVE PRE AND POST-OPERATIVE EDUCATIONAL INTERVENTION FOR OLDER ADULTS UNDERGOING TOTAL HIP AND KNEE REPLACEMENT

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Abstract

Post-operative pain control for patients undergoing total hip replacement (THR) and total knee replacement (TKR) continues to present a dilemma for providers and patients, decreasing mobility and increasing the risk of adverse outcomes (Kremers, et al., 2013). There is little research on the effect of common symptom self-management strategies implemented postoperatively for THR and TKR patients (Fredericks, Guruge, Souraya, & Wan, 2010). In addition to the lack of research on the use of symptom-self management, few post-operative pain control studies have been conducted with the elderly population (Laforest etal., 2008).

The purpose of this pilot project was to implement postoperative education in a select population of elderly patients undergoing THR or TKR in combination with the pre-operative education which was standard of care at the site. The primary endpoints were to improve self-efficacy over the course of the intervention period and to decrease pain in the population.

The study design was a descriptive report to report pain scores, self-efficacy scores, and related demographics in a sample of elders who elected to participate in the post-operative educational intervention. A randomly selected retrospective group was analyzed for pain scores and demographics for comparison.

The data were analyzed using Statistical Analysis Software (SAS) version 9.3. Pearson's correlations compared pain scores and Pain Self-Efficacy Questionnaire (PSEQ) scores. The results suggested a negative correlation between pain scores and self-efficacy scores; that is, as self-efficacy scores increased, pain scores tended to decrease.

PSEQ scores were compared at multiple points using the paired t-test. A statistically significant difference was seen in scores between pre-procedure and post-procedure scores at both 24 and 48 hours post-discharge. PSEQ scores increased at each time point.

Average pain scores for the inpatient stay were compared between the intervention group and the retrospective comparison group. Pain scores in the intervention group were slightly lower overall, but no statistically significant difference in pain scores was found.

These results suggest that in this group a post-operative educational intervention may increase self-efficacy in older adults undergoing THR or TKR.

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CHAPTER 1

INTRODUCTION

Total hip replacement (THR) and total knee replacement (TKR) are rapidly becoming two of the most common elective inpatient surgeries in the United States (Ghomrawi, Schackman, & Mushlin, 2012). In 2003 the number of THRs and TKRs performed in the United States were 202,500 and 402,100 respectively (Kurtx, Ong, Lau, Mowat, & Halpern, 2007). These numbers are expected to double by the year 2015 according to growth trends, even without factoring in the growing elderly population (Kurtx, et al., 2007). The physical burden of these procedures will grow with the number of replacements, especially as more patients undergoing surgery will be Medicare patients, with rigid reimbursement, length of stay, and readmission policies. The cost of admission and risk of re-admission increases with comorbidities which are more prevalent in the elder population including hypertension and Type 2 Diabetes (Kremers et al., 2013). Though there is evidence that disease self-management of these comorbidities contributes to a reduction in admission rates and length of hospital stay, there is little research on the effect of common symptom self-management strategies implemented postoperatively for THR and TKR patients (Fowler, Kirschner, Van Kuiken, & Baas, 2007).

Background

THR and TKR are often effective elective surgeries for patients whose quality of life has decreased because of pain and functional disability resulting from osteoarthritis (Hoogeboom et al., 2009). Non-surgical interventions are typically attempted initially prior to surgery, including physical therapy, weight loss, and management with pain medication. Surgical candidates are evaluated for several different factors; these include radiological evidence of severe osteoarthritis, pain, functional disability, and depression associated with pain and functional

disability (Lovfendahl, Bizjajeva, Ranstam, & Lidgren, 2010). Currently, there are no national criteria in the United States for THR or TKR, although this is likely to change due to the evolution of national healthcare (Hassan, Schackman, & Mushlin, 2012).

After surgery patients are generally admitted to an inpatient orthopedic unit for three to four days. Medicare will pay for three days for an uncomplicated THR or TKR, after which the patient is discharged directly home with outpatient therapy and home care if needed, or to a skilled nursing facility for up to 30 days (*Medicare benefit policy manual*, 2011). Between 58 and 64% of all patients in the United States undergoing TKR or THR are discharged directly to home after a three day hospital stay where they are expected to manage their own medications and symptoms. While admitted, patients participate in physical therapy and brief postoperative patient education regarding mobility precautions. Postoperative pain is treated acutely with intravenous opioids and oral analgesics including narcotics, non-steroidal anti-inflammatories (NSAIDs), and cyclooxygenase-2 (COX-2) inhibitors (Otten & Dunn, 2011).

Managing Postoperative Pain

While postoperative pain control for THR and TKR has been researched extensively, there is little evidence on how to best manage postoperative pain at home, especially among the elderly. Postoperative pain continues to be an issue for patients and hospitals despite the development of effective analgesics and increases in staff education (Crawford, Armstrong, Boardman, & Coulthard, 2011). Poor pain control negatively affects the institution as well; evidence shows that poor pain control contributes to decreased patient satisfaction, poor mobility, longer lengths of stay, increased readmissions, and increased office visits (Innis, Bikaunieks, Petryshen, Zellermeyer, & Ciccarell, 2004). All of these factors increase the

physical burden for institutions already struggling in a competitive and poorly funded healthcare system.

Institutions have implemented variable strategies to decrease the financial impact of postoperative pain control. This change has been influenced by the adoption of pain control policies by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) 2000 which resulted in the standardization of pain evaluation and management in accredited facilities (Narasimhaswamy, Vedi, Xavier, Tseng, & Shine, 2006). Specifically, JCAHO requires routine pain assessment and documentation; staff education in pain management and competency assessment; adequate pain control to allow functional rehabilitation; and education of patients and families relative to pain and symptom management especially in preparation for discharge (Curtiss, 2001). These standards have resulted in improved pain control in several facilities, yet the emphasis has been placed on staff rather than focused on thorough patient education (Innis et al., 2004).

The lack of standardization of post-operative education for patients undergoing TKR and THR may contribute to decreased satisfaction and functional outcomes (Ben-Morderchai, Herman, Kerzman, & Irony, 2010). Caregivers may feel as though they are not prepared to care for a family member after discharge, and anxiety at the time of discharge may contribute to poor knowledge-retention (Klein-Fedyshin, Burda, Epstein, & Lawrence, 2005). However, multi-modal pre-discharge education has been shown contribute to increased satisfaction and improved outcomes for both surgical and medical inpatients, and structured post-operative education may improve satisfaction scores in total joint replacement patients (Johnson & Stanford, 2004; Ben-Morderchai et al., 2010)

Research has also been conducted on effective modalities of oral analgesia. Philip, Reese, and Burch (2002), performed a meta-analysis of studies evaluating the cost of opioid-based pain control and found that opioid-sparing pain control techniques were associated with slightly better outcomes related to mobility and side effect profile, but opioid-sparing analgesics were found to increase the work of personnel, especially nurses, making the financial impact inconclusive. Further trials have shown that opioid treatments are associated with adverse events such as bowel obstruction, increased time to mobility, and respiratory depression (Odera et al., 2007; Kessler, Shah, Gruschkus, & Raju, 2013). Such negative outcomes ultimately impact costs for the institution, especially for patients who have insurances such as Medicare, who restrict the allotted days for a standard procedure.

While these studies are useful in identifying varying methods of control, but the majority have been conducted with a younger population. The geriatric population, those 65 years and older, is a minority group in research because of differences in drug metabolism, clinician bias, and lack of standardization of pain assessment tools for elders (Robinson, 2007). These factors have contributed to the parody of evidence-based standards for pain control in the elderly.

Population Considerations

Those undergoing THR and TKR patients are typically older, with a median age of 69 in the United States and an increased likelihood of comorbid disease requiring multiple medications. The number of elderly persons has been steadily increasing worldwide, and it is estimated that by 2030, 20% of the population in the United States will be at least 65 years old (Anderson, Goodman, Holtzman, Posner, & Northridge, 2012). Because of the trends in aging, any educational intervention that promotes symptom self-management after THR or TKR must include some particular consideration for the older patient.

While pain experience is subjective and individualized, physiologic changes related to aging may affect the individual's perception of the experience. There is some evidence that older persons may have a higher initial pain threshold, with a lower pain tolerance for a maximum pain level (Hallingbye, Martin, & Viscomi, 2011). Physiologic changes can also contribute to barriers in effective postoperative pain management for the elderly. For example, decreased renal function may increase drug accumulation as well as potential toxicity. Hallingbye, Martin, and Viscomi (2011), also report that older patients are at a higher risk for orthostatic changes in blood pressure, loss of balance, and sedation after administration of opioids.

Physiologic changes in the older adult may also present as barriers to patient education. Older adults may take longer to learn new information than do younger adults (Rigdon, 2011), and they may benefit more from organizational learning strategies. Because of these factors the older adult may benefit more from longer learning sessions with methods such as note taking with a planned review later in the day (Rigdon). Elders also tend to experience a functional decline in vision and hearing so adjustments must be made to accommodate these needs when planning educational strategies (Rigdon).

In addition to the physiologic changes that may affect both the elderly person's experience of pain and his or her learning patterns, personal beliefs in this age group may also contribute to decreased pain management. Elderly patients may be more likely to be passive when in pain, waiting for the nurse to give them pain medication rather than asking, or allowing family members to make the decision for them; they may also fear addiction to narcotics (Hofland, 1992). There is also evidence that elders may be resigned to pain, believing that it is a normal part of aging (Ruzicka, 1998).

THR and TKR are elective surgeries that can improve quality of life by increasing functional ability in debilitated individuals. However, postoperative pain control is an issue for these surgeries that potentially impacts functional outcomes, patient satisfaction, and may increase costs for the institution and ultimately society. Research in postoperative pain control has focused primarily on different analgesic therapies, rather than interventions involving patient participation in their own pain control. The majority of patients undergoing THR and TKR are elderly, but little research on postoperative self pain-management has been done with this population. Postoperative education for TKRs and THRs should be geared toward the elderly, involve the patient, and direct caregivers to improve self-management and pain control.

CHAPTER 2

LITERATURE REVIEW

Search Methods

In order to determine the state of the science relative to patient education and symptom self- management for patients undergoing THR and TKR, an extensive literature search was conducted which encompassed three primary subjects: pre-operative education studies in THR and TKR patients, postoperative education studies, and self-management interventions for pain. The search for relevant studies was conducted through multiple databases, including PUBMED, CINAHL, PROQUEST, and COCHRANE. The key terms and phrases used were preoperative education for joint replacement patients; postoperative education for joint replacement patients; discharge education; postoperative patient education; discharge education for orthopedic patients; education for joint replacement patients; pain self-management; symptom self-management interventions; and combinations of those keywords and phrases. Studies from 1998 through 2013 were evaluated.

Preoperative studies were included in this review if they were a) in English, b) conducted with THR or TKR patients, c) included pain control and/or patient satisfaction/expectations as a measurable outcome, d) used a preoperative education intervention, and e) were experimental trials with an experiment and a control group. Because of the lack of available research on the effects of postoperative education in the THR/TKR population, four other studies which focus on postoperative patient education are included for their contribution in evaluating how postoperative education has worked in other patient populations (Ben-Morderchai et al., 2011; Fredericks, et al. 2010). Self-management interventions for pain control from other disciplines

were also reviewed, including chronic musculoskeletal pain, especially interventions tailored to the elderly. Using these criteria, 16 studies in total were included in this review.

Preoperative Studies

The preoperative studies in this review each used a different educational approach for patients. Sjöling, Nordahl, Olofsson, and Asplund (2003) had success with a randomized, experimental, single-center design that implemented a preoperative private educational session with a nurse for the intervention group. This session provided information encouraging the active involvement of the patient in his or her own pain control. The preoperative session also reviewed the benefits of well controlled postoperative pain and the benefits of performing well in physical therapy. Both the intervention and the control group were oriented to the visual analog scale (VAS) for pain. Pain scores as measured by the VAS scale did not differ significantly between groups; median pain scores on a scale of 1 to 10 on day 3 were 3 and 2.3 for the control and treatment groups, respectively. The treatment group had significantly fewer VAS scores charted overall, which the authors hypothesize may be because they had less pain. This may have limited the results of the study, as the differences in pain scores were not found to be statistically significant. When comparing patient satisfaction scores, 100% of patients in the treatment group reported they were satisfied with their pain management while 87% reported satisfaction in the control group.

Thomas and Sethares (2008) conducted a quasi-experimental study in which a convenience sample of patients scheduled for a THR or TKR in one hospital elected to receive either standard preoperative education or a multidisciplinary preoperative educational session. In total, 152 patients with a mean age of 68.7 $\pm$ 10.9 were enrolled with 78 in each group. Seventy-eight percent of the group underwent TKR while the remaining 22% received THR. There were

no significant differences in pain scores, measured on the 10 point VAS between the treatment (mean 2.75 ± 1.82) and control subjects (mean 3.5 ± 2.6). Satisfaction was measured only in the treatment group, with a mean score of 40.8 ± 4.7 on a 5 point scale with a maximum score of 45. Limitations of this study include the use of a convenience sample, differences in the educational interventions themselves, and the use of one pain measurement each day.

A randomized, controlled trial conducted by Mancuso, Graziano, Briskie, Peterson, Pellicci, Salvati, and Sculco (2008) evaluated whether preoperative education regarding long term expectations would change perceptions for THR and TKR patients. The investigators used the Hospital for Special Surgery Total Hip Replacement (THR Survey) or the Hospital for Special Surgery Total Knee Replacement (TKR Survey), to evaluate the different procedure groups for pain, mobility, and quality of life expectations in a group of 146 patients scheduled to undergo THR or TKR in a single hospital. Among participants 71 patients between the ages of 60 and 80 were randomly assigned to receive preoperative education modified to include long term recovery goals and 75 received the standard preoperative education. Expectations were evaluated before and after the intervention. The THR group was found to have significantly improved expectations post-intervention while the TKR group did not. This trial may have been limited because it was a single-center study and randomization was by class (THR or TKR) rather than individual.

Kearney, Jennrich, Lyons, Robinson, and Berger (2011) conducted a comparative non-randomized study that evaluated whether standard preoperative education for THRs and TKRs in a regional hospital had any effect on perceived pain and preparedness for surgery, as well as any effect on postoperative complications, pain, and ambulation ability. The study consisted of 150 patients who were asked for consent to participate the second postoperative day. In the sample 71

patients with a mean age of 64.5 elected not to receive preoperative education and 77 with a mean age of 67.25 agreed to participate. Patients then completed a survey and pain management data was collected from the inpatient documentation. Consenting patients were given a self-administered follow-up survey which they returned to the surgeon's office. According to the survey, patients who received the education had significantly better perceived pain control ($p < .002$) than the control group but did not have any significant changes in their documented pain scores. A limitation of this study may have been that the participants were able to choose whether to attend the structured pre-operative educational session, and as a result may have been more motivated to learn at baseline than their counterparts.

One group of investigators conducted a randomized trial with a preoperative pain management program with a group of 40 patients with a mean age of 71 awaiting THR at an orthopedic office. Assessments were performed prior to randomization, three months after the program, and one year after the THR procedure. Measurements included pain, impact of pain as determined with the Arthritis Impact Scale (AIMs), analgesic use, and mobility. Patients in the pain management group reported less pain than those in the control group prior to surgery; patients in the experimental group also had improvement in the AIMs scores and in functionality at the one-year assessment when compared to the control group (Berge, Dolin, Williams, & Harman, 2004). This study did not assess for comorbidities that may have affected overall outcomes.

Daltroy, Morlino, Eaton, Poss, & Liang (1998) conducted a randomized controlled trial with 216 TKR and THR patients using four experimental groups. The mean age of the group was 64 with 53% undergoing a TKR and 47% undergoing a THR. The first group watched a slideshow with information about the surgery and postoperative care and was taught relaxation

techniques (n = 52), the second only watched the slideshow (n = 58), the third only received relaxation training (n = 58), and the fourth did not receive any preoperative education (n = 54). Patients were evaluated for pre and postoperative anxiety and pain using the institutional numerical pain scale. There was no significant effect in any groups on pain reduction according to institutional documentation. However, patients in education groups with preoperative anxiety had a reduction in postoperative anxiety when compared to the group that did not receive preoperative education. This study may have been limited as it was conducted at a single site, and patients who had had a prior total hip or knee replacement were excluded.

The preoperative studies reviewed found that while preoperative education may have an impact on postoperative pain experience, the most consistent area of impact was patient satisfaction. The majority of the patients in these studies were between the ages of 64 and 70, indicating that a preoperative educational intervention may be beneficial in the elder population undergoing TKR and THR.

Pain Self-Management Interventions

Pain self-management interventions found in this literature search focused on populations in long term or primary care rather than acute care settings. Currently the majority of interventions found in the literature focus on chronic pain rather than acute postoperative pain, therefore, the evidence for postoperative interventions is limited. Cognitive-behavioral strategies were combined with patient education to help patients learn how to cope with pain in these studies. The research studies included in this analysis were conducted primarily with chronic pain patients including arthritis and cancer patients. In total, six studies are reviewed in this section.

Two studies evaluated interventions for elderly persons with chronic, non-specific joint pain. Ersek, Turner, McCurry, Gibbons, & Kraybill (2003) conducted a randomized controlled trial directed at self-management of chronic pain with residents living in long term care facilities. Voluntary participants were randomly assigned to an Educational Booklet (EB) group receiving an educational handout, or a self-management group (SMG). The SMG cohort participated in seven 90 minute group sessions held at the participating facilities by doctorally trained health professionals, including nurses and social workers. Participants received education on definitions of pain, communicating with providers about pain, and methods of pain control. Members of the SMG group were encouraged to set realistic goals, including mobilization and pain goals, to be achieved by the end of the sessions. The authors found that the SMG cohort had significant improvement in pain intensity and physical function, with 43% improvement as opposed to 13% in the EB group as measured on the Visual Analog Scale (VAS). Limitations of this study include a small sample size (n=45) and a homogenous sample consisting primarily of well-educated Caucasian women.

Another self-management study on community-dwelling elders over the age of 65 with chronic pain was conducted by Nicholas, et. al, 2013, in which psychologists led the intervention group in eight two hour sessions on self-management strategies for four weeks. Forty-nine patients were included in the pain self-management group, 53 were in the Exercise-Attention control group, and 39 were in the waiting list group. Pain self-management education included instruction on functional exercises, relaxation techniques, and goal setting, along with homework for the next session. The pain self-management group was found to have significantly less pain at the end of the treatment when compared to the other two groups. One interesting limitation

pointed out by the researchers was that participants who withdrew from the study had higher-self reported baseline levels of depression, which is correlated with chronic pain.

Two trials reviewed self-management strategies for older persons with arthritis. One study evaluated the efficacy of a telephone self-management program for elders over the age of 60 with osteoarthritis (Blixen, Bramstedt, Hammel, & Tilley, 2004). Thirty-two participants were recruited from area rheumatology clinics and randomly assigned to an experimental or control group. The experimental group received weekly osteoarthritis management modules in the mail, a relaxation audiotape, and weekly nurse-delivered follow-up phone calls. Pain and function were evaluated using the Arthritis Impact Scale (AIMs) evaluated at the end of the six-week intervention. The intervention group reported a slight decrease in pain and increase in functional status, but no significant difference in self-management behaviors including medication use and exercise when compared with the control group. The authors hypothesized that the difference between groups may have been more related to the follow up phone call rather than to the modules themselves. This sample size was relatively small (n=32) and the groups were predominately Caucasian and well-educated; these results may not translate well to a more diverse population.

A second self-management study conducted with elders with arthritis used an intervention called "I'm Taking Charge of My Arthritis," using one hour individual home visits by a health care professional educating participants on subjects including exercises, attitude, and dealing with health care providers (Laforest, Nour, Gignac, Parisien, & Poirier, 2008). One-hundred and thirteen participants with a mean age of 77.7 years were randomized to the educational intervention or control group. Functionality and stiffness were measured using the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) and pain was

measured using the VAS. The authors found decreases of 3% in pain and 11% in stiffness in participants in the experimental group, while participants in the control group had an increase of 11% in pain and 70% in stiffness. This study did make use of a large sample size (n=100) and a randomized controlled trial design. The authors pointed out, however, that the study may have been limited because the health care professionals administering the program were highly motivated and this may have positively affected the results.

Lastly, one study utilized a Goal Attainment Scaling (GAS) intervention for patients with chronic back pain (Fisher & Hardie, 2002). In this study using a convenience sample of 149 participants with a mean age of 42.5, the intervention group worked with an interdisciplinary team to identify problem areas, such as mobility, sleep, and other functional issues. The interdisciplinary team developed individualized goals that the participants worked on over a period of two weeks. Participants who met their goals had an increase in functional ability as measured by the Oswestry Low Back Pain Disability Questionnaire (ODQ).

The majority of self-management interventions reviewed were conducted with groups over the age of 65. Each of the studies reviewed found that self-management interventions for chronic pain were effective in contributing to reduction of pain.

Postoperative Studies With Related Populations

While there were no studies located that evaluated postoperative educational interventions to measure pain and satisfaction outcomes for patients with either THRs or TKRs, four studies are included here that were conducted with other populations because they contribute to a framework for a postoperative educational intervention for THR and TKR patients.

Ben-Morderchai et al., 2010, conducted a non-randomized prospective study with 95 patients being discharged from an orthopedic unit at a hospital. These patients included THR, TKR, spinal surgery, and other orthopedic patients. Forty seven patients with a mean age of 56.14 in the experimental group were given structured discharge instructions that included booklets with questions and answers specific to the surgery. The 48 patients with a mean age of 52.89 in the control group were given standard discharge instructions. The patients were interviewed 6 weeks postoperatively with questionnaires including an institutional satisfaction and pain assessment that had been tested for reliability and validity. Patients in the intervention group complained of less pain (48% compared to 70.8%) and reported higher satisfaction ($p < .006$).

The second postoperative education study reviewed was conducted to identify patient needs at 12, 24, and 72 hours after outpatient arthroscopic knee surgery. (Flanagan, 2009). This qualitative study was conducted with a convenience sample of 77 patients with a mean age of 56. The investigators used open-ended questions to interview the patients over the phone and concluded from patient comments that patients needed nursing guidance primarily at the 24 hour mark after surgery. The information gained from this study is valuable to the design of postoperative follow-up phone calls because of its analysis of patient needs. This study is limited by the use of a convenience sample and non-experimental design.

A subsequent study evaluated the effectiveness of a nurse-coached telephone intervention for outpatient knee arthroscopy patients. (Jones, Duffy, & Flanagan, 2011). The patient sample consisted primarily of patients less than 50 years of age, with a mean age of 45.9 in the intervention group and mean age of 47.1 in the control group. Fifty two randomly selected patients were called by a nurse at 24, 48, and 72 hours postoperatively, while 50 received

standard discharge instructions. Symptom distress scores as measured by the Symptom Distress Score questionnaire (SDS) were significantly less after 72 hours in the intervention group ($p < .0001$) when compared to the control group. This study may be limited in its application for older populations because of the relatively young age of the participants.

A meta-analysis was conducted by Fredericks, Guruge, Sidani, and Wan (2010) to evaluate current postoperative educational interventions. There were 11 studies included that focused on symptom experience, self-care knowledge, and self-care behavior as outcomes. The meta-analysis did not include a review of the assessment tools used. In 60.4% of the studies, the patient sample consisted of patients 50 years of age or younger, with the remaining 39.6% comprised of patients 50 years of age or older. A meta-analysis of these showed greater effect size with interventions that used high dose (multiple sessions), individualized plans, and multimedia interventions.

Postoperative research demonstrated success in decreasing pain and increasing satisfaction with the use of both written and verbal education. Increased pain control was improved by the use of multi-media and multiple dose education as well as with postoperative nurse initiated follow up calls.

Summary

In this literature review, the preoperative studies analyzed provide evidence that there is improvement in pain control with the use of a preoperative educational intervention in patients undergoing TKRs and THRs. Those studies compared to standard preoperative education showed improved outcomes with multidisciplinary education, individualized sessions with a nurse, and education focused on forming realistic outcome goals. Interventional groups

compared with control groups that did not receive preoperative education had significantly better pain control than the control group.

Self-management of pain trials were all conducted in a primary care or long-term care setting with patients experiencing chronic pain. Interventions were conducted by interdisciplinary, nursing, and psychologist staff, with positive pain-related outcomes. In addition, the interventions were conducted over a relatively long period of time, with the shortest being two continuous weeks.

Postoperative study results demonstrated success in decreasing pain and increasing satisfaction with the use of both written and verbal education. Increased pain control was improved by the use of multi-media and multiple dose education as well as with postoperative nurse initiated follow up calls.

Common themes among the reviewed interventions were goal-setting, individualized education, multi-disciplinary efforts, and multi-modal methods of delivery. These were the most effective in improving self-efficacy scores as well as pain. Up until recently, research focus on controlling post-operative pain for patients undergoing THRs and TKRs has been on analgesics and staff delivery, rather than on the patient. As the landscape of health care in the United States continues to change, it has become clear that previous methods of care that do not involve the patient are not sustainable outside of the direct oversight of the care professional. In order to make a positive impact on the pain of these patients as they transition to home, health care professionals must begin to implement new educational strategies that empower the patients.

CHAPTER 3

CONCEPTUAL FRAMEWORK

The purpose of this chapter is to detail the conceptual foundation used to guide the development and implementation of this project. As this practice project incorporates both administrative and adult health management elements, two theories were selected that address the different needs of each field.

The project is guided by the PARIHS framework for the administrative dimension. This model was initially developed by Kitson, Harvey, and McCormack and furthered by a team led by Jo Rycroft-Malone, which has diligently refined the framework to reflect the combination of processes involved in creating evidence-based practice change (Rycroft-Malone, 2004). The second model used is that of the Theory of Symptom Self-Management, a recently developed middle-range theory led by Amy Hoffman that conceptualizes the influence of perceived self-efficacy on the combination of factors influencing symptom self-management (Hoffman, 2013). Though the theory was initially developed for use with cancer patients, it is applicable to chronic disease and pain self-management.

The PARIHS Framework

The three overarching elements of the PARIHS framework are *evidence, context, and facilitation* (Rycroft-Malone, 2004). The relationships between these dimensions are integral to the success of the implementation of evidence based interventions to improve symptom management for TKR and THR patients as they transition to home. *Evidence* refers to the research supporting the intervention and change, in combination with the clinical experience of those implementing the change and the patient experience of patients receiving the intervention. In self-management of symptoms after THR or TKR, the evidence is the studies supporting the

interventions, resulting in the patient experience of the change, theoretically leading to improved symptom self-management. The studies reviewed did not focus on clinician experience of the change, making this concept a new area for study for the field of postoperative symptom self-management.

The second element of the PARIHS framework, *context*, is the environment in which the evidence based change will be implemented. For this project, the site of evidence-based change would at first be the nursing unit to which patients would be admitted to postoperatively, and secondly the patient's home environment. The initial setting for change, on the inpatient unit, must be evaluated by involving the affected nursing and support staff and providing ways for them to give feedback on the methods implemented. In the same way, patients and their involved family members and friends should have an understanding of self-management strategies that translates into their home life. Without an environment that is ready and receptive for change, the implementation of new interventions may not work and may lack sustainability (Brown & McCormack, 2005).

Finally, *facilitation* is the enabling of implementing evidence based practice (Rycroft-Malone, 2004). Initiating change without guidance may lead to the change being implemented incorrectly or not at all. When implementing an evidence based intervention on an inpatient unit, the change will initially take extra time and will likely require changes in comfortable routines. The facilitator will assist both the individual and staff as a whole by offering help to improve time management, listening to feedback, and developing strategies to simplify the integration of the new change (Brown & McCormack, 2005). The facilitator should also assist the patient in implementing symptom self-management strategies by being available for questions and problem solving within the context of the patient's own environment.

Within the three primary dimensions of the PARIHS framework are the concepts of culture, leadership, and evaluation. These three components are intertwined and will also contribute to the success or failure of an evidence based change (Squires et al., 2012). A culture that is receptive toward change will be more likely to be willing to implement new strategies than a culture that is not. Health care professions, especially nurses and physicians, have historically continued to build upon foundations of tradition, rather than looking at all the evidence available and remodeling their care and standards (Amalberti, Auroy, Berwick, & Barach, 2005). Because of this even a relatively small change in practice must take place in an environment that will facilitate and promote, rather than undermine the change.

The change culture is influenced by the formal (managers, charge nurses, clinical coordinators), and informal (staff nurses, support staff) leaders that work on the unit. These leaders may be motivated to promote change by evaluation feedback of the benefits of change, leading back to the initial concept of evidence. Ongoing evaluation with evidence of positive change continues to promote the change culture. With the implementation of a new postoperative educational intervention, success will be measured by changes in pain scores, satisfaction scores, and patient self-efficacy. The outcomes will determine whether the intervention is effective, and will also be a factor when the intervention is evaluated by further stakeholders.

The Theory of Symptom Self-Management

The Theory of Symptom Self -Management (TSSM) was selected to complement the PARIHS theory by providing a framework for effective self-management strategies for patients. The TSSM integrates several different concepts and their interactions. The basis for evaluation is *perceived self-efficacy for symptoms management* (PSE) – how the patient perceives his or her abilities to manage his or her own symptoms. This state of being is motivated primarily by four

sources of information that comprise *self-efficacy enhancing interventions*: direct mastery experience or performing of an activity; vicarious experience, which is observing another individual in a similar situation performing the activity; verbal persuasion, in which the patient believes in his or her capabilities because another individual has influenced this belief; and awareness of individual strengths and weakness in achieving a goal (Hoffman, 2013).

PSE directly influences *symptom-self management,* the ability of the patient to manage his or her own symptoms. This is influenced by the *symptoms* themselves and their characteristics, including duration and intensity. The symptoms and symptom self-management influence *performance outcomes* which are the functional and cognitive result of symptom self-management. Each of these are affected by *patient characteristics,* including the patient environment and the physiological and psychological state of the patient (Hoffman, 2013).

The TSS is a flexible theory that is applicable to symptom-self management in a variety of disease contexts. It provides structural guidelines while still allowing for the individual application of the theory. Work with this theory has been in the field of oncology up until this point, and researchers have found success in its implementation in non-small cell lung cancer patients to reduce cancer related fatigue symptoms post thoracotomy (Hoffman et al., 2013).

In the context of postoperative symptom self-management for older patients undergoing THR or TKR, the TSSM will be applied specifically for this population. The population characteristics may include barriers specific to the elderly population, such as sensory loss and changes in learning patterns. The postoperative symptoms include not only pain, but fatigue, loss of mobility, and symptoms related to medication side effects, including constipation, drowsiness, and nausea. In order to reduce the symptom and side effect burden, patients must be empowered to participate in their pain control through individualized education and care. The performance

outcomes for THR and TKR patients will be pain control and self-efficacy as evaluated by the Visual Analog Scale (VAS), the Arthritis Self-Efficacy Scale (ASES), and the institutional satisfaction questionnaire.

Summary

Use of self-efficacy strategies such as those outlined in Hoffman's theory have been linked to clinical improvement in persons with arthritis and other chronic diseases (Marks, Allegrante, & Lorig, 2005). The TSSM will guide the use of symptom-self management interventions for patients who have undergone TKR or THR with a flexible framework that encompasses the patient, influencing factors, self-efficacy strategies, and outcomes. The PARIHS framework will provide a basis for the implementation of evidence based change, laying the foundation for initial implementation, facilitation and feedback, and finally evaluation.

CHAPTER 4

METHODS

The purpose of this chapter is to describe the methodology and approach used to evaluate the effects of a post-operative educational intervention conducted with elderly persons undergoing THR or TKR. Specifically, this section will review the background of the project, setting of the intervention, and the methods used in participant recruitment and education.

Background

THR and TKR have become common elective surgeries in the United States. The goal of these surgeries is to improve quality of life for patients for whom the pain and physical loss of function accompanying osteoarthritis has become debilitating (Hoogeboom et al., 2009). Over the years there have been several advancements in the surgical approaches and in medications used to treat postoperative pain in THRs and TKRs; however, postoperative pain continues to be problematic for this group (Crawford, Armstrong, Boardman, & Coulthard, 2011).

This dilemma is further complicated by the aging population undergoing THR and TKR. These patients have a median age of 69 in the United States. This age group undergoes physiologic changes that affect the metabolizing of analgesics for pain and they are more likely to be taking multiple medications that may interact with the prescribed post-operative analgesics (Hallingbye, Martin, & Viscomi, 2011). Physiologic changes also affect the way in which this population learns and retains information (Rigdon, 2011).

Existing evidence for patient involvement in post-operative pain control has focused on cardiac, abdominal, and general surgery patients, with less research for patients undergoing THR or TKR (Fredericks, Guruge, Sidani, & Wan, 2010). As a result, there is not a clear road map for the implementation of an evidence-based intervention for the target population. Because of this it

is vital that an intervention to improve self-efficacy in post-operative pain control for elders is developed and individualized for the clinical setting, organizational culture, and target patient population.

Clinical Setting

The clinical setting for this project is a 49 bed, non-profit, community hospital with a 20 bed inpatient medical-surgical unit where total joint replacement patients are admitted. The hospital is located in a city with a population of between 7,000 and 8,000, and also serves several nearby towns. The community is economically based in manufacturing and agriculture, with 10.4% of county residents having 16 or more years of education, as opposed to the state average of 14.3% (Education, health, religion, N.D.). The hospital itself is very much part of the community, employing the largest percentage of the population in the area.

The inpatient unit itself has recently been remodeled to promote single-patient rooms with capacity for overflow if necessary. The physical therapy area is located next to the unit to facilitate the movement of joint replacement patients, and patients are placed in the rooms closest to the physical therapy area postoperatively if possible.

As a small, non-profit hospital, resources have been limited in the development of evidence-based interventions for the THR and TKR population group. The unit director cites lack of a clear guideline for post-operative education as an issue both for staff and for patients. Analgesics are ordered "PRN" (*Pro re nata* or as needed), so nursing staff does not administer the medication unless the patient requests it. Because the patients are not educated in how often they can receive the pain medication, they frequently do not request the medication until they are in significant pain, inhibiting their ability to participate in therapy. The director also noted that there have been several incidents in which side effects, especially constipation, have become

detrimental. This includes one incident in which the patient developed a small bowel obstruction postoperatively and had to undergo abdominal surgery with the placement of a colostomy. This, the process for postoperative education is unclear and does not actively involve the patients or the nursing staff. These issues are multifactorial and necessitate both staff and patient education

Project Design

The purpose of this project was to implement postoperative education in a select population of elderly patients undergoing THR or TKR in combination with the pre-operative education which is standard of care at the site. The primary endpoint was to evaluate changes in self-efficacy following the educational intervention in study group. The secondary endpoint was to compare pain scores between the intervention group and a retrospective group of randomly selected patients meeting the same criteria. Finally, this project recorded time spent with each patient to evaluate feasibility for implementation with nursing staff at the clinical site.

Sample Inclusion and Exclusion Criteria

Participants were selected as part of a convenience sample of patients undergoing THR or TKR at the clinical setting.

Inclusion Criteria

1. Participant is 65 years or older.
2. Participant is voluntarily willing to participate in the study and comply with study requirements.
3. Participant is able to speak and read English.
4. Participant is undergoing a THR or TKR and plans to be admitted to the clinical setting.

Exclusion Criteria

1. Participant is younger than 65 years old.
2. Participant has a documented dementia or cognitive disability that would inhibit the patient in the ability to make his or her own decisions.
3. Participant is not willing to participate in the study and comply with requirements.

Recruitment methods and human participant considerations

Potential participants were recruited during a preoperative education session. Interested participants received informed consent at the time of enrollment (see Appendix A). Following the informed consent process, the participants completed the Pain Self Efficacy Questionnaire which was administered to each individually by the investigator.

There were no added clinical risks foreseen with participation in this study. Participants continued to receive current clinical site standard of care for preoperative and postoperative education, with the addition of the educational intervention and the administered self-efficacy questionnaires.

This project was approved by the Human Research Review Committee (HRRC) at Grand Valley State University (GVSU) as seen in Appendix B. The project was presented to the Pennock Hospital Ethics Committee prior to implementation and the committee chose to accept the approval of the GVSU HRRC as sufficient for implementation at the site. After discussion with the Statistical Consulting Center of GVSU, a recommendation was made to add a comparison group to identify a difference in pain control with the intervention. A protocol revision requesting the addition of a retrospective comparison group was submitted to the HRCC of GVSU and was approved as seen in Appendix C.

Informed Consent Process

The investigator reviewed the consents individually with interested participants at the pre-operative education session. Ample time was given to potential participants for questions. A copy of the signed informed consent and the DNP students contact information was provided to the participants. There was no payment or other incentives for participants volunteering to take part in the study. Participants were permitted to withdraw from the study at any time without penalty. This process is outlined in the final approved protocol as seen in Appendix H.

Data Management and Storage

The informed consent forms and completed questionnaires were kept in a locked private filing cabinet accessible only to the investigator in the research offices at a nearby facility where the investigator conducts clinical research. Identifiable patient information was kept in an electronic enrollment log stored on an encrypted flash drive that was locked in the private research office of the investigator. All other data was de-identified using non-specific participant numbers for data evaluation which was conducted with the assistance of the Grand Valley State University Statistical Consulting Center.

Data Collection Instruments

The Pain Self Efficacy Questionnaire (PSEQ) subscale of the Arthritis Self-Efficacy Scale (ASES) was used for evaluation of self-efficacy in the intervention group (Appendix D). The tool was modified with permission to suit the needs of the population as seen in Appendix E. The PSEQ is an eight-item tool that uses a scale of one to ten with one being “very uncertain” and ten being “very certain.” The subscale has an internal consistency reliability of 0.76, and a

test-retest reliability of 0.87 (Brady, 2011). The validity of the PSEQ has been tested with correlations between the PSE and health status measures (Brady, 2011).

The Smith Pain Management Tool (SPMT) is a pain-evaluation tool first developed by a Masters of Nursing student at Grand Valley, Michelle Smith, as part of a graduate thesis project. The tool (Appendix F) uses a large, colorful pain scale that incorporates both the numerical pain scale and pain-management techniques and is used with permission (Appendix G). Suggestions for interventions that are most effective at each pain level are listed within the tool, providing the patient with a guide for his or her current pain level. Following the pain scale is a pain medication schedule for the patient to track his or her medication on as well as a place to list questions for the nurse or DNP student. The tool has been modified with permission to use a font-size of at least 12 for ease of readability and the wording has been modified to be at a fifth grade reading level. The tool is evidence-based and incorporates the standard numerical pain scaled used by Pennock Hospital in pain assessment.

Description of Intervention

The baseline PSEQ was administered to consenting participants at the pre-operative educational session. At this time, the investigator reviewed the SPMT with each participant individually and explained the pain scale. The investigator also provided a brief discussion on the oral and intravenous analgesics typically used by the site including information on side effects. The investigator informed the participants on what to expect on each inpatient day, including when the investigator would provide inpatient education. A medical history was collected from each patient for demographic information.

Special considerations were planned for participants who would likely be unable to fully engage in an education session on the post-operative evening because of anesthesia and/or side

effects related to surgery. Patients and families were informed that if they were unable to participant on the evening of surgery, they would be seen the following day. The plan included notifying the nurse so that reinforcement of the plan for education was consistent. The investigator planned ahead to introduce herself to staff hospital personnel and wear appropriate identification at all times. Participants who underwent a spinal block were seen on the evening of their surgery. At this time the investigator evaluated the participant's pain using the SPMT and reviewed pain self-management interventions with the patient including mobilization and cold therapy. The investigator also educated the patient regarding medication side effects, decreasing medication side effects, techniques to prevent adverse events such as blood clots, and preparing for discharge. The investigator met with the participant's nurse to review the patient's condition with the nurse and encourage the use of goal-setting and regular pain medication therapy. If significant issues presented the investigator discussed the patient's condition with the attending physician.

On the first, second, and third postoperative days, this intervention was repeated with each individual patient. Patients were encouraged to ask questions and if family was present they were welcome to join the discussion and ask questions as well. At the time of discharge the investigator reminded the patient and family that they would receive follow-up phone calls.

After discharge from the hospital, the investigator called the participant to answer any questions and administer the self – efficacy scale over the phone at the 24 and 48-hour mark. The participant's participation was complete at this point.

Data collection, Statistical analysis, and Dissemination

The investigator scheduled time to personally collect and enter data from the PSEQ as well as demographics, including comorbidities, and time since last pain medication. To better

compare the efficacy of the educational intervention, arrangements were made to gather data retrospectively from the medical records of 11 patients who previously underwent TKR or THR. Forms were created to gather data over established time frames and the investigator met with the Statistical Consulting Center at Grand Valley State University to analyze the data. Pain scores and self-efficacy scores collected at each time point were analyzed using the appropriate statistical analysis, including Pearson's correlation and two-way *t-tests*.

The results will be presented in a poster to other students and faculty as part of the graduation requirements in the DNP program. This poster will also be used to present results to stakeholders at Pennock Hospital, including nursing staff, nursing management, and other interested parties. The study and results will be included in the DNP student's dissertation defense presented to the dissertation committee and open to the public as part of the graduation requirements of the DNP program. In the future, the study and results may be presented or published in other venues, such as professional conferences or journals.

Summary

This project evaluated the effect of post-operative education on self-efficacy scores in a convenience sample of eligible older patients undergoing THR or TKR at a small West Michigan hospital. The intervention consisted of one pre-operative session and up to three post-operative sessions, followed by post-operative phone calls at 24 and 48 hours after discharge. A retrospective chart review of pain scores in a randomized group that had not received the intervention was compared to the intervention group, evaluating any difference in pain scores.

Chapter 5

Results

The purpose of this chapter is to describe the results of the educational intervention conducted with hospitalized elders who underwent total hip replacement (THR) or total knee replacement (THR) in a 58 bed regional acute care hospital. The specific aim of this intervention was to increase patient self-efficacy over the course of the hospitalization and 48 hours post discharge. Data was collected from the participants using an investigator-developed demographic form, patient interviews and the electronic medical record of the patient. This project was approved by the Human Research and Review Committee of Grand Valley State University and the ethics committee of the participating community hospital.

Participants

Consistent with the study protocol (Appendix F), patients were introduced to the study during an established pre-surgical education class offered to all patients scheduled for THR or TKR. In total, 12 eligible patients attended pre-surgical classes and all were successfully recruited as participants. Of these twelve, eleven completed the intervention. One participant was dropped from the study due to an unanticipated medical complication that prohibited her from beginning the intervention. Specifically, the eleven participants each completed the PSEQ at pre-procedure, 24 hours after discharge, and 48 hours after discharge time points. No complications were reported by the patients.

A retrospective comparison list of 30 charts of patients who met participation criteria was compiled using the hospital electronic medical record (EMR) from the six month period prior to study initiation. Of these eleven were randomly selected for a chart review of pain scores, type of

surgery and the identification of medical comorbidities. This group was compared to the intervention group in pain scores, age, type of surgery, and medical comorbidities.

Demographics and comorbidities

Participants ranged in age from 65 to 92 and the intervention and control group were generally equal with the preponderance of participants in the 65-75 age range (Intervention Group M = 72.9, Control Group M = 72.8). The groups were equal with respect to gender with eight females and three males in each group. Likewise the number of TKR and THP was relatively equal (Table 1). Hypertension was the most common comorbidity in the intervention (81.8%) and comparison group (72.7%) followed by hyperlipidemia and hypothyroidism.

Table 1

Demographic Characteristics

Variable	**Intervention Group** (N=11)	**Comparison Group** (N=11)
Female	8	8
Age in years		
65-75	8	7
75-85	2	3
85 and up	1	1
Hypertension	8 (72.7%)	9 (81.8%)
Hyperlipidemia	4 (36.4%	6 (54.6%)
Hypothyroidism	3 (27.3%)	4 (36.4%)
Type 2 Diabetes	0	2 (18.2%)
Anxiety	1 (9.1%)	1 (9.1%)
Fibromyalgia	1 (9.1%)	0
Depression	1 (9.1%)	1 (9.1%)
Procedure	Total Knee = 6	Total Knee = 5

Pain score results

Pain scores were collected retrospectively from the electronic medical record of both the intervention group and the comparison group. Using nursing assessment data, pain scores were averaged for each inpatient day and then were compared between groups. Most patients stayed between two and four days, while some patients who had undergone anterior hip replacements were discharged home after only one night in the hospital. The hypothesis was that pain levels would be improved in patients who had received the self-efficacy intervention.

Differences in mean pain scores between the two groups were assessed using SAS (Statistical Analysis Software) version 9.4. Scores were compared using an independent samples t-test. There was no statistically significant difference between the two groups, $p = .43$, 95% CI [1.41, 2.154]. However, pain scores were slightly lower overall in the intervention group. Additional statistics are reported in Table 2.

Table 2

Pain Scores

	Mean	SD	***p***	***t***
Comparison	2.92	1.478	0.434	.8
Intervention	2.41	1.505	0.434	.8

Pain Self-Efficacy Questionnaire

PSEQ scores were collected pre-operatively and at 24 and 48 hours after discharge in the intervention group. Pain scores were also collected at each time point. It was hypothesized that self-efficacy scores would increase at each intervention period while pain scores would decrease.

Pearson correlation coefficient was used to measure the relationship between pain scores and self-efficacy scores at each time period. Table 3 depicts the correlation relationship between pain score and total self-efficacy score at each time period. These results suggest that there is a negative correlation between pain scores and self–efficacy scores; that is, as self-efficacy scores increase, pain scores tended to decrease in this study.

Table 3

Correlations Between Pain scores and PSEQ Scores

	r	*p*	*α*
Pre-procedure	-.746	<0.01	.8238
24 hours post-discharge	-.542	<0.05	.7549
48 hours post-discharge	-.633	<0.05	.8159

Trends in PSEQ scores

PSEQ scores were compared using a paired *t*-test between each evaluative time period as shown in Table 4. There was a statistically significant difference in scores between pre-procedure and 24 hours after discharge, $p<0.01$, $M = 59.73$, 95% CI [5.872, 14.748]. Likewise, a statistically significant difference was found between pre-procedure scores and scores 48 hours after discharge, $p<0.05$, $M = 68$, 95% CI [5.306, 14.083]. This supports the hypothesis that self-efficacy scores would likely improve over the course of the intervention.

Table 4

Changes in Scores at Each Time Period

	M	SD	*p*	*t*
Pre-Procedure (T1) to 24 hours after discharge (T2)	59.73	8.404	<0.01**	-3.27
T1 to 48 hours after discharge (T3)	68.00	7.714	<0.05*	-2.91
T2 to T3	67.00	3.414	0.93	-0.09

Each question in the PSEQ was evaluated individually for changes in scores over time using the paired t-test as depicted in Table 5. As noted in the previous table, scores tended to be higher over the course of time. Out of the eight questions in the scale, five showed a statistically significant difference between time periods when compared individually. These questions were related to self-efficacy in keeping pain from interfering with activity, improving mood, dealing with the frustration of pain, and managing pain as compared to others.

Table 5

Changes in Scores at Each Time Period by Question

How certain are you that you can keep your knee or hip pain from interfering with the things you want to do?	Mean	SD	*p*	*t*
T1 to T2	-1.364	1.912	<.05*	-2.37
T1 to T3	-1.100	1.912	<.01**	-2.91
T2 to T3	0.400	1.429	0.13	.88
How certain are you that you can keep the fatigue caused by your knee or hip surgery from interfering with the things you want to do?				
T1 to T2	-0.818	1.991	0.06	.8
T1 to T3	-1.189	2.89	0.06	-1.36
T2 to T3	-.364	1.69	0.16	-.71

How certain are you that you can keep your knee or hip pain from interfering with your sleep?				
T1 to T2	-0.818	2.751	0.12	-0.99
T1 to T3	-1.273	1.849	<.05*	-2.28
T2 to T3	-0.455	1.516	0.12	-1.00
How certain are you that you can do something to help yourself feel better if you are feeling blue?				
T1 to T2	-0.818	1.888	0.06	-1.44
T1 to T3	-1.273	1.849	<.05*	-2.28
T2 to T3	-0.455	1.036	0.06	-1.46
How certain are you that you can decrease your pain quite a bit?				
T1 to T2	-0.911	2.386	0.07	-1.26
T1 to T3	-0.546	2.018	0.13	-0.90
T2 to T3	0.366	1.027	0.08	-0.9
How certain are you that you can deal with the frustration of your knee or hip pain?				
T1 to T2	-1.636	1.629	<0.01**	-3.33
T1 to T3	-1.273	1.618	<0.01**	-2.61
T2 to T3	0.364	0.674	<0.05*	1.79
How certain are you that you can regulate your activity so as to be active without aggravating your knee or hip pain?				
T1 to T2	-0.909	1.514	<0.05*	-1.99
T1 to T3	-0.727	1.618	0.06	-1.49
T2 to T3	0.182	0.751	0.15	0.80
As compared with other people with knee or hip pain like yours, how certain are you that you can manage pain during your daily activities?				
T1 to T2	-1.000	2.617	0.08	-1.27
T1 to T3	-1.091	2.119	<0.05*	-1.71
T2 to T3	-0.091	1.045	0.26	-0.29

Summary

This project examined the effects of a post-operative educational intervention on pain and self-efficacy scores conducted with eligible elderly hospitalized patients who had undergone THR and TKR. Data was collected from the medical records of the intervention group and a randomly selected comparison group comprised of eleven patients who met criteria for inclusion and underwent THR or TKR but did not participate in the intervention. Both groups had similar demographics, with three men and eight women in each group. Participant age ranged from 65 to 92, with the majority of participants in both groups being under the age of 75.

Pain scores collected over the course of the hospital stay were compared between the two groups using the Pearson correlation coefficient. There was a slight difference in pain scores between the two groups with the intervention group trending slightly lower but not reaching statistical significance.

Self-efficacy scores were compared to pain scores at pre-procedure, 24 hours after discharge, and at 28 hours after discharge. Results suggested a negative correlation between the two groups, with pain scores tending to decrease as self-efficacy scores increased. Self-efficacy scores were then compared between time periods. A statistically significant difference was observed between the pre-procedure scores and 24 hours post-discharge ($p<0.01$) as well as between pre-procedure scores and 48 hours post-discharge ($p<0.05$). Individual questions from the PSEQ were evaluated across time periods.

CHAPTER 6

DISCUSSION

The purpose of this chapter is to provide a discussion relative to success of this project and sustainability of the project within the practice site. Strengths and limitations of the study will also be reviewed. Finally, the role of the DNP will be addressed as it relates to clinical study studies of this nature. Implications for further study and practice will be described.

Clinical site

The PARIHS theory was the guiding theory for this project to support evidence-based change. In this theory, the concepts of evidence, context, and facilitation are integrated as a framework for evidence-based practice implementation (Rycroft-Malone, 2004). In this study, context is the clinical environment and the evidence includes the literature review which supports the implementation of this project and the results of the project itself.

The clinical setting and context for this site is a small community hospital located in a rural county in the Midwest that does not have the population size or resources to dedicate to an orthopedic inpatient unit. Modest changes have been made on the unit to facilitate the recovery of total joint replacement patients, including moving toward single patient rooms and locating the physical therapy area on the same floor as the unit where patients who have undergone total joint replacements are admitted.

The hospital competes with three larger hospitals in the area, and the primary advantage that the hospital has over these is the sense of community that comes with its small-town location. Implementing a patient-oriented practice change such as a post-operative educational intervention for total joint replacement patients aligns well with institutional values and resources.

At the time of project implementation, the nursing staff was encountering multiple challenges, including JCAHO inspections, hourly rounding, and additions to required electronic medical record (EMR) documentation that demanded their attention. It was for this reason that the intervention was conducted by the DNP student researcher; however, the intervention could be adapted for use with general nursing staff. Particular attention was given to the amount of time spent with patients during the intervention as it was thought that this would be useful for subsequent implementation with staff nurses.

Feasibility for Nursing Staff

Educational sessions were timed in order to address feasibility for implementation by the unit nurses. These sessions were ten to twenty minutes long for each inpatient session. The times recorded included position changes, assisting patients to the bathroom, and personal comfort issues such as giving the patients fresh water. The average time period for each inpatient session was approximately fifteen minutes. The length of time spent for follow-up phone calls was between five and ten minutes each, averaging approximately eight minutes each. These phone calls included the administration of the self-efficacy questionnaire, which took up to five minutes of the discussion.

The DNP student conducted all inpatient educational sessions once during the day, however, it is important to note that this would not necessary if a staff nurse were conducting these sessions. In fact, it would possibly be more beneficial to the patient to break up the educational sessions throughout the day, as multi-dose interventions have been found to be most effective in pre-operative education (Fredericks et al., 2010). Additionally, this would provide continuity for the patient and help to develop a rapport between the nurse and patient. This intervention could feasibly be conducted as appropriate with hourly rounds.

The hospital recently implemented hourly rounding, an evidence-based practice in which the nursing staff checks on the patient once an hour to address needs. There is significant evidence that this practice increases patient satisfaction, decreases call light use, and reduces patient falls (McCartney, 2009). At the time of rounding, nurses address patient needs, including pain and positioning. These times are suitable for brief educational sessions of two to three minutes on the issue at hand, such as pain control.

Financial Feasibility

There were minimal costs associated with the intervention as conducted in this study. A reasonable estimation for the institution in purchasing the laminated sheets for this tool would be 60 dollars, with 20 sheets available for the approximate ten inpatient TKR and THR patients seen per week.

Though the cost of the tool itself is low, it is important to recognize that there would potentially be other costs associated with the intervention if it were implemented by the institution with general nursing staff. The first cost would be educational sessions for the nurses. Current literature in implementing evidence-based practice suggests the use of an educational session along with follow-up in the clinical setting (Forsell, et al., 2011). The educational session would need to incorporate goal-setting techniques, a review of non-pharmacologic interventions, prevention of adverse outcomes, and a review of techniques for teaching the older patient. This could be initiated as an online module, a method that has been used by the institution, or as a mandatory educational period. In this area of West Michigan, base pay is approximately 25 dollars an hour for inpatient nursing staff. The institution could choose to reimburse that hour for increased staff buy-in to the educational session. This cost would have to include the use of a nurse educator or the set-up of a module.

The educational intervention itself took approximately fifteen minutes on average in this pilot study. As the intervention is flexible and tailored to individual patient needs, it could be divided up into shorter sessions throughout the day. Still, if the staff nurse has three TKR or THR patients, the intervention could incur additional time spent with each patient. This time could present a barrier to nursing staff buy-in.

Potential Benefits

One of the primary potential benefits of this intervention is that it directly addresses several patient questions on the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS). HCAHPS is a standardized, publicly reported survey developed in part by Centers for Medicare & Medicaid Services (CMS) that is used for comparing consumer evaluation of hospitals (HCAHPS Fact Sheet, 2013). Out of 21 questions in the survey, nine are addressed in part by this intervention alone. Three questions address nursing communication with patients, two address pain control, two address medication education, and two are regarding discharge education. At an institution as small as the community hospital, a change in the HCAHPS score of one patient could make a difference in publicly reported regional hospital rankings.

Another potential benefit of implementing this intervention is that it could be incorporated into the recently implemented hourly rounding program at the institution. Hourly rounding is intended to address pain control, patient comfort needs, and incorporates the use of patient goal setting, all of which are techniques that are used in the self-efficacy intervention (McCartney, 2009). The incorporation of these two interventions together may simplify the process of implementing a new process for staff nurses as well.

An integral part of the PARHIS theoretical framework that would be crucial to analyzing the benefits of this intervention is continued evaluation (Rycroft-Malone, 2004). In order for the intervention to become valuable both to nursing staff and to administration, results could be reported out regularly in the form of HCHAPS scores and pain scores. This would also provide administration with a method to evaluate the efficacy of the intervention over a long term period.

Supporting evidence

The results of this study suggest that there is an increase in patient pain self-efficacy from the pre-operative time point to the post-operative time points at 24 and 48 hours. This supports JCAHO standards regarding education of patients and families on pain and symptom management (Curtiss, 2001).

The intervention as a whole also supports the *triple aim*, a primary focus of the Institute for Healthcare Improvement (IHI) that is intended to improve the efficiency and effectiveness of health care (Berwick, Nolan, & Whittington, 2008). The three aims of this plan are improving the patient care experience, improving population health, and decreasing costs. The post-operative educational intervention conducted in this pilot study improves care by supporting patient involvement in care, may improve population health by reducing the risk of adverse events, and is cost-effective.

Though the intervention may be beneficial to the institution because of alignment with JHACO standards, there was no statistically significant evidence that the intervention decreased pain scores, an important quality measure. However, there was a trend of lower pain scores in the intervention group that might have been statistically significant in a larger sample size. There would also be costs associated with educating nursing staff on the project, and continued evaluation would be necessary as outlined in the PARIHS framework (Rycroft-Malone, 2004).

Strengths

The evidence-based intervention implemented in this pilot project was a strength of the study because of several reasons. The intervention gave participants the opportunity to learn individually on each inpatient day, providing opportunity for daily reinforcement. The educational sessions were unhurried but brief, allowing ample time for questions. On multiple occasions there was opportunity to educate family and caregivers as well as the patient, for which the families expressed appreciation. This method of multi-dose sessions is supported by evidence that suggests that older persons learn more effectively with added practice and slower teaching (Boulton-Lewis, 2010).

Pain control issues were addressed prior to discharge, beginning with the first day of surgery. Specifically, this occurred with two different participants who were experiencing severe nausea and lethargy due to the prescribed narcotics, which were changed to another type of oral analgesia. Another participant had a history of narcotic abuse and was fearful of recurrent addiction following surgery. The investigator discussed this with the physician who agreed to prescribe non-steroidal anti-inflammatory medication for the participant to decrease the potential for abuse. There was also interpersonal collaboration with nursing staff, respiratory therapy, and physical therapy staff.

Limitations

There were limitations of this study that should be noted for interpretation of the results. The study consisted of a small convenience sample from one community hospital. The majority of the subjects in this group were between the ages of 65 and 75, so results may not accurately depict the outcomes of a very old population over 75. Also, this was an early feasibility project designed to determine if recruitment of participants was possible, if the intervention was

acceptable to patients, and finally, to examine if pain scores could be improved with a prescribed intervention. The randomly selected sample collected for retrospective comparison of pain scores did not receive the PSEQ.

Another issue that is important to note is that the pain assessment tool in the electronic medical record had the option of selecting "no signs of pain," which could mean that the patient was sleeping and a true pain score was not collected. These were added to the average pain scores as zero values for no pain. Thus, results may have been quite different had these non-specific pain description not been factored in, or if they had been assigned an average. Due to the time frame for study completion, the data was not re-evaluated in this instance. However, inn future studies such data could be addressed as missing data points, or could be excluded from the study altogether.

Implications for research

There are several lessons learned from this pilot project that are applicable to future research. Future studies could generate stronger evidence with larger sample sizes and a stronger research design using randomization and comparison groups, with attention to diverse populations. The use of such designs improves the likelihood of studying a more diverse population and increase confidence in study results (Mylenyk & Fineout-Overholt, 2013).

Future research should also focus on studying patients over the age of 75. Older patients present further complexity in comorbidities and learning styles. The participants in this study were relatively healthy and had few comorbidities, so they may not be representative of the population at large.

DNP roles

The roles of a DNP must remain flexible to meet the needs of an ever-changing health care system. The DNP roles that were essential for the completion of this project were scholarship, innovation, interprofessional collaboration, and clinical expertise. As a scholar, the DNP must examine the most current literature for application in evidence-based practice. There must also be continuous evaluation of practice implementations to recognize areas for improvement.

The use of interprofessional collaboration engages all the parties involved in a patient's care, including nurses, physicians, therapists, and nurse practitioners. This teamwork helps to overcome barriers to communication and facilitates the care process. Chism (2010) also points out that interprofessional collaboration is more successful when the clinicians are clinically competent and able to trust each other's judgment. Clinical expertise is also necessary to establish trust with patients.

Finally, the DNP as an innovator evaluates practice needs and seeks new ways to meet the needs that are consistent with ongoing clinical site assessment. The innovation must also be flexible and realistic, able to be tailored to the needs of the organization as a whole. An innovator overcomes barriers to care and evidence-based practice.

Conclusion

As demographics in the United States change, THR and TKR are expected to increase significantly in number (Kurtz, Ong, Lau, Mowat, & Halpern, 2007). In the past, little research has been conducted that focuses on post-operative pain control for elderly persons undergoing these procedures. Out of necessity, health care has moved toward the objectives of the triple aim, decreasing costs, improving patient care, and improving patient health. Because of this, interventions must be cost-effective and empower the patient when possible.

The use of pilot projects for the implementation of evidence-based practice is useful for evaluating institutional need and benefits. DNP-prepared nurse practitioners are uniquely equipped to lead this type of institutional change because of their roles as innovator, expert clinician, interprofessional collaborator, and scholars.

APPENDICES

Appendix A

This research protocol has been approved by the Human Research Review Committee at Grand Valley State University. File No. 14-158-H Expiration: April 3, 2015.

Consent to Act as a Participant in an Intervention Study and HIPAA Authorization for Release of Health Information for Study Purposes

Title: Implementing an Integrative Pre and Post-Operative Educational Intervention for Elderly Patients Undergoing Total Hip and Knee Replacement

Project Managers: Ruth Ann Brintnall, PhD, AOCN, CHPN, APRN-BC
Carolyn Fox, RN, BSN, Doctor of Nursing Practice (DNP) student
Kirkhoff College of Nursing

What is the purpose?
Total Knee Replacement and Total Hip Replacement are quickly becoming two of the most common surgeries that people choose to have in the United States. As more people in the United States grow older, these surgeries are becoming more common. Current study results suggest that education before and after surgery that teaches patients how to manage their own pain improves patients' pain after surgery, satisfaction, and their ability to manage their own pain. Still, there is not very much research that focuses on helping people over 65 who have total hip replacement or total knee replacement control their own pain after surgery and when they go home.

This project collects information about how well patients, like you, feel they can manage their own pain (self-efficacy). It will also collect information about your pain and pain control. Being in the project will also provide added education after the surgery in addition to the education that you already receive before surgery at Pennock Hospital.

Why am I being invited to participate and how are participants selected?
You are being asked to take part in the project because you are having a Total Hip Replacement or Total Knee Replacement surgery planned at Pennock Hospital and are 65 years old or older.

Who is doing this study?
Carolyn Fox, a registered nurse who is a Doctor of Nursing Practice (DNP) student at Grand Valley State University, is doing this study as part of her graduation project. She will be the one who sees you in the hospital and will call you when you are at home. Ruth Ann Brintnall, who is a registered nurse and professor at Grand Valley State University, is helping to oversee the project.

What procedures will my participation involve?
If you agree to participate, you will receive a survey today about your pain and activities of daily living. The Doctor of Nursing Practice Student (DNP student) will review a pain scale with you that has suggestions about how to manage your pain depending on how much pain you are having. The DNP student will also review a pain medication diary for you to use in the hospital and while you are at home after your surgery. You will be given copies of both of these the day after your surgery. Your overall treatment will not change in any way if you choose to participate in this project– you will receive this education and surveys in addition to what you would normally receive at Pennock hospital.

After your surgery the DNP student will visit you on the first day after your surgery to go through your joint replacement notebook with you and answer any questions you might have. The DNP student will

also look at your pain medication diary with you and record the pain medicine that you have had from your chart. The DNP student will review the pain scale with you and teach you ways to control your pain that can be used in addition to pain medicine both in the hospital and at home.

Before you go home after your surgery, the DNP student will visit you again to go through your joint replacement notebook with you and answer any questions you or your family may have. The DNP student will again review the pain medication diary and pain scale with you and show you how to use these at home.

After you go home, the DNP student will call you in 24 hours (1 day) and then again in 48 hours (2 days) to answer any questions that you might have about your pain. She will have you answer a short survey over the phone. After this phone call your participation in the study will be complete.

Each visit in the hospital is expected to take about ten to fifteen minutes. The follow-up phone calls are expected to take about five to ten minutes.

There are no added costs to you for participating in this project. There is no added payment to you for participating.

What are the possible risks of my participation?
There are no known risks to you from participating in this project. You will continue to receive the same treatment and follow-up care that you would normally receive at Pennock Hospital along with the additional education from the DNP student.

There is a small chance that the privacy of your information may be lost. You should know that the DNP student will take careful steps to make this less likely. For example, when the DNP student looks at the final data, she will not use your name, medical record number, or any other identifying information in the data sheets that would allow someone to link this information back to you. A specific number will be assigned to your medical record information stored in a secure data log saved on a secure flash drive. Information linking the number to your name and other personal information will be stored in a locked filing cabinet at Grand Valley State University. Only the project managers (Dr. Brintnall and Carolyn Fox) will have access to this document.

What are the possible benefits of my participation to me?
We cannot promise that you will receive any direct benefit as a result of your participation in the project. However, you may have a better understanding and ability to control your own pain after the surgery than you might have if you choose not to participate.

What are the possible benefits of my participation to society?
The knowledge that the DNP student gains from your participation may benefit other people who are undergoing this same type of surgery in the future.

Who will know about my participation?
Any information from your medical record that is placed into the data log will be kept as private as possible. In addition, you will not be identified by name in any publication of the results of the study involving the use of your medical record information.

Is my participation in the project voluntary?
Your participation in this study is completely voluntary. You do not have to participate. You may stop at any time. You should know that you will not be treated any differently if you choose to participate or choose not to participate.

This research protocol has been approved by the Human Research Review Committee at Grand Valley State University. File No. 14-158-H Expiration: April 3, 2015.

How will my privacy be protected?
Your name will not be given to anyone other than those on the project team (Carolyn Fox and Ruthann Brintnall). All the information collected from you or about you will be kept private to the fullest extent allowed by law. In very rare instances especially authorized university or government officials may be given access to the records for purposes of protecting your rights. Your information will be kept for at least six years to follow federal law.

How will the results of this project be reported and how can I learn about the results?
The results of this project will be reported as part of a poster presentation to other students and professors in the Doctor of Nursing Practice program at Grand Valley State University. They will also be included in a final project presentation at Grand Valley State University that the public may come to. In the future, the DNP student may submit the results as part of an article to be published in a journal so that others can learn about this type of project and how it works.

If you wish to learn about the results of this project you may request that information by contacting:
Carolyn Fox, RN, BSN, DNP student
foxca@mailgvsu.edu
(616) 450-6223 (cell)

HIPPAA[1] Authorization To Use and Disclose Individual Health Information for Research Purposes

1. Purpose. As a research participant, I authorize Carolyn Fox, RN, to use and disclose my individual health information for the purpose of conducting the research project entitled *Implementing an Integrative Pre and Post-Operative Educational Intervention for Elderly Patients Undergoing Total Hip and Knee Replacement.*

2. Individual Health Information to be Used or Disclosed. My individual health information that may be used or disclosed to conduct this research includes my medical history, age, gender, medication list, and pain scores.

3. Parties Who May Disclose My Individual Health Information. The researcher may obtain my health information from: Pennock Hospital.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information disclosed by parties listed in item 3 and information disclosed by me during the course of the research may be received and used by Carolyn Fox, RN.

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign the Authorization, I may not be allowed to participate in this study or receive the research related intervention that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to:
Carolyn Fox, RN, BSN, DNP student
5900 Byron Center Ave
Wyoming, MI, 49519

If I withdraw this authorization, the researcher may only use and disclose the protected health information already used for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this study and no longer covered by this authorization. However, the research team and the GVSU Human Research Review Committee (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect your privacy and limit the disclosure of identifying information about you

7A. Also, there are other laws that may require my individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities and public health measures.

This authorization does not have an expiration date. I have read this information and I will receive a copy of this authorization form after it is signed.

AGREEMENT TO PARTICIPATE

By signing this consent form below you are stating the following:

- The details of this research study have been explained to me including what I am being asked to do and the anticipated risks and benefits;
- I have had an opportunity to have my questions answered;
- I am voluntarily agreeing to participate in the research as described on this form;
- I may ask more questions or quit participating at any time without penalty.

_____ (Initial here) I have been given a copy of this document for my records.

Print Name: _____

Sign Name in ink: _____

Date Signed: _____

Printed Name of DNP student: _____

Signed Name of DNP student: _____

Date Signed:_____

Contact Information

If you have any questions about this study you may contact the lead DNP student as follows:
NAME: Carolyn Fox PHONE: (616) 450-6223
E-MAIL: foxca@mail.gvsu.edu

If you have any questions about your rights as a research participant, please contact the **Research Protections Office** at Grand Valley State University, Grand Rapids, MI
Phone: 616-331-3197 e-mail: HRRC@GVSU.EDU

[1] HIPAA is the Health Insurance and Portability and Accountability Act of 1996, a federal law related to privacy of health information.

Appendix B

GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

DATE:	April 3, 2014
TO:	Ruthann Brintnall, PhD
FROM:	Grand Valley State University Human Research Review Committee
STUDY TITLE:	[554964-1] Implementing an Integrative Pre and Post-Operative Educational Intervention for Elderly Patients Undergoing Total Hip and Knee Replacement.
REFERENCE #:	14-158-H
SUBMISSION TYPE:	New Project
ACTION:	APPROVED WITH CONDITIONS
APPROVAL DATE:	April 3, 2014
APPROVAL EXPIRATION:	April 3, 2015
REVIEW TYPE:	Expedited Review

Thank you for your submission of materials for this research study. The Human Research Review Committee has approved your research plan application as compliant with all applicable sections of the federal regulations, Michigan law, GVSU policies and HRRC procedures. All research must be conducted in accordance with this approved submission.

Please insert the following sentence into your information/consent documents as appropriate. All project materials produced for participants or the public must contain this information.

> ***This research protocol has been approved by the Human Research Review Committee at Grand Valley State University. File No. 14-158-H Expiration: April 3, 2015.***

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. *Federal regulations require that each participant receive a copy of the signed consent document.*

The following information is required in order to maintain current approval with the HRRC. Failure to submit within 30 days, unless otherwise noted, constitutes non-compliance with HRRC procedures and may result in a suspension of approval.

A number of points are raised by reviewers pertaining to data security and methodoloical analysis that do not affect approvability and are offered in a sense of collegical support for a successful project. However, the courtesy of a response to the specific questions and requests for additional information is requested.

1. **Informed Consent: Subjects will be signing an informed consent form that explains the participation but does not identify a time commitment during each of the visits. This would**

be beneficial for the subjects. There is no mention on the data security of the consent form which should be provided as this can identify the subject: Please provide.

2. Data collected on the subjects will be stored on an encrypted flash-drive for 3 years. Since you are obtaining HIPAA protected private health information, the data must be kept for a minimum of 6 years after the completion of the study. The consent form including the HIPAA authorization is sufficienett in providing the subjects with information about what personal data will be collected and analyzed.
3. You should obtain IRB approval from the institution where the subjects will be recruited and is safeguarding the medical records of interest. Please indicate whether you plan to do or have already done this.
4. You propose to implement a low risk educational intervention addressing post-operative pain control. The major elements of the intervention are a pain management information tool and a joint replacement education booklet. Subject pain level will be assessed pre-operatively, 24 hours post-discharge from the hospital and 48 hours post-discharge and have requested EXPEDITED review. Based upon the minimal level of risk described in this proposal, this research qualifies for EXPEDITED review category 7.
5. The intended target subjects are patients 65 years old or older who will undergo either a total hip replacement or total knee replacement. It is unclear whether the sample will be limited to unilateral procedures or if those undergoing bilateral replacements will also be included. Please clarify.
6. Sample size of 10 to 20 was chosen for investigator convenience. Patients will be selected as a sample of convenience and, therefore, may not be representative of the target population.
7. As the protocol does not indicate that knee subjects will be considered to be different than hip subjects (one group vs. two groups), you have developed a one group repeated measures design (3 repeated measures). The specified statistical analysis, Friedman's Exact Test (unknown to this reviewer) may imply a Friedman's Two-Way ANOVA. Although the data will be non-parametric data, the design does not meet the criteria for a two-way ANOVA. The appropriate analytical technique would be the Kruskal-Wallis One-Way ANOVA.
8. It is unclear how the Pain Management Plan data will be used. Please comment.
9. The HRRC recommendd that you compare the results of the two pain assessment tools: Smith and Pennock pain scale. The Smith tools appears to have the likelihood of introducing bias into self-assessment with its apparent great differences between face-color categories. Additionally, if one tool is always given before the other. The subject's response to the first tool may influence how that patient responds to the second. Randomization of the order of assessment is suggested.
10. The proposal suggests that you are interested in Self-Management and resulting pain levels, but no discussion of whether a correlation between these two has been included. Do you plan to see if a subject's Self-Management assessment is correlated with the level of pain experienced? If so, you should make an effort to determine how this will be accomplished. If the Stanford scale produces a single value, The HHRRC suggests looking at Spearman's correlation. If this scales questions result in independent answers, exploration of further techniques that would be needed in order to avoid the problems associated with multiple analysis should be pursued.
11. No benefits to the subjects are promised or implied. The purpose of the study seems to mainly be to complete part of the requirements for your education program:
12. NOTE: Using the specified design, you will not be able to determine whether the educational intervention improved pain management.
13. Risk is minimal and there are potential knowledge gains. The HRRC recommends that you change in ANOVAs as noted above. The other comments are for your consideration as they will increase the scientific benefit derived from the project but they do not affect approvability

This approval is based on the HRRC determination that no greater than minimal risk is posed to research participants. This study has received expedited review, 45 CFR 46.110 category 7, based on the Office of Human Research Protections 1998 Guidance on Expedited Review Categories.

Please note the following in order to comply with federal regulations and HRRC policy:

1. Any change to previously approved materials must be approved by this office prior to initiation. Please use the *Change in Approved Protocol* form for this submission. This includes, but is not limited to, changes in key personnel, study location, participant selection process, etc.
   See *HRRC policy 1010, Modifications to approved protocols.*
2. All UNANTICIPATED PROBLEMS and SERIOUS ADVERSE EVENTS to participants or other parties affected by the research must be reported to this office within 7 days of the event occurrence, using the UP/SAE Report form. If the adverse event includes a fatality, hospitalization, or security breach of sensitive information immediately notify the Human Research Review Committee Chair, Dr. Paul J. Reitemeier, 331-3417 **AND** Human Research Protections Administrator, Mr. Jon Jellema, in the Office of the Provost, 331-2400.
   See *HRRC policy 1020, Unanticipated problems and adverse events.*
3. All instances of non-compliance or complaints regarding this study must be reported to this office in a timely manner. There are no specific forms for this report type.
   See *HRRC policy 1030, Research non-compliance.*
4. All required research records must be securely retained in either paper or electronic format for a minimum of 3 years following the closure of the approved study. This includes original or digitized copies of signed consent documents. Research studies subject to the privacy protections under HIPAA are required to maintain selected research records for a period of at least 6 years after the close of the study.
5. **At least 60 days prior to current approval expiration**, please submit a Continuing Review form:
   - Protocols that are active and open for enrollment require both the Primary Investigator and Authorizing Official to electronically sign the Continuing Review submission in IRBNet.
   - Protocols that are active for data analysis or long term follow-up ONLY require the Principal Investigator's signature but do not need to be further authorized.
   - A copy of the informed consent/assent form currently in use in the study must accompany the submission unless the study has been closed to enrollment, and active only for data analysis, for more than 1 year.

If you have any questions, please contact the Research Protections Program, Monday through Thursday, at (616) 331-3197 or rpp@gvsu.edu. The office observes all university holidays, and does not process applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.

Appendix C

GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

DATE:	June 9, 2014
TO:	Ruthann Brintnall, PhD
FROM:	Grand Valley State University Human Research Review Committee
STUDY TITLE:	[554964-3] Implementing an Integrative Pre and Post-Operative Educational Intervention for Elderly Patients Undergoing Total Hip and Knee Replacement.
REFERENCE #:	14-158-H
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVED
EFFECTIVE DATE:	June 9, 2014
REVIEW TYPE:	CHANGE IN PROTOCOL

Thank you for your submission of materials for this research study.

The requested change is to add a retrospective chart review of a new study cohort of 10-20 patients that have undergone total knee or hip replacement and meet current criteria for active study participants who are part of the educational Intervention. The new participants will serve as a reference group in relationship to the effect of pain in the intervention group. The revised protocol reflects the changes requested.

1. **This change will not change the risk level of the study but notification of the planned change should be submitted to the institution from where the charts will be reviewed nonetheless.**
2. **The stated rationale for this requested change is** *"that the single-cohort study would not demonstrate a correlation between the intervention and pain."* **This may not be a correct interpretation of the intent of this change. A historical control group will enable you to determine the potentially causative, not correlational, relationship between the intervention and the pain outcomes. The specified statistical analyses are ones that check for differences, not correlations.**
3. **Subject to the notification and approval of Pennock Hospital (either their own privacy board review or thair acceptance of GVU's privacy board), this requested change is approved and the HRRC applauds you for strengthening your research design and modifying your data analysis plan.**

Your request has been APPROVED. You may implement the changes to your study as described.

Your project retains its original expiration date of April 3, 2015. Please include a brief summary of these approved modifications in your continuing review application, which should be submitted at least 60 days prior to approval expiration.

If you have any questions, please contact the Research Protections Program, Monday through Thursday, at (616) 331-3197 or rpp@gvsu.edu. The office observes all university holidays, and does not process

applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.

Appendix D

Stanford Arthritis Self-Efficacy Scale

For each of the following questions, please circle the number that corresponds to how certain you are that you can do the following tasks regularly at the present time.

1. How certain are you that you can decrease your pain quite a bit?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

2. How certain are you that you can keep your knee or hip pain from interfering with your sleep?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

3. How certain are you that you can keep your knee or hip pain from interfering with the things you want to do?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

4. How certain are you that you can regulate your activity so as to be active without aggravating your knee or hip pain?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

5. How certain are you that you can keep the fatigue caused by your knee or hip pain from interfering with the things you want to do?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

6. How certain are you that you can do something to help yourself feel better if you are feeling blue?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

7. As compared with other people with knee or hip pain like yours, how certain are you that you can manage pain during your daily activities?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

8. How certain are you that you can deal with the frustration of dealing with your knee or hip pain?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

Appendix E

Carolyn Fox <foxca@mail.gvsu.edu>

Hello,

I am a Doctor of Nursing Practice student at Grand Valley State University in Grand Rapids, MI. My graduate dissertation involves self efficacy measurement in joint replacement patients. I would like to use the pain questionnaire section of the Athritis self-efficacy scale, but I would like to adapt it for this study by using the phrase "postoperative pain" and "knee or hip pain" in place of "arthritis or fibromyalgia pain." Would this be permissible? I will reference Stanford in my documents and am happy to share the results with you if you are interested when the study is completed. Thank you for your help!

Carolyn Fox, RN, BSN, DNP student
(616) 450-6223

Self Manage Licensing <self-manage-licensing@stanford.edu> Jan 15
to me

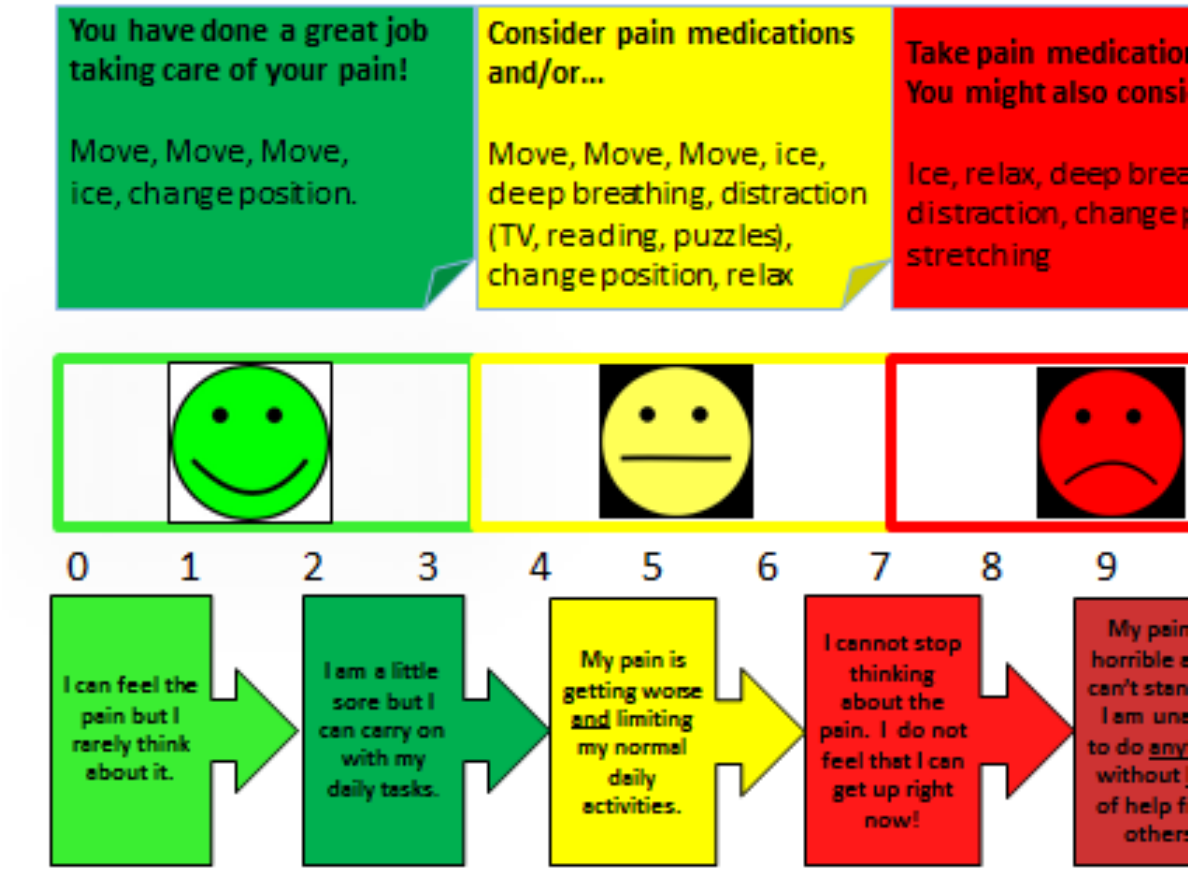
Yes you can certainly do this. These scales for anyone to use as they wish

Stanford Patient Education Research Center
Self-Management Program Licensing
1000 Welch Road, Suite 204
Palo Alto, CA 94304
http://patienteducation.stanford.edu

From: Carolyn Fox [mailto:foxca@mail.gvsu.edu]
Sent: Saturday, January 11, 2014 10:04 AM
To: self-manage-licensing@stanford.edu
Subject: Adaptation of arthritis self-efficacy scale

Appendix F

Smith Pain Management Tool



Thank you for participating in this study. You have been given the Total Joint Surgery Education Guide and we are prepared to review it with you. Please list any questions you may have about your surgery, Total Joint Surgery Education Guide, or your time here at Pennock Hospital.

_____

_____

_____

_____

_____

There is research that suggests that when patients actively participate in their pain management they have less pain when they return home after surgery. We want you to be able to effectively manage your pain by the time you go home. Provided in this packet are a pain scale with suggestions for how to manage your pain at each level both while you are in the hospital and at home. It may also be helpful for you to keep track of your pain medication by writing down what you take for pain and when you take it in the pain management area below.

At Pennock Hospital, you will be asked to rate your pain between 1 and 10 using this scale each time we talk about your pain.

8/1/13

No Pain **Moderate Pain** **Worst Pain**

Mild Pain **Severe Pain**

0 1 2 3 4 5 6 7 8 9 10

0=no pain----------10=worst pain ever

Please use this section to keep track of your pain management plan while you are in the hospital*

Scheduled Pain Medications

Medication	Schedule

As Needed Pain Medications

Medication	Next due

Other things (ice, rest, distraction) which help to relieve my pain

Pain Relief Method	Date and Time Used

Carolyn Fox **<foxca@mail.gvsu.edu>**
to Michelle

Hi Michelle,

I have been reading your protocol more as I continue to write my dissertation and have been really surprised by the ideas we seem to have in common. I started out on an Ortho unit as well, and I have always thought it was a little ridiculous that the patients were not more involved in their own pain management, which is why I chose to do my project on that. I also have enjoyed reading about the idea of empowering the nurses, which I think is an ongoing issue in most hospitals on med-surg units. Ruthann suggested that I look at your intervention and incorporate it into my own, if that would be alright with you. I would likely need to make some changes to the font and colors because my target population is elderly. I think it would be great to use something that you worked so hard on and implement it at another site. Please let me know what you think - I will certainly understand if you prefer that I don't use it, but I think it would work really well in my project, and I would give you due credit of course :)

Michelle Smith **<smithmic@mail.gvsu.edu>** 8/3/13

to me

you have my permission to use it and to change the colors and font as needed. I am happy to help! I was not able to implement this tool at my site as part of my clinical immersion because of cost issues so I would be thrilled if all of my work was useful somewhere:) Please send me a copy of your dissertation after it is complete. I would be very interested to see it!

Appendix H

Implementing an Integrative Pre and Post-Operative Educational Intervention for Older Adults Undergoing Total Hip and Knee Replacement

DNP student: Carolyn Fox

Version Date: 1.11.2014

1. Significance and Purpose

Total hip replacement (THR) and total knee replacement (TKR) are rapidly becoming two of the most common elective inpatient surgeries in the United States [4]. In 2003 the number of THRs and TKRs performed in the United States were 202,500 and 402,100 respectively [6]. The cost of admission and risk of re-admission increases with comorbidities which are more prevalent in the elder population including hypertension and Type 2 Diabetes [5]. Though there is evidence that disease self-management of these comorbidities contributes to a reduction in admission rates and length of hospital stay, there is little research on the effect of common symptom self-management strategies implemented postoperatively for THR and TKR patients [3].

Those undergoing THR and TKR patients are typically older, with a median age of 69 in the United States and an increased likelihood of comorbid disease requiring multiple medications. The number of elderly persons has been steadily increasing worldwide, and it is estimated that by 2030, 20% of the population in the United States will be at least 65 years old [1].

Research in postoperative pain control has focused primarily on different analgesic therapies, rather than interventions involving patient participation in their own pain control. The majority of patients undergoing THR and TKR are elderly, but little research on postoperative self-pain-management has been done with this population.

The purpose of this project is to implement postoperative education in a select population of elderly patients undergoing THR or TKR in combination with the pre-operative education which is standard of care at the site. The goal is to provide study participants with the tools and knowledge to efficiently and safely self-manage their post-operative pain. The primary endpoints are to improve self-efficacy and decrease pain in the population.

2. Project Design, Instruments, and Procedures

A. Design

This feasibility pilot project is designed to integrate pre and post-operative education for self-management of pain control during and post hospitalization among elders (>65) who undergo THR or TKR. This pilot study will determine if recruitment and retention of elderly patients in an acute care setting is possible and examine trends in pain control and self-efficacy using the Smith pain self- management tool and the Pain Self-Efficacy (PSE) subscale. Ten to twenty participants are expected to be enrolled in the study because of time constraints related to the DNP students projected graduation date.

In addition to these active subjects, ten to twenty patient charts will be randomly selected from a sample of fifty charts of patients that meet inclusion and exclusion criteria. The DNP student will gather data from these charts as a comparison group with the intervention group.

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B. Instruments
The modified Pain Self Efficacy (PSE) subscale of the Arthritis Self-Efficacy Scale (ASES) will be used for evaluation of self-efficacy in the population sample. The subscale has an internal consistency reliability of 0.76, and a test-retest reliability of 0.87 (2). The validity of the PSE has been tested with correlations between the PSE and health status measures (2).

The Smith Pain Management Tool developed by Michelle Smith(7) will be distributed to participants. The tool uses a large, colorful pain scale that incorporates both the numerical pain scale and pain-management techniques. Suggestions for interventions that are most effective at each pain level are listed within the tool, providing the patient with a guide for his or her current pain level. Following the pain scale is a pain medication schedule for the patient to track his or her medication on as well as a place to list questions for the nurse or DNP student. The tool has been modified with permission to use a font-size of at least 12 for ease of readability and the wording has been modified to be at a fifth grade reading level. The tool is evidence-based and incorporates the standard numerical pain scaled used by Pennock Hospital in pain assessment (7).

C. Participants and Procedures
Qualifying potential participants will be screened as part of a convenience sample of patients undergoing THR or TKR at Pennock Hospital.

Active participants will be recruited at the pre-operative joint camp educational session. These occur one to two weeks prior to the THR or TKR procedure. The PSE will be administered to consenting participants at this session. The DNP student will review the self-management tool and pain scale with the participants individually and answer any questions they may have. The DNP student will also provide the participants with information on the oral and intravenous analgesics typically used by the site including information on side effects. A limited health history documenting common comorbidities (Type 2 Diabetes, hypertension, osteoarthritis, fibromyalgia, and depression) and a full medication list will be collected from patients at this time. The DNP student will provide the participants with her contact information for questions about the study.

On post-op day one, the DNP student will round on the participant to answer any questions and evaluate the participant's pain using the stoplight pain chart. The DNP student will review self-management interventions with the patient including mobilization and cold therapy. The DNP student will meet with the participant's nurse to review the patient's condition with the nurse and encourage the use of the stoplight pain chart every four hours with the patient to evaluate pain.

On the date of discharge the DNP student will follow up with the patient in the hospital to answer any questions and review mobility exercises, pain medications, and side effects with the patient prior to discharge. The DNP student will call the participant at 24 and 48 hours after discharge from the hospital to answer any questions and administer the self –efficacy scale over the phone to determine self-efficacy scores. At this time the DNP student will also collect a pain score. The participant's participation will be complete at this point.

There are no potential clinical risks foreseen with the participation in this study. Participants will continue to receive current clinical site standards for preoperative and postoperative education,

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with the addition of the experimental intervention and the administered self-efficacy questionnaires.

This research study may involve the potential risks of a breach of confidentiality of the medical record information and associated privacy of the participants. Such risks will be minimized by 1) removing direct participant identifiers during statistical analysis (i.e., names and birth dates); 2) storage of patient enrollment log on the principal DNP student's secure, password protected computer; and 3) limiting access to information to the DNP student and her dissertation chair. Direct patient identifiers will be used only in the participant enrollment log and will be kept on an encrypted flash drive which only the DNP student will have access to. The original informed consent forms will be stored in a locked filing cabinet accessible by the DNP student located in a locked office suite in the Metro Health Hospital research department where the student works as a research coordinator.

The DNP student will also decrease the risk of a breach of health information by collecting only necessary patient-specific data for identification in the enrollment log. This will consist of the full patient name, date of birth, procedure date and type of procedure. Identifying numbers will be assigned to subjects and these will be used for statistical analysis. The DNP student will also decrease the risk of a breach of health information by collecting only necessary patient-specific data for identification in the enrollment log. This will consist of the full patient name, date of birth, procedure date and type of procedure, patient medical history and medication list.

The patient medical history will be collected to assess comorbidities that may affect patient recovery, pain, and medication tolerance. For example, a patient with a medical history of fibromyalgia may have higher pain scores than one who does not. This should be reflected in the data so that it is not skewed. A patient medication list must be collected to identify possible medication interactions and appropriately address patient questions related to medication.

The retrospective chart review will gather the same data for the patient reviewed as that of the active participants, with the exception of Self-Efficacy scores. This includes pain scores for each inpatient day, medical history, concomitant medications, age, and sex.

3. Target Population and Sample Selection

Potential participants will be selected as part of a convenience sample of patients undergoing THR or TKR on the orthopedic unit of a rural general hospital.

Inclusion Criteria

1. Participant is 65 years or older.
2. Participant is voluntarily willing to participate in the study and comply with study requirements.
3. Participant is able to speak and read English: this is because the pain management tool and questionnaire are in English.
4. Participant is undergoing a unilateral THR or TKR and plans to be admitted to Pennock Hospital (Subjects with bilateral THR or TKR are excluded because those subjects have an increased risk of post-operative complications and increased length of hospital stay).

Exclusion Criteria

1. Participant is younger than 65 years old.

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2. Participant has a documented dementia or cognitive disability that would inhibit the patient in the ability to make his or her own decisions.
3. Participant is not willing to participate in the study and comply with requirements.
4. Participant is legally blind and unable to read the tool.

There are no foreseeable direct benefits that can be promised to study participants. There may be an increase in measurable self-efficacy scores and as a result decreased pain levels. There may be benefits to other patients in the future from the information collected in the project.

4. Data Management and Storage

Data collection and storage will be conducted by the DNP student. Measurable data will be stored on an encrypted flash drive. An electronic enrollment log will be stored on the Grand Valley State University N drive. This information will be stored for six years following study completion per OHRP guidelines.

5. Consenting Process

The Doctor of Nursing Practice (DNP) student will review the consents with interested participants at the pre-operative education session. Ample time will be given to potential participants for questions. A copy of the signed informed consent and the DNP students contact information will be provided to the participants. There will be no payment or other incentives for participants volunteering to take part in the study.

The DNP student has undergone CITI training and is also an experienced research coordinator at an area institution.

6. Statistical Methods and Dissemination

The data collected will be analyzed with the assistance of Grand Valley State University's Statistics department. Self-Efficacy scores will be analyzed over repeated time points using the non-parametric Friedman's test. Pain scores will be evaluated between the two groups using Friedman's test or repeated measures two-way ANOVA as the data permits.
The results will be presented in a poster to other students and faculty as part of the graduation requirements in the DNP program. This poster will also be used to present results to stakeholders at Pennock Hospital, including nursing staff, nursing management, and other interested parties. The study and results will be included in the DNP student's dissertation defense presented to the dissertation committee and open to the public as part of the graduation requirements of the DNP program. In the future, the study and results may be presented or published in other venues, such as professional conferences or journals.

7. Data Collection Tools

The DNP student has e-mail documentation of permission from Michelle Smith, MSN, to use and adapt the Smith Pain Management Tool. The tool has been revised to read at a fifth grade reading level and uses a font size of 12 or greater for ease of readability. Stanford patient education permits the use of their questionnaire tools without written permission. The DNP student has e-mail

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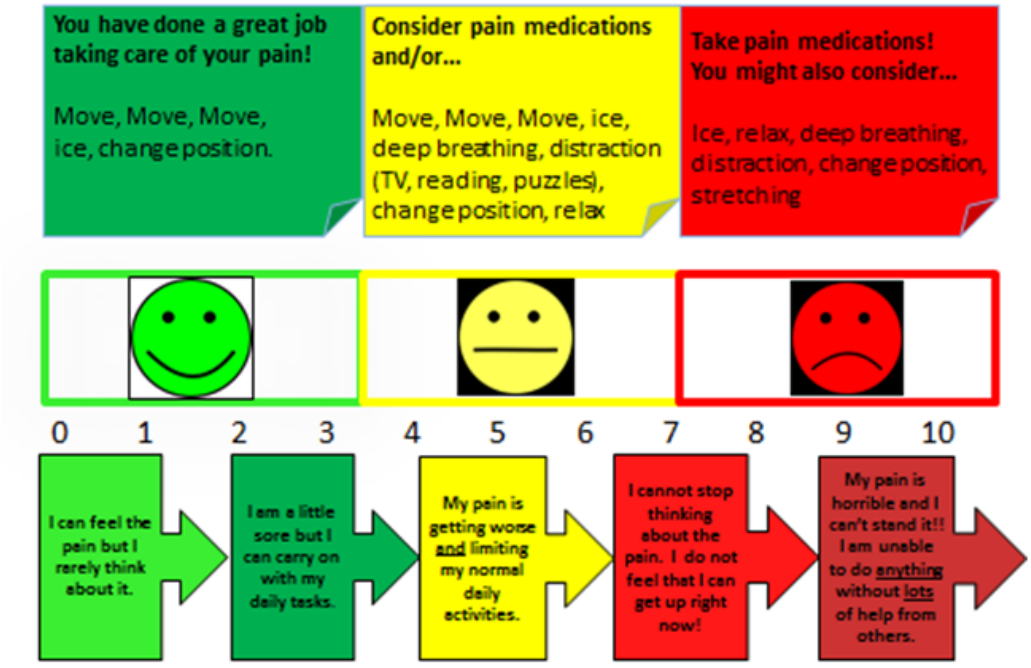
documentation of permission from Stanford patient education to replace the words "arthritis or fibromyalgia pain" with "knee or hip pain."

Smith Pain Management Tool



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