A Randomized Controlled Trial of an Individualized Preoperative Education Intervention for Symptom Management Following Total Knee Arthroplasty

by

Rosemary Ann Wilson

A thesis submitted in conformity with the requirements

for the degree of

Doctor of Philosophy

Graduate Department of Nursing Science

University of Toronto

A Randomized Controlled Trial of an Individualized Preoperative Education Intervention for Symptom Management Following Total Knee Arthroplasty

Rosemary Ann Wilson

Doctor of Philosophy

Graduate Department of Nursing Science

University of Toronto

2011

Abstract

Total knee arthroplasty (TKA) is a common surgical procedure for the treatment of patients with pain and immobility as a result of osteoarthritis or rheumatoid arthritis. Pain-related interference, pain and nausea are recovery-limiting in these patients in the immediate postoperative period. Preoperative educational interventions that include pain communication and management information have been shown to decrease pain in joint replacement patients (McDonald & Molony, 2004).

This randomized controlled trial compared usual preoperative education to an individually delivered preoperative education program. Participants (N=143) were randomized to intervention or usual care groups during routine preadmission testing. The usual care group received the usual preoperative teaching. The treatment group received the usual care teaching, a booklet containing content specific to symptom management after TKA, an individual teaching session during the preadmission testing visit and a telephone follow-up support call during the week before surgery. The primary outcome for this study was pain-related interference with activity and was measured using the Brief Pain Inventory Interference subscale (BPI-I) (Cleeland et al., 1994) on postoperative day three. Secondary outcomes were

pain, nausea and expected postoperative activity and were measured on postoperative days one, two and three.

There were no differences between groups in any of the outcomes for this study. BPI-I total scores were 24.4±14.4 in the intervention group and 22.4±15.1 in the usual care group (P=0.5) on the third postoperative day. Overall results demonstrated that although TKA patients had severe postoperative pain and severe nausea, they received inadequate doses of analgesia and anti-emetics. Available evidenced based protocols and practices in the health care environment were not followed

Individualizing education content was not sufficient to produce a change in postoperative symptoms for these patients. Further research involving the modification of environmental and system factors affecting the provision of symptom management interventions is warranted.

Keywords: Total knee arthroplasty, pain, nausea, preoperative education

Acknowledgements

I would like to thank Dr. Judy Watt-Watson for her unfailing guidance and support during my time in the PhD program at the University of Toronto. Words cannot express my appreciation for all she has done on my behalf. I am also grateful to my committee members, Dr. Ellen Hodnett and Dr. Joan Tranmer for their wisdom and clarity, especially in the final stages of this project. Thank you also to Dr. Andrew Day for his support during the data analysis.

The nurses of the orthopedics unit at Kingston General Hospital and the Pre-Surgical Screening Centre at Hotel Dieu Hospital were a constant support during the design and conduct of this trial. They endured my constant questions and presence in their work environment with good humour and collegiality. I am grateful for their efforts and enthusiasm in the practice of nursing.

To my colleagues in the Department of Anesthesiology and Perioperative Medicine, I could not have completed this program without your support and encouragement. My Pain Service compatriots, Drs. Melanie Jaeger, David Goldstein, Brian Simchison, Mike McMullen, John Murdoch, Rachel Rooney, Tarit Saha, Vidur Shyam and Richard Henry. You have stood behind me all these years, endured my long hours and academic days. To Drs. Joel Parlow and John Cain: I am so grateful to you for all you have done for me and for making me part of the anesthesiology family.

My good friends, Jennifer Perry, Kelly McLean, Tracy Kent-Hillis, the Peters (all of them), Ze, Kathleen, Wilma, Joe, Teresa and Daniel – thanks for being there. Liz VandenKerkhof, my friend, mentor and cheerleader: thank you for your unfailing support and advice and Elizabeth Dogherty my friend and research assistant, thanks for working so hard on

this trial. Thanks to my friends at the Kingston Yacht Club and to Monica Parry for making the weekly train rides to Toronto always amusing.

To my family, I owe you so much. Mom and Dave, where would I have been without the babysitting, the editing, the meals, the list is endless. I am so grateful to you both. My beautiful sons John and Thomas who have never known a time when Mom was not in school, thank you for being yourselves and just being with me. Mary Adam, who in service to her profession, looked after me in Toronto and mothered me when I needed it most. To Andrew, you are truly the best – thanks for keeping me smiling.

I dedicate this thesis to my father, Dr. John Wilson, to my good friend Margaret Page and my mother Beverley Coulson who have all been the inspiration for my practice and my on-going education and to my Grandmother Kitty Peach (Katharine McKinnon) who, as a UT Public Health graduate in 1927, started the family tradition.

Table of Contents

List of Appendices

List of Tables

List of Figures

Chapter One

Background and Problem Statement

Total knee arthroplasty (TKA) is a common, successfully performed joint replacement procedure for pain and immobility associated with knee joint compromise. Arthritis is the most common pre-operative diagnosis (76% osteoarthritis; 15% rheumatoid arthritis) with the majority being female (74%) (Furnes et al., 2002). In 2006-2007, 35,302 primary TKA procedures were performed in Canada. In 2006/2007, 19,247 TKA were performed in Ontario alone, a 159% increase over a ten year period. The age standardized rate for TKA per 100,000 population is 116 for men and 161 for women in Ontario (CIHI, 2009). The purpose of joint replacement for patients with osteoarthritis or rheumatoid arthritis is to reduce pain and knee joint stiffness and thereby increase mobility and function. This procedure has been associated with a significant benefit at 6 months and a year post-TKA in joint range of motion and health related quality of life compared to preoperative states (Heck, Robinson, Partridge, Lubitz, & Freund, 1998; Weale, Halabi, Jones, & White, 2001; Weiss et al., 2002). Most patients (98%) receiving new knee replacements can expect 10 to14 years of new joint function before revision may be required (Jones et al., 2005). Pain is the primary symptom precipitating the need for revision arthroplasty, with those patients reporting pain being 5.7 times more likely to have the procedure (Furnes et al).

The TKA procedure involves the replacement of three articular surfaces including the distal femur, proximal tibia and the posterior surface of the patella, with synthetic material cemented in place (Jones et al., 2005). The procedure requires a midline incision over the anterior aspect of the joint. In Kingston, anesthesia for most patients involves the use of central neuraxial (spinal) blockade using local anesthetic. Postoperative analgesia involves intravenous

patient controlled opioid analgesia with the addition, in some cases, of a temporary or single injection femoral nerve blockade.

Early mobilization is the goal of care following TKA surgery (Laskin & Beksac, 2004). Knee range of motion is a common indicator of postoperative joint function. Reduction of pain on movement in the early recovery period has been associated with increased knee range of motion (Capdevila et al., 1999; Cheville et al., 2001; Eggers, Jenkins & Power, 1999; Singelyn et al., 1998; Wang et al., 2002). Pain that limits rehabilitation after TKA has significant implications for longer-term knee function (Bardsley & Cleary, 1999; Dennis, 2001; Heck et al., 1998; Kurosaka et al., 2002). Pain-related interference with activities has been documented to be moderate to severe in the day prior to hospital discharge (Strassels et al., 2002).

Pain and nausea are common symptoms for patients following this procedure. Moderate to severe pain on movement and at rest has been documented during the first three postoperative days (Brander et al., 2003; Crutchfield, Zimmerman, Nieveen, Barnason, & Pozehl, 1996; Salmon, Hall, Perrbhoy, Shenkin, & Parker, 2001; Strassels, Chen, & Carr, 2002; Wu et al., 2003). Pilot data from the study site show similar findings of moderate to severe pain intensity on post-operative day one (Wilson, Goldstein, VanDenKerkhof, & Rimmer, 2005). Similarly, nausea has been found to be worse on postoperative day one but have the greatest impact on patients on day two (Wu et al.). The prevalence of nausea in pilot data was 87.5% on postoperative day one, decreasing to 25% on postoperative day two (Wilson et al.).

Trials of pharmacologic interventions for pain following TKA have had varied success in the early recovery period. The use of regional analgesia techniques such as femoral nerve block (Ben-David et al., 2004; Chelly et al., 2001; Ganapathy et al., 1999; McNamee et al., 2002; Ng et al., 2001; Singelyn et al., 1998; Wang et al., 2002) and epidural analgesia

(Capdevila et al., 1999; Klasen et al., 1999; Lorenzini et al., 2002; Murdoch et al., 2002; Singelyn et al., 1998) have been found to reduce pain at rest and pain on movement but results are limited to the first 24 to 48 hours. Lower limb motor weakness associated with these techniques limits their usefulness at the study site where weight bearing activities are part of rehabilitation. As a result use of opioid analgesics is usual practice in the early postoperative period.

Opioid analgesia has been associated with higher rates of nausea. Intrathecal opioid administration (usual at the study site) has been reported to have the highest prevalence of nausea. Sites et al (2003) reported 75% of TKA patients who received intrathecal morphine had nausea compared with 30% in the femoral nerve block comparison group. Postoperative use of parenteral or oral opioids has been documented to increase the risk of developing nausea in consensus guidelines for the management of postoperative nausea and vomiting (Gan et al., 2003). Preemptive use of anti-nausea agents has had moderate success in TKA patients (Chen, Frame, & White, 1998; Gan et al., 2003; Lacroix, Lessard, & Trepanier, 1996; Loewen, Marra, & Zed, 2000). Non-pharmacologic options in less rigorously controlled studies (e.g. acupressure bands, aromatherapy) in the peri-operative or post-operative period have also resulted in varying degrees of success in reducing nausea (Anderson & Gross, 2004; Schultz, Andrews, Goran, Mathew, & Sturdevant, 2003). Use of perioperative hydration techniques aimed at blood volume expansion in other surgical groups has been found to reduce nausea (Ali et al., 2003; Yogendran et al., 1995) but this intervention has not been studied for TKA patients.

The interrelationship between pain and nausea and pain and mobility and their prevalence after TKA underlined the need for an intervention that addresses the treatment of these symptoms. Educational interventions for orthopedic patients that are delivered

preoperatively using a variety of standardized delivery methods have been found to reduce pain in the early postoperative period (Dillon-McDonald et al., 2001; McDonald & Molony, 2004; Sjoling et al., 2003). Preoperative education has also been documented to reduce anxiety (Johansson et al., 2005; McDonald et al., 2006; Sjoling et al.) and improve exercise performance (Lin et al., 1997). Systematic reviews of this intervention however report that the impact on pain is equivocal and recommend an education approach that is individualized in terms of content delivery (Johanssen et al., 2005; McDonald et al., 2006; Shuldham, 1999). Individualized patient education for orthopedic surgery patients has not yet been examined but this approach has been successful in improving symptom outcomes in other patient groups (DeWit et al, 2001; Sherwood et al., 2005; Velji, 2006).

The purpose of the present study therefore was to investigate the impact of an individually delivered pre-operative education intervention on pain-related interference, pain and nausea for patients undergoing unilateral total knee arthroplasty. The conceptual framework used for this trial was an adaptation of Wilson and Cleary's (1995) Conceptual Model of Health Outcomes. The framework guided the design and delivery of the intervention and measurement of the trial outcomes. The primary outcome was pain-related interference with activity, consistent with the functional status domain of the model. Secondary outcomes were pain, nausea and analgesic and anti-emetic administration.

Problem statement

TKA is a common surgical procedure in older adults. The outcome of TKA surgery is restoration of knee joint function and the reduction of discomfort in arthritic patients. Early mobilization after the surgical procedure is important to re-establishing joint mobility. As a result, concentration on symptoms affecting mobilization during activity is of the utmost importance. Research findings have indicated that TKA patients continue to have pain and nausea in the immediate post-operative period despite the use of a variety of pharmacologic and non-pharmacologic analgesic and antiemetic interventions. The interconnected nature of pain, nausea and activity requirements after TKA demands a focused and multimodal effort of analgesia and nausea management toward facilitating early mobilization. Although preoperative educational interventions with content related to pain management have reduced pain in orthopedic groups, results have been variable. Individualizing educational content, a strategy that has been successful in other patient groups, has not been tested in orthopedic patients toward improving postoperative symptoms and related interference.

Chapter Two

Review of the Literature and Conceptual Framework

The literature review will first describe the sample demographics and pathophysiology amenable to treatment by the TKA surgical procedure. The surgical procedure and the related symptom experience in terms of interference with activity, pain and nausea will then be presented. The pathophysiology of postoperative pain and nausea will be incorporated into this section as well. The current practice in the management of pain and nausea using physical, pharmacologic and patient education interventions will be outlined. The chapter will conclude with a discussion of the conceptual framework to reduce pain related interference with activity, pain and nausea for patients in the early postoperative period after TKA.

Sample characteristics

The amelioration of joint pain and physical disability that is a result of knee joint arthritis is the most common indication for TKA in older adults (Furnes et al., 2002). In a postal survey of 1277 patients identified as having knee problems in a larger screening survey, Tennant and colleagues found respondents aged 75 years and older had ten times the prevalence of total knee arthroplasty than those aged 55-64 years (Tennant et al., 1995). Women were three times more likely to have had TKA as men. Similarly, Furnes and colleagues found 74% of arthritic patients undergoing TKA overall are female (Furnes et al.). The sex distribution of arthritis of any type is age dependent; the majority of patients younger than 55 years are male and the majority of those over 55 years are female (Crowther & Mourad, 2002). Overall, TKA patients are relatively elderly (Kumar, McPherson, Dorr, Wan, & Baldwin, 1996; Salmon et al., 2001). Furnes et al reported mean age of 70 years in a large sample of TKA patients (n=7174). In 2007, Canadians having TKA surgery were 68 years on average (CIHI, 2009).

In terms of physical functioning related to the need for TKA, Tennant and colleagues report that patients over 55 years who required TKA had significantly lower physical and social function and vitality than those not requiring TKA ($p<0.05$), and 98.3% of respondents requiring TKA had arthritis (Tennant et al., 1995). Although the proportions of osteoarthritis and rheumatoid arthritis in this study were not reported, others have found the distribution to be 76% and 15% respectively (Furnes et al., 2002). Physical function in a study of similar 176 post-surgical patients improved for over half of the sample when compared to preoperative states (Weiss et al., 2002).

Pathophysiology of osteoarthritis and rheumatoid arthritis

Intractable osteoarthritis or rheumatoid arthritis, characterized by pain and joint immobility, is the primary indication for TKA. Osteoarthritis is a non-inflammatory joint disease that causes degeneration and loss of articular cartilage in the synovial joint (Moore, 1985). Osteoarthritis is described as being either secondary or idiopathic/primary. Secondary osteoarthritis occurs as a result of repetitive joint stress over time due to obesity, occupational or recreational activities, trauma related joint instability, or congenital abnormality causing abnormal joint deterioration. Idiopathic osteoarthritis has no known cause but shares the same pathologic characteristics: erosion of the articular cartilage; subchondral sclerosis; and osteophyte formation (Crowther et al., 2002). In both types of osteoarthritis, articular cartilage is lost through enzymatic breakdown of the cartilaginous matrix. Patients with osteoarthritis of the knee joint generally present with pain and stiffness that is worse with load-bearing activity. Pain secondary to degeneration of this joint is thought to be related to muscle spasm, increased subchondral pressure, synovitis, capsular stretch, ligament strain and elevation of the periosteum (Crowther et al.).

In contrast, rheumatoid arthritis is an autoimmune disease that causes chronic inflammation of connective tissues (Crowther et al., 2002). The primary inflammatory site in the knee is the synovial membrane, although inflammation may spread to the joint capsule, ligaments, tendons and articular cartilage. The exact cause of rheumatoid arthritis is not known but it is likely to be the result of a combination of genetic, environmental and hormonal factors on an individual's susceptible immune system. Cartilage damage in rheumatoid arthritis is a result of the degradation of the cartilaginous layers by inflammatory mediators (T cells, cytokines and tumor necrosis factor-alpha). Tissue hypertrophy occurs as a result of leukocyte infiltration which, as a result of circulatory compromise and hypoxia from vessel involvement and increased demands, causes metabolic acidosis in the joint and the release of hydrolytic enzymes (Crowther et al.). These enzymes further degrade the articular cartilage, contributing to joint pain and stiffness as in osteoarthritis.

The initial clinical presentation of rheumatoid arthritis is more generalized than osteoarthritis but local joint pain and stiffness, is the primary purpose for pursuing joint replacement in these patients (Brander et al., 2003; Moran & Horton, 2000; Furnes et al., 2002). The TKA procedure and postoperative recovery is similar for patients with either type of arthritic process as are the beneficial effects of this procedure.

Total knee arthroplasty (TKA)

The perioperative and immediate postoperative periods after TKA are the time period of interest in this trial. As such, attributes of the surgical procedure, contributing to postoperative symptoms and related considerations will be outlined in this section.

Surgical procedure

TKA is a surgical procedure involving the replacement of both the tibial plateau and the distal end of the femur in patients, removing damaged articular surfaces that affect joint

function and cause pain. Also referred to as tricompartmental arthroplasty, TKA may also involve resurfacing of the inside of the patella and may be anterior cruciate ligament sparing (Mont, Lee, Sheldon, Lennon, & Hungerford, 2002). The joint is accessed through a midline, vertical incision either directly over or lateral to the patella (Hoppenfeld & deBoer, 1994; Parentis et al., 1999). Articular surfaces are replaced with nylon polymer and surgical steel prosthetic components and affixed for the most part with bone screws. In some cases, surgical cement that may contain antibiotic is used in addition to hardware. The knee joint is carefully aligned prior to closure of the soft tissue, and moving the new knee through range of motion tests the integrity of the new joint. The average TKA procedure takes between 60 and 90 minutes from the induction of anesthetic to skin closure. Following the completion of the procedure, the degenerative process in the joint capsule is considered arrested (Moore, 1985).

Blood and fluid management during a TKA procedure are the responsibility of the attending anesthesiologist. Blood loss at the surgical site is partially controlled by maintenance of the patient's blood pressure at relatively low levels and with electrocautery and tourniquets as applied by the surgical team. Despite these efforts, intra-operative estimated blood losses have been reported to be 261(89) mL and vary with duration and surgical manipulation during the procedure (Furnes et al., 2002; Sites et al., 2003). Additional insensible fluid losses and post-operative mean blood losses into closed suction drains and occlusive bandaging have been reported to be 568 mL (range 175-1275 mL) and 55mL (range 10-400 mL) respectively (Esler, Blakeway, & Fiddian, 2003). Mean total blood loss associated with TKA has been reported to be high as 1518 mL (Lotke, Faralli, Orenstein, & Ecker, 1991), resulting in a reported blood transfusion requirement mean of 1.6 units (range 1-5 units) in 46% of patients (Bierbaum et al., 1999).

Postoperative symptoms following TKA

The primary goal of TKA is the reduction of pain and joint dysfunction. The symptom experience of patients after TKA surgery includes moderate to severe pain and nausea in the first three days (Wu et al., 2003). Pain during this time period has also been documented as interfering with activity on the day prior to hospital discharge (Strassels et al., 2002). Similarly nausea has been documented to impact well-being in the immediate postoperative period (Wu et al.) and has a prevalence of 87.5% in a pilot sample at the study site (Wilson et al., 2005). The interrelationship between pain and nausea and the need for rehabilitation activity to re-establish joint function suggests that interventions with this group of patients must include these variables. The following section will review pain and nausea.

Pain.

Moderate to severe pain intensity has been documented in the first three days following TKA (Brander et al., 2003; Strassels, Chen & Carr, 2002; Wu et al., 2003; Salmon et al., 2001). Salmon et al., comparing pain for TKA versus total hip arthroplasty patients, found that pain was worse for TKA patients on postoperative days one and three ($p<0.01$). Laskin and Beksac (2004) stress the importance of early knee joint flexion after surgery to 85 or 90 degrees and suggest aggressive pain management plays a crucial role. Review of the TKA literature identified seven descriptive studies measuring pain in the immediate postoperative period using the McGill Pain Questionnaire (MPQ), Visual Analogue Scales (VAS) or Numerical Rating Scales (NRS) (see Appendix A). Pooling data from these studies was not possible because of variability in data collection methods and times. Pain intensity scores were moderate to severe, with a relatively narrow standard deviation in all seven studies. For example, Strassels, Chen and Carr reported mean pain scores of 5.4 ± 2.7 and 4.0 ± 2.1 on postoperative days one and three respectively (Strassels et al., 2002). Similarly, Wu and

colleagues reported VAS mean pain scores to be 3.4±2.6 and 2.2±2.1 at rest and 5.0±2.7 and 3.8±2.1 with movement on postoperative days one and three respectively (Wu et al., 2003). Pain intensity scores at rest and with activity were positively correlated with physical components scores (PCS) of the SF-12 on postoperative days one, two, four, five, seven and fourteen (Wu et al., 2003).

Using the MPQ, Crutchfield and colleagues reported that greater than 40% of TKA patients described pain as 'throbbing' on day one and 'sharp', 'tender', 'tiring', 'annoying' and 'tight' on days one and three (Crutchfield et al., 1996).

Pain transmission.

Unrelieved acute pain and continuing stress response may lead to long term physiological and psychological consequences for the individual (Carr & Thomas, 1997; Kehlet, 1994; Kehlet, 1997). Central sensitization of neurons in the dorsal horn of the spinal cord from repetitive nociceptive input can cause physiologic changes that create the conditions for a persistent pain problem (Bausbaum & Jessell, 2000; Ji, Kohno, Moore & Woolf, 2003; Woolf, 1983).

The Gate Control Theory (Melzack & Wall, 1965) proposed that pain is not simply a function of the degree of tissue damage alone but is influenced by attention, anxiety, suggestion, prior experience and other psychological variables. According to this theory, neural mechanisms in the substantia gelatinosa of the dorsal horn of the spinal cord act like a gate that determines the flow of impulses from peripheral nerves to the brain. Large myelinated fibres (A beta) carrying non-noxious inputs from the periphery can block transmission of "t-cells" and close the gate to further impulse transmission. Noxious stimuli being transmitted by the smaller non- or minimally myelinated fibres (A delta and C) tend to open it. The balance of inputs from these two types of fibres determines whether nociceptive input is transmitted

further to the thalamus, limbic system and cerebral cortex. This theory was the first to refer to a "central control" involving descending mechanisms that could influence pain perception and gave direction to future research.

Primary afferent fibres terminate in the laminae of the dorsal horn of the spinal cord – specifically the substantia gelatinosa and the marginal layer at lamina I and II. Wide dynamic range neurons in the dorsal horn respond to both noxious and non-noxious stimuli (Bausbaum et al., 2000). Therefore, sensory input from non-nociceptive A beta fibres can have an inhibitory response and block noxious stimuli from being transmitted by second order neurons to the thalamus, limbic system, and cerebral cortex. Pain perception is modulated centrally through a descending system that involves the periaqueductal grey area in the midbrain, the nucleus raphe magnus in the medulla, and the dorsal horn. Analgesia occurs when descending pathways are activated that directly and indirectly inhibit nociceptors and activate opioid receptors the spinal cord. Inhibitory neurotransmitters such as endogenous opiates, serotonin and norepinephrine are thought to facilitate this inhibitory process (Bausbaum & Jessell, 2000).

More recent work has focused on activation and sensitization of primary afferent nociceptors after tissue injury by inflammatory mediators. An inflammatory response results from the release of excitatory neurotransmitters such as substance P and the production prostaglandins and leukotrienes from the arachidonic cascade involving cyclooxygenase (Julius & Bausbaum, 2001). Interventions to reduce the release of these mediators, such as ice or the administration of non-steroidal anti-inflammatory drugs (NSAIDS) can contribute to the reduction of nociceptive activity peripherally (Bausbaum & Jessell, 2000).

Melzack and Casey (1968) suggested that pain perception was complex and involved three interrelated dimensions: sensory-discriminative; motivational-affective; and cognitive-evaluative. The multidimensionality of the pain experience explains the complexity and

variability of individual's pain perception. Anxiety, for example, is thought to modify ascending neural impulses produced by noxious stimulation and is capable of affecting decision making or response processes that influence pain (Melzack, 1978). In addition, cognitive expectations can affect the activation of the sensory apparatus and can influence inhibitory mechanisms (Wall, 1996). The subjectivity and variability of responses to pain have major implications for postoperative care.

In summary, unrelieved pain that can interfere with mobility and the required early discharge has been documented in the early postoperative period for TKA patients. Pain theories point to the use of strategies such as pharmacology and non-pharmacological interventions that can increase the inhibitory mechanism related to the multidimensionality of the pain experience. The latter explains the complexity and variability of individual pain experience and the need for both cognitive, psychoemotional and pharmacological approaches (Melzack & Wall, 1996).

Nausea.

Post-operative nausea and vomiting continue to be significant factors in patient well-being and functional recovery following TKA. The prevalence of nausea has been associated with a reluctance to use analgesics and antiemetics, resulting in inadequate pain relief (Waterman, Leatherbarrow, Slater, & Waterman, 1999). Only one descriptive study was found that described nausea in the postoperative period following TKA. Wu and colleagues (2003), in a study of 37 TKA and total hip arthroplasty patients, found the worst nausea was on post-operative day one, while the largest impact of nausea on patient well-being emerged using the SF-12 Mental Component Score on post-operative day two ($r=0.53$: $p<0.01$). Pilot data ($N=30$) confirmed that nausea was worse on the first postoperative day for 87.5% of the sample, decreasing to 25% on the second postoperative day (Wilson et al., 2005).

Analgesic intervention studies also confirmed the predisposition of these patients to have nausea in the immediate postoperative period (Appendix B). Nausea was variable and dependent upon both the anesthetic technique employed and the postoperative analgesic regimen. Review of 28 randomized controlled analgesic trials revealed a wide range in the incidence of nausea as an adverse outcome of the intervention for participants in the first 48 hours after TKA surgery. Neuraxial analgesic interventions using opioids (i.e. epidural and intrathecal routes of administration) were associated with the highest prevalence of nausea. Similar to other studies (Cole, Craske & Wheatley, 2000; Macalou et al, 2004; Lorenzini et al, 2002; Chelly et al, 2001), Sites et al. (2003) reported 75% of TKA surgery patients who received intrathecal morphine experienced nausea in the first 48 hours post-operatively versus 30% in the comparative femoral nerve block group. The combination of intrathecal morphine and femoral nerve block is usual practice at the trial site. Klasen, Optiz, Melzer, Theil and Hempelmann (1999) also described a uniformly high incidence of nausea among patients receiving epidural opioids.

Opioids are thought to induce nausea and vomiting by a direct action on the chemoreceptor trigger zone (Thompson, 1999). Nausea rates associated with parenteral and oral interventions are fairly consistent even with lesser opioid administration. Nausea is a well-known adverse effect of opioid analgesic administration. Hubbard, Newman, Traylor and Dhadda (2003) compared the non-steroidal anti-inflammatory drug (NSAID) parecoxib sodium plus Patient Controlled Analgesia (PCA-IV) morphine to placebo and reported nausea rates of 46.3% and 54.9% respectively alongside a significant decrease in morphine consumption in the intervention group ($p<0.05$). Another study of NSAIDs and parenteral opioid combination cited similar nausea incidence, regardless of the level of opioid consumption (Reynolds et al., 2003). Confirming this finding, Bianconi and colleagues (2003) compared intraarticular (IA)

morphine with local anesthetics via the same route. Nausea incidence was reported as 53% in the IA morphine group compared with 44% in the local anesthetic group, despite significantly fewer rescue opioid analgesics used in the latter group ($p<0.05$).

The pathophysiology of postoperative nausea and vomiting is known to be multifactorial in nature (Gan et al., 2003). In contrast to the physical symptom of vomiting, nausea is a subjective, sensory response to a number of differing stimuli, including pain (Huether, 2002). Afferent sensory input from the chemotrigger zone, the vagus and vestibular nerves and the limbic system are thought to provide stimulus to the vomiting centre in the medulla (Thompson, 1999). Serotonin, histamine and acetylcholine mediate these stimuli in response to conditions in the gastrointestinal tract, the cardiovascular and respiratory systems and the auditory labyrinth.

Gan et al. (2003) developed consensus guidelines for the prevention and management of postoperative nausea in surgical patients, identifying three categories of predisposing factors. Table 1 presents three categories of patient specific, anesthetic related and surgery related characteristics.

Table 1

Risk factors for post-operative nausea and vomiting **(Gan et al., 2003)**

Patient Specific	Anesthetic-related	Surgery-related
Female sex	Use of volatile anesthetics within 0-2 hours of surgical procedure	Duration of surgery: each 30 minute increase in duration increases risk by 60% (e.g. baseline risk of 10% is increased to 16% after 30 minutes)
Non-smoker		
History of post-operative nausea and vomiting	Use of nitrous oxide	
History of motion sickness	Use of intraoperative and post-operative opioids	Type of surgery

TKA patients have three of the risk factors described within these categories: predominantly female; use of intraoperative and postoperative opioids; and relatively lengthy surgical procedure. Seventy-four percent of these patients are female (Furnes et al., 2002), contributing one risk factor from the Patient Specific category. The routine use of intrathecal anesthetics rather than general or inhalation anesthetic is risk reducing; however, the use of intrathecal opioids during the perioperative period and the common addition of intravenous patient controlled analgesia using opioids add a risk factor related to the anesthetic category. The third risk factor inherent in the TKA population is related to the length of the surgical procedure. Time from induction of anesthetic to skin closure has been estimated to be 60-90 minutes. Nausea risk increases from baseline to 26% for a 60 minute procedure (Gan et al., 2003). Overall/baseline nausea risk with no risk factors identified is 10%.

Orthostatic variations in blood pressure have been positively associated with post-operative nausea and vomiting. Pusch and colleagues (2002) found that women who had greater than 35 mmHg variations in systolic blood pressure had significantly more nausea after gynecologic surgery ($p<0.01$). Vestibular activation as a result of blood pressure variation is well known to produce nausea (Thompson, 1999). Dehydration has been reported to be a common finding in the older adults who have had surgery (Martin & Larsen, 1994). Fasting pre-surgical states for a minimum of twelve hours worsens the pre-procedure fluid status and as a result, patients are entering the operating room already dehydrated. Moreover, age-related loss of thirst sensation in healthy older adults (Phillips, Johnston, & Gray, 1993) and decreased mobility secondary to painful arthritic knee joints creates a physical barrier to appropriate fluid intake. Intra-operative estimated blood losses have been reported to be as high as 261±89 mL and vary with duration and surgical manipulation during the procedure (Furnes et al., 2002; Sites et al., 2003). Additional insensible fluid losses and post-operative mean blood losses into

closed suction drains and occlusive bandaging have been reported to be 568 mL (range 175-1275 mL) and 55mL (range 10-400 mL) respectively (Esler et al., 2003). Mean total blood loss associated with TKA has been reported to be 1518 mL (Lotke et al., 1991) resulting in a reported blood transfusion requirement mean of 1.6 units (range 1-5 units) in 46% of patients (Bierbaum et al., 1999).

In summary, nausea after TKA surgery remains a common problem that may be compounded by the requirement for opioids, a risk factor for the development of nausea (Gan et al., 2003), although parenteral opioid sparing techniques have had minimal effect on its prevalence in the first three postoperative days. Perioperative neuraxial opioid, a commonly used intervention at the study site, has been associated with the highest incidence of nausea during this time period.

Interference with activity

Interference with activity in this trial was defined as the degree to which pain interfered with general activities, sleep, mood, walking, movement from bed to chair, and relations with others as measured by the Brief Pain Inventory Interference subscale (Cleeland & Ryan, 1994) and walking specific distances, walking to the bathroom and shower, sitting at the bedside or in a chair, and attendance at physiotherapy sessions as measured by the TKA Activity Questionnaire designed for this trial.

The importance of good pain control in achieving flexion and general knee motion postoperatively has been identified in the literature (Harvey, Barry, Johnson, & Elloy, 1993; Kurosaka, Yoshiya, & Mizuno, 2002; Laskin et al., 2004; Williams-Russo et al., 1996). The achievement of optimal or near normal range of motion is an indicator of success after TKA that influences patient care in the early postoperative period (Bardsley & Cleary, 1999; Dennis, 2001; Heck et al., 1998; Kurosaka et al., 2002). Functional outcomes in TKA patients in

analgesic intervention studies in the early postoperative period indicate that knee joint range of motion (a common indicator of joint function) is improved when pain intensity is reduced. Five studies reported a relationship between range of motion and a reduction in pain on movement (Capdevila et al., 1999; Cheville et al., 2001; Eggers, Jenkins & Power, 1999; Singelyn et al., 1998 Wang, et al., 2002). For example, Singelyn et al. (1998) found epidural analgesia and femoral nerve block decreased pain and also increased range of motion ($p<0.001$). Regardless of mobilization and/or physiotherapy method, it is clear that providing appropriate analgesia in the early postoperative period influences knee joint range of motion.

Pain-related interference with general activity, early mobilization and physiotherapy can have significant consequences for patients after TKA. The implications of pain management for knee joint function are particularly intensified given the trend to dramatically shorten postoperative hospital stays (Teeny, York, Benson, & Perdue, 2005). Pain-related interference on the day prior to hospital discharge using the Brief Pain Inventory Interference subscale has been reported to be problematic for general activity (5.3±4.4), mood (4.1±3.8), walking ability (6.8±3.5) and sleep (4.9±3.8) (Strassels et al., 2002). Although the sample size was small the results are congruent with other more methodologically rigorous studies (Crutchfield et al., 1996; Wu et al., 2003). In a pilot at the study site, mean pain scores [NRS(0-10)] with movement measured mid morning on each of the first three days after surgery in TKA patients from the trial site were found to be 5.3±2.4, 4.6±2.5, and 5.5±2.1 respectively (Wilson et al., 2005).

In summary, the requirement for mobility for the first three postoperative days and early discharge, when which patients reported moderate to severe pain underlines the need for aggressive pain management to meet expected hospital discharge on the fourth day in this centre. Consistent with this approach, accelerated rehabilitative activities immediately

postoperatively, alongside a decrease in pain scores, have revealed a trend toward shorter hospital stay in two feasibility studies involving TKA patients (Beard, Murray, Rees, & Choong, 2002; Isaac et al., 2005).

Pilot data

An examination of the characteristics of the postoperative TKA population for each of postoperative days one to four was conducted using participants drawn from the pain service database. Ethics approval was obtained from the hospital Research Ethics Board in December 2005. Data were abstracted from the charts of 16 participants who underwent surgery during August 2005. Variables abstracted included the following: intensity of resting and pain on movement; the incidence of post-operative nausea; anti-emetic administration; estimated intraoperative blood losses; intraoperative fluid replacement; and, opioid administration.

Consistent with other studies of TKA (Furnes et al., 2002), the mean age was 68±10 years and 62.5% of the sample was female. Pain on movement was in the moderate to severe range and consistent through the study period. Results for pain are presented in Appendix G. Opioid analgesic administration varied considerably, tending to be unrelated to analgesic delivery method (i.e. femoral nerve block + PCA-IV vs. PCA-IV alone). Median intravenous morphine administration was 38.5 mg (IQR=42) on day one and oral morphine administration was 55 mg (IQR=89) on day three. Nausea incidence on postoperative day one was almost universal at 87.5%, dropping to 25% on postoperative day two.

Intraoperatively, pilot study participants received an average of 1900 mL of intravenous crystalloid (Ringer's Lactate, 0.9% saline) and 270 mL intravenous colloid fluid replacement and lost 462.5 mL of blood. Replacement of blood loss alone would have required a 3:1 crystalloid fluid replacement rate, in this case approximately 1300 mL, or an equivalent amount of intravenous colloid fluid (Kaye & Kucera, 2005). Assuming a conservative 1000

mL preoperative fluid deficit secondary to a 12 hour fasting period, 500 mL insensible and 250 mL third space losses, in addition to a baseline fluid requirement for 400-500 mL during the operative period, the average participant received only modest fluid replacement that may not have addressed a longer term hypovolemic state.

Postoperative interventions for TKA patients

Research that has examined interventions for the treatment of pain and nausea for TKA patients in the early postoperative period can be divided into non-pharmacological, pharmacological and hydration interventions. Trials of these interventions are summarized in Appendices B to F.

Non-pharmacological interventions.

Four trials of non-pharmacological interventions for analgesia after TKA were found (Appendix C). Two studies examined the impact of cold therapy bandaging on pain intensity and range of motion (Morsi, 2002; Smith, Stevens, Taylor, & Tibbey, 2002). Both examined pain beyond 48 hours postoperatively. Only one of the studies reported an improvement in pain intensity (4.2 ± 0.74 versus 6.3 ± 1.3, $p<0.001$) and joint range of motion across study measurements when compared to usual care (nurse administered analgesia) in a sample of 60 participants having planned, staged bilateral TKA (Morsi, 2002). However, in an unusual cross-over method, each participant in this study was assigned to the control group and the treatment group for each of the TKA procedures, introducing bias and limiting the usefulness of these findings. Additionally, the intervention in this case involved confinement to bed for six days post-surgery except for brief periods of physiotherapy in order to facilitate the application of the cold therapy bandage.

Two studies compared guided imagery to usual care. The first, a pilot study (N=13), explored the use of guided imagery alone compared to usual care (Antall & Kresevic, 2004).

The second compared a combined approach of guided imagery , music, relaxation techniques and heat, cold and massage instruction (N=65) (Pellino et al., 2005) to music therapy plus usual care. Both studies examined the effect of the interventions across the first three postoperative days. Data provided by Antall and Kresevic were descriptive in nature, reporting a trend toward lower pain scores in the intervention group (5.3 versus 2.4). Pellino et al. examined pain-related interference with activity during this time period as well. Worst pain difference were reported as non-significant at 7.66±2.32 versus 7.98±1.66, 6.95±2.41 versus 7.43±1.6 and 6.9±2.10 versus 7.10±2.24 in treatment and usual care groups on postoperative days one, two and three respectively (level of significance not provided). Opioid analgesics administered on postoperative day two were less in the treatment group (33.67±29.51 versus 19.06±12.89, t=-2.39, $p<0.05$).

No studies examining physical or non-pharmacological interventions for the prevention of nausea after TKA were identified. One related study examined a non-pharmacologic, physical intervention in a population that included ambulatory orthopedic patients (Anderson et al., 2004). This RCT in the post anesthetic recovery period reported no significant difference in VAS nausea scores with patients inhaling peppermint or alcohol aromatherapy versus saline. Acupressure bands with and without conventional anti-emetic pharmacologic therapy were compared to placebo for nausea with 103 postoperative gynecologic patients (Schultz et al., 2003). No significant differences were found between treatment and control groups on either of postoperative days zero or one (73% versus 33% versus 55%: X^2=7.57, p=0.056; and, 44% versus 33% versus 29% respectively; X^2=1.33, p=0.722).

Pharmacological interventions.

A multitude of pharmacological analgesic interventions has been examined in the TKA patient population. Twenty eight randomized controlled trials were identified that included any

outcomes measured in the early postoperative period (Appendix B). Although all but six studies reported pain intensity as a variable (Ben-David, Schmalenberger, & Chelly, 2004; Chelly et al., 2001; Forster & Rosenberg, 2004; McNamee, Parks, & Milligan, 2002; Ng, Cheong, Lim, Lim, & Puhaindran, 2001; Rathmell, Pino, Taylor, Patrin, & Viani, 2003), only one study examined the impact of the intervention on pain interference on the eighth postoperative day. Study duration was variable, but the majority of studies ranged from 24 hours (n=26) to 48 hours (n=8) after surgery, with a single study continuing the measurement period to eight days (Cheville et al., 2001). All but three studies (Barrington et al., 2005; Cheville et al., 2001; Wang et al., 2002) reported pain measures either before physiotherapy had been initiated or during the use of continuous passive motion devices. Five studies were found that compared knee joint range of motion in intervention and control groups in the immediate postoperative period (Capdevila et al, 1999; Cheville et al., 2001; Eggers et al., 1999; Klasen et al., 1999; Singelyn et al., 1998; Wang et al., 2002), but no studies examined pain interference in the first three days after surgery.

Thirteen randomized controlled trials were examined in a systematic review of the efficacy of continuous epidural analgesia in TKA patients. Results were limited to measurements taken within the first 24 hours after surgery (Choi et al., 2003). Pooling of pain measurements was possible for 11 of the 13 studies. Results indicated that epidural analgesia produced better pain relief as compared to systemic opioid analgesia [standardized mean difference (SMD) -0.77: 95% confidence interval (CI) -1.24, -0.31]. However, the effect was limited to early postoperative pain and was not statistically significant at 18 to 24 hours postoperatively (SMD -0.29: 95% CI -0.73, 0.16).

Peripheral nerve blockade, using both single and continuous dosing after TKA, has been compared to systemic opioid alone in the first 24-48 hours (Ben-David et al., 2004;

Chelly et al., 2001; Ganapathy et al., 1999; McNamee et al., 2002; Ng et al., 2001; Singelyn et al., 1998; Wang et al., 2002). Two studies that examined pain scores at physiotherapy in patients receiving femoral nerve block plus PCA-IV versus PCA-IV alone showed statistically but not clinically significant reduction in pain on movement. Wang and colleagues reported a significant reduction in pain scores at physiotherapy at 24 hours for the femoral nerve block/ PCA-IV group (6.2±2.8 versus 7.8±1.6, $p<0.05$) (Wang et al., 2002). Singelyn and colleagues has similar results (1.7±1.0 versus 2.7±1.4, $p=0.04$) (Singelyn et al., 1998). The effect of these interventions on pain and related interference in activities beyond 48 hours after surgery is not known. Additionally, the difficulty with mobilizing patients with lower limb motor nerve blockade limits the usefulness of these interventions in clinical centres that promote early weight-bearing activity. Overall, it appears that epidural analgesia using local anesthetics produces the most robust effect on the reduction of pain in the immediate postoperative period when compared to opioid analgesia.

The impact of epidural analgesia on patients' abilities to engage in functional activities after surgery has not been examined. The theoretical interference of decreased lower limb motor function inherent in lower thoracic and lumbar epidural blockade with weight-bearing physiotherapy activities is problematic (Silvasti & Pitkanen, 2001). Additionally, the risk of epidural hematoma associated with the concomitant use of standard anti-coagulant therapy, routine in postoperative TKA care, may preclude its use (Horlocker et al., 2010). As a result, in the trial site, the most common postoperative analgesic method employed is single shot femoral nerve block, patient controlled intravenous opioid analgesia for two days followed by oral opioid and routine non-opioid analgesia.

In summary, the variability in effectiveness and the practicalities associated with non-opioid or opioid sparing analgesic techniques after TKA support the clinical requirement to use

opioid analgesia as the primary strategy for pain relief. However, comparison of analgesic trials is problematic as the reporting of pain occurs mainly without inclusion of specific data. The clinical significance and impact of the interventions on postoperative outcome achievement are not addressed. In addition, many studies report only resting pain ratings and do not include any dynamic, flexion or weight-bearing measurements. Few studies report mean scores with standard deviation and most have relatively small sample sizes. As a result, the generalizability of study findings is problematic.

Only two randomized controlled trials were found that compared pharmacologic agents for postoperative nausea in TKA patients (Appendix D) (Chen et al., 1998; Grattidge, 1998). Both studies used prophylactic administration of the agent at the end of the surgical procedure. Despite the established benefit of prophylactic use of 5-HT3 receptor antagonists (ondansetron, granisitron, dolasetron and tropisetron) (Loewen et al., 2000), Chen and colleagues (1998) found prophylactic prochlorperazine to be superior to ondansetron in the prevention of nausea over the 48 hours study period (incidence 56% versus 81%, $p=0.02$). The use of prophylactic subhypnotic propofol did not significantly decrease nausea incidence when compared to placebo in the second study (Grattidge, 1998). Two further studies were identified that included general orthopedic patients in a broader postoperative population (Lacroix et al., 1996). Recurrence of nausea or retching in this study was reduced 60 minutes after the administration of metoclopramide or droperidol when compared to subhypnotic propofol (24%, 4% and 58% respectively, $p<0.02$). Requirements for antiemetic therapy beyond the immediate post-anesthetic period were not different among the three groups (Chen et al., 1998). In a similar study by Parlow and others, the dopamine receptor blocking antiemetic, haldoperidol, was used for postoperative nausea prophylaxis after spinal anesthetic that included intrathecal morphine (Parlow, Costache, Avery, & Turner, 2004). One hundred and twenty-two lower

limb orthopedic or urologic surgery patients were randomized to three groups receiving either haldoperidol 1mg, 2mg or placebo. A dose-dependent decrease in postoperative nausea was found with the higher dose haldoperidol reducing the incidence of nausea by 50% in the first 12 hours after surgery ($p=0.012$). Overall, 60% of patients were classified by the authors as treatment failures within the first 12 post-operative hours and 65% at 24 hours. In this study, treatment failure was considered to be nausea greater than one on a six point nausea score, vomiting or the use of rescue anti-emetics. However, haldoperidol administration is associated with adverse effects that include extrapyramidal reactions and cardiac rhythm disturbances (White, McPherson, McCann, Sadler & Fyvie, 2006).

Hydration interventions.

No studies were found that addressed the use of hydration interventions, intravenous or oral, to decrease nausea after TKA. A single study examined the effects of a transfusion requirement decision-making flowchart on the incidence of allogenic or autologous transfusion requirements after TKA and THA (Muller et al., 2004). The flowchart allowed providers to differentiate between hypovolemia and anemia and provide appropriate rehydration using intravenous crystalloid or colloid solutions. Persistence of symptoms following fluid administration was characterized as an indication for transfusion. Although dizziness and hypotension were included as a defining symptom of hypovolemia and anemia in the intervention tool, these symptoms were not measured after the intervention. Use of the decision-making flowchart reduced the incidence of transfusion by 15% for allogenic and 23% for autologous blood products.

The use of blood volume expansion through intravenous fluid therapy has been shown to have beneficial effects on nausea in other groups (Appendix E). In a study of 200 laparoscopic cholecystectomy patients, Yogendran and colleagues demonstrated a statistically

significant decrease in nausea, drowsiness and dizziness at 24 hours post-operatively in a participants receiving 20mL/kg isotonic saline versus 2mL/kg isotonic saline intraoperatively ($P<0.05$) (Yogendran, Asokumar, Cheng, & Chung, 1995). In a similar study, Sinclair and colleagues used calculated stroke volume to direct colloid fluid challenges intra-operatively and compared results to control conditions. Participants in the intervention group had a shorter mean time to hospital discharge 10 (range 9-15) days versus 15 (range 11-40) days ($p<0.05$) (Sinclair, James, & Singer, 1997). Rates of nausea independent of other postoperative complications were not provided in this study. However, supplemental intraoperative fluid administration has been found to significantly reduce post-operative nausea elsewhere when compared to conservative fluid therapy (incidence 23% vs 73%: $p=0.013$) in gynecologic surgery (Ali, Taguchi, Holtmann, & Kurz, 2003) and multiple surgery types (incidence 7% vs 18%, $p<0.05$) (Gan et al., 2002). The impact of a similar intervention on the postoperative TKA population is, as previously mentioned, unknown. No studies have been identified that promoted the establishment of an euvolemic state, either with intravenous supplementation or oral intake prior to surgery in any population toward reducing the incidence of postoperative nausea.

Studies of patients following TKA surgery have clearly documented the prevalence of pain, nausea and interference with activity. Interventions to improve these outcomes have had mixed results. Johnson et al, (1997) suggested that an approach that encourages patients to be an active participant in the health care process was essential for self-care decision-making. Specifically, Johnson et al.'s (1978) early data demonstrated that providing patients with concrete information about symptom sensations including pain and how to ask for analgesia and instructions about postoperative activity before surgery improved pain distress ($p<0.05$) and mood ($p<0.05$) in the immediate postoperative period. This study therefore will examine

the impact of an educational intervention that is individualized on interference with activity, pain and nausea after TKA surgery.

Preoperative education interventions

Seven randomized controlled trials were found that compared a standard preoperative education intervention to usual care. Three included only TKA patients (Beaupre, Lier, Davies, & Johnston, 2004; Lin, Lin, & Lin, 1997; Sjoling, Nordahl, Olofsson & Asplunf, 2003) , while the remaining four included total hip arthroplasty patients as part of the sample (Bondy, Sims, Schroeder, Offord, & Narr, 1999; Dillon-McDonald, Freeland, Thomas, & Moore, 2001; McDonald & Molony, 2004; Roach, Tremblay, & Bowers, 1995) (Appendix F). Four trials introduced education related to pain management following surgery through use of a video and written material (Dillon-McDonald et al., 2001; Lin et al., 1997; McDonald et al., 2004), verbal review of written material (Sjoling et al., 2003) or the provision of a comprehensive program including a class, written material, question and answer sessions and pain management video (Roach et al., 1995). None of the studies addressed the prevention of postoperative nausea, hydration or antiemetic therapy.

The impact of the interventions in these trials on pain outcomes was variable. For example, McDonald and Molony's (2004) trial of 41 older adults having joint replacement surgery that compared an intervention of pain communication skills and pain management education and standard preoperative information, found that pain (MPQ-SF) was lower in the pain communication and pain management education group ($F= 2.50$, $p<0.05$). Average pain ratings [NRS(0-10)] were 6.2±4.1 and 3.6±2.5 on postoperative day one. Dillon-McDonald et al. (2001) also reported a modest reduction in pain over time using a standardardized preoperative intervention that focused on the importance of pain and pain communication in 31 TKA and total hip arthroplasty patients (Effect size .38, $F=2.49$, $p<0.05$). Sjoling et al.

(2003) found a reduction in the proportion of patients reporting pain ratings of four or more over the first three postoperative days in a study of 60 TKA patients who received a standardized preoperative intervention that focused on the pain communication and the importance of analgesia to facilitate activity ($p<0.05$).

Two systematic reviews of preoperative patient education for orthopedic surgery patients (Johansson, Nuutila, Virtanen, Katajisto & Salantera, 2005; McDonald, Green & Hetrick, 2006) and one for general surgical patients (Shuldham, 1999) concluded that the impact of preoperative education on outcomes such as pain and length of stay was variable depending on the methodologic rigor of the trials reviewed. Results of these reviews also highlighted a reduction in anxiety as an outcome of preoperative education. Consistent with this finding, Sjoling and colleagues (2003) found a significant decrease in state anxiety ($p=0.009$) as did Bondy et al. (1999) with the provision of two booklets and an informational video in a sample of 134 total joint replacement patients ($p=0.035$).

The impact of preoperative education on functional outcomes was also variable. Two studies examined the impact of preoperative education on range of motion and exercise performance after TKA surgery. Lin et al. (1997) reported better exercise performance and knee flexion in the intervention group in a trial of 60 TKA patients in the immediate postoperative period while Beaupre et al. (2004) reported no differences in knee flexion at 3 months. Content of these programs included the importance of postoperative mobility, management pain on movement and exercise instruction.

Educational content and delivery method.

Chang et al. (2004) used focus groups to examine the concerns of patients contemplating TKA in a qualitative assessment of 37 arthritis patients. Participants identified pain after surgery, methods of pain relief, addiction to medications and function after surgery

as concerns requiring information. In a grounded theory study of the experience of 9 TKA patients, Marcinkowski et al. (2005) reported participants identified the need to accept help with symptoms and interact with health professionals as part of the trajectory of care for TKA patients. Educational interventions used in trials for TKA patients addressed this content. All trials that provided pain management education also provided information about effective communication of pain to health care providers (Dillon-McDonald et al., 2001; Lin et al, 1997.; McDonald & Molony, 2004; Roach et al., 1995; Sjoling et al., 2003). Three trials (Dillon-McDonald et al., Lin et al.; Sjoling et al.) reinforced the importance of pain management and maintaining pain at a comfortable level when moving through the use of analgesics. Intervention content regarding the use of non-pharmacologic interventions was documented in three trials (Dillon-McDonald et al.; Roach et al.; Sjoling et al.).

Specific education that focused on communicating pain and the use of analgesics has been used in other patient groups. Watt-Watson et al. (2004) addressed common patient concerns with taking analgesics in addition to reviewing the importance of pain relief and pain communication in a study of 406 coronary artery bypass patients. Patients in the intervention group reported fewer concerns about taking analgesics (22.6±14.7 versus 18.5±14.1, $p<0.05$) and fewer concerns about addiction (3.7±3.6 versus 4.8±3.8). Women in this study had more concerns about asking for help with medications for pain than men (29.1±18.5 versus 22.4±16.2, $p<0.02$).

Stern and Lockwood (2005), in a systematic review of 15 randomized controlled trials, concluded that pre-admission written material combined with verbal instruction was more effective and resulted in better performance of postoperative exercises or skills than information provided postoperatively. As well pain education that resulted in improved postoperative outcomes for orthopedic patients has been provided through written material

combined with video (Dillon-McDonald et al., 2001; Lin et al., 1997; McDonald et al., 2004), verbal review (Sjoling et al., 2002) or with class and video (Roach et al., 1995).

Preoperative education has been found to impact pain, anxiety and function although the results were inconsistent in TKA patients. Watt-Watson et al.'s (2004) findings that most patients would not ask for analgesics despite having fewer concerns about addiction and taking analgesics because they expected clinicians to know when these were needed suggested that discussion of these beliefs about postoperative symptom management on an individual patient level would be important. Recommendations in systematic reviews by Johansson et al. (2005) and McDonald et al. (2006) for the individualization of preoperative educational content and the consideration of experiential dimensions of the patient experience have not been documented in trials in TKA patients.

Individualized patient education.

Although no trials were found of an individualized education intervention for TKA patients, evidence for this approach was found with other groups requiring pre-procedural information. Individualization of patient education was found to lower symptom severity (Sherwood et al., 2005; Velji, 2006), improve fatigue (Yates et al., 2005) and decrease pain and anxiety (Benor et al., 1998) in cancer patients undergoing chemotherapy and radiation therapy. DeWit et al. (2001) found a reduction in the proportion of patients reporting inadequate pain control following an educational intervention that tailored pain communication and management information to individual patient concerns (56% versus 41%, p=0.01).

In summary, trials of preoperative education for TKA patients have had variable postoperative impact. Including content that addresses pain communication, the use of analgesics and non-pharmacological interventions, the importance of good pain control for improving function and dispelling misbeliefs about symptom management was found to be

effective for this group of patients using a standardized approach. Reduction in postoperative pain was found in 3 trials of interventions that included this content (Dillon-McDonald et al., 2001; McDonald & Molony, 2004; Sjoling et al., 2003). Individualizing the preoperative educational content to address each patient's concerns was not found in orthopedic studies but did result in positive outcomes for oncology patients (DeWit et al., 2001; Sherwood et al., 2005; Velji, 2006). Meeting postoperative goals with TKA patients requires aggressive symptom management for the promotion of early mobility. Evidence from this review indicated that an individualized preoperative education intervention involving discussion as well as written materials with patients may facilitate this.

Summary of literature review

Review of the literature confirmed TKA patients had moderate to severe pain (Brander et al., 2003; Salmon et al., 2001; Strassels et al., 2002; Wu et al., 2003), nausea (Wu et al.) and pain-related interference with activity (Strassels et al.). Pilot data from the trial site were consistent with this review (Wilson et al., 2005). Evidence from trials of single strategy interventions for TKA patients was equivocal. Pharmacologic and physical non-pharmacologic interventions to address pain in the TKA population have not produced practical, and in some cases, clinically significant effects on pain and nausea on postoperative days one to three. Review of 28 trials of pharmacologic interventions for pain identified variable impact on postoperative pain and function. For example, a systematic review of epidural analgesia documented a reduction in pain limited to the first postoperative day (Choi et al., 2003). Similarly, trials of anti-emetic interventions had variable benefit (Chen et al, 1998; Grattidge et al, 1998; Parlow, Costache, Avery & Turner, 2004). Non-pharmacologic physical interventions did not show any reduction in pain (Pellino et al., 2005; Smith et al., 2002).

Preoperative educational interventions using a variety of strategies have reduced pain after TKA surgery (Dillon-McDonald et al., 2001; McDonald & Molony, 2004; Sjoling et al., 2003) and improved exercise performance (Lin et al., 1997). Systematic reviews document the variability in pain outcomes and address methodologic limitations of trials that have tested this intervention. Research using focus groups of TKA patients to identify information concerns supported providing content that included the importance of pain communication and management, function after surgery and addressing misbeliefs about analgesia (Chang et al., 2004) and is consistent with content used in other patient groups (Watt-Watson et al., 2004).

Although individualized preoperative education has not been tested in orthopedic patients, this approach has been used successfully to reduce symptoms in cancer patients (Benor et al., 1998; DeWit et al., 2001; Sherwood et al., 2005; Velji, 2006; Yates et al., 2005). This study will therefore examine the impact of an individualized preoperative education program on pain-related interference with activity, pain and nausea on days one, two and three for patients after TKA surgery. An individualized approach is hypothesized to improve upon results of standardized educational interventions and is consistent with recommendations made by Johanssen et al. (2005) and McDonald et al. (2006).

Conceptual Framework

The conceptual framework for this trial was based on the symptom and functional status domains of the health outcomes and health related quality of life model by Wilson and Cleary (1995). An overview of the original model will be presented prior to a discussion of the components of the intervention that will give direction to this trial. The primary outcome for this trial was pain-related interference with activity.

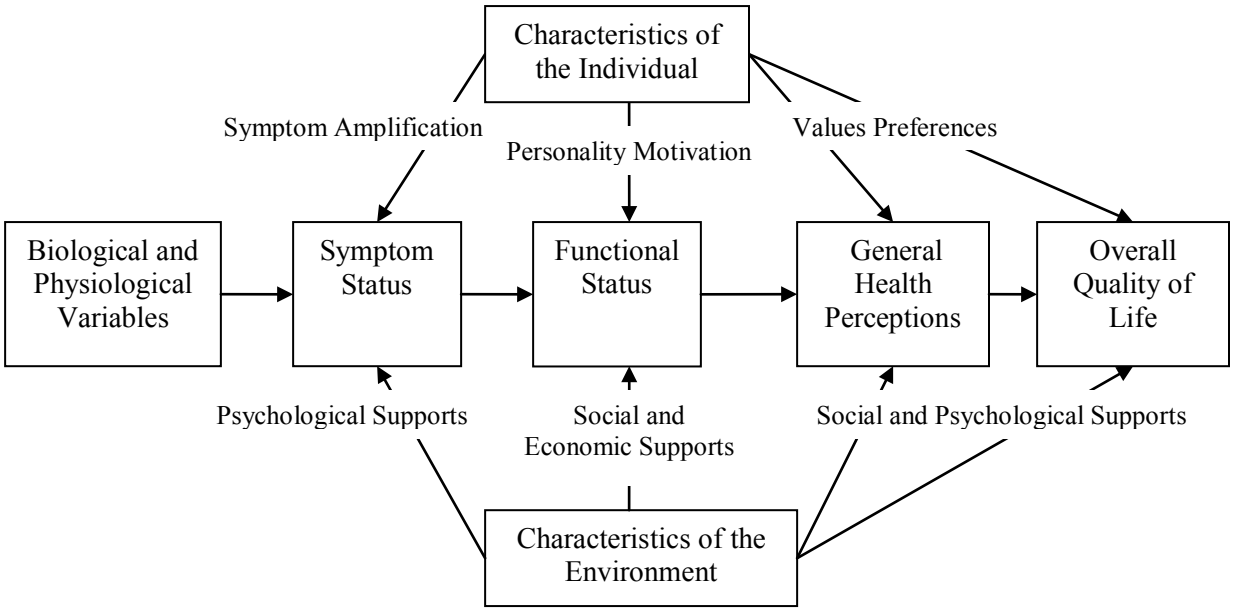


Figure 1. Wilson and Cleary's (1995) model of domains associated with health related quality of life

Overview of conceptual model.

Wilson and Cleary (Figure 1.) propose a conceptual model that presents health status and health related quality of life as the dependent result of a linear continuum of biologic, physiologic and psychosocial variables (Wilson & Cleary, 1995). This model explains the interconnected nature of these variables and individual and environmental characteristics. The model is made up of five domains: biological and physiological; symptoms; functioning; general health perceptions; and, overall quality of life. Biological and physiological factors are all those aspects of the individual that are commonly measured in routine clinical practice: diagnoses, laboratory values, physical assessment findings and mediating factors that result from changes in human tissue function (Wilson et al., 1995). Symptoms generally cause individuals to seek health care and are an important part of treatment along with biological and physiological factors. Wilson and Cleary acknowledge an inconsistency in the relationship between biology and symptoms, and posit that other determinants may contribute to symptom manifestation. Functional status includes measures of physical, social, role and psychological

function. The model represents the continuum that exists between biological, physiological and symptom factors and functional status. General health perceptions provide a subjective component, acknowledging that individual perceptions are an important predictor of functional status and health care utilization (Wilson et al., 1995). Overall quality of life is the outcome of the cumulative effects of all other model domains. Individual characteristics factor into the model as affecting the symptom, functional status, general health perceptions and overall quality of life domains. Symptom amplification, the effects of personality and motivation on functional status and values and preferences as impacting general health perceptions are delineated (Wilson et al., 1995). Similarly, characteristics of the environment in terms of psychological, social and economic supports have an impact each of the domains of general health perceptions, quality of life and symptom status as well as functional status.

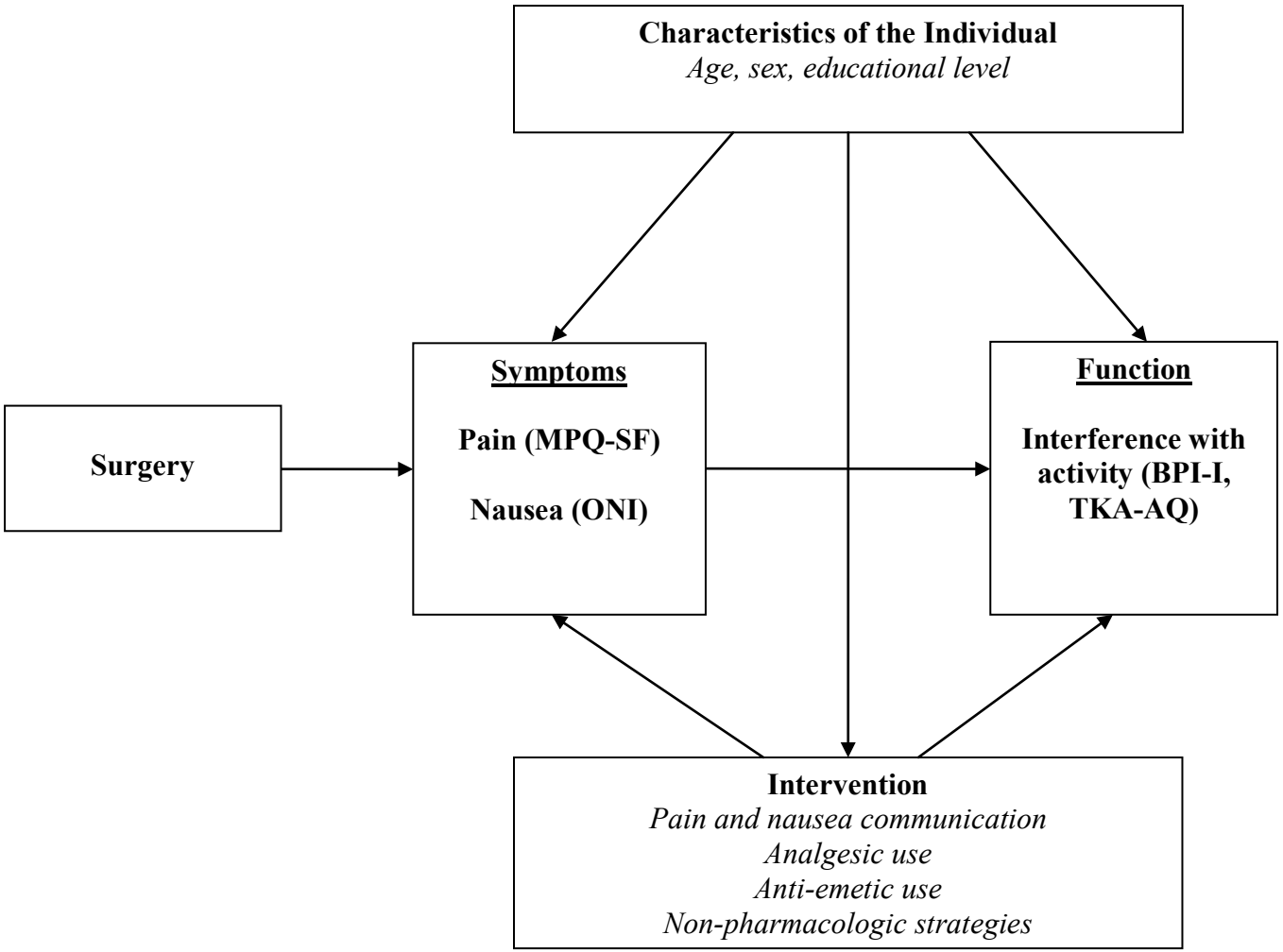


Figure 2. Conceptual Framework: Adaptation of Wilson and Cleary's (1995) model

Adaptation of Wilson and Cleary's model

Wilson and Cleary's (1995) health outcomes model provides an ideal framework for delineating the relationship between the research questions and the impact of the trial intervention (see Figure 2). Patients have pain and nausea after TKA (Wu et al., 2003) that interferes with usual activities (Strassels et al., 2002). Reduction in pain has been associated with increased knee joint mobility in the early postoperative period (Capdevila et al., 1999; Cheville, et al., 2001; Eggers et al., 1999; Singelyn et al., 1998; Wang et al., 2002). The components of Characteristics of the Individual, Biological and Physiological Variables, Symptom Status and Functional Status of Wilson and Cleary's Health Outcomes Model (1995) were used to frame the intervention and outcomes measurement. The biological and physiological variables domain of the model is represented for this trial by the surgical procedure and is linked directly to the symptom status domain. The link between symptom status and functional status in the conceptual framework is of considerable importance as early activity and knee flexion is a goal of postoperative rehabilitation (Bardsley & Cleary, 1999; Dennis, 2001; Heck et al., 1998; Kurosaka et al., 2002). Essential to the recovery and early improvement in postoperative functional status, symptom status in terms of pain and nausea was a secondary outcome in this trial.

Surgery.

Surgery that included tissue injury, the initiation of nociceptive and inflammatory processes and central sensitization represented the biological and physiological variables of interest in this trial. Surgical excision of the arthritic joint in TKA surgery involved interruption in the integrity of three bony surfaces and the soft tissues and ligaments around the knee joint (Mont, Lee, Sheldon, Lennon, & Hungerford, 2002). The incision used in all cases

was vertical and midline over the patella. The surgical procedure was a direct contributor to the variables in the Symptom Status domain in the study model.

Symptom status: Pain and nausea.

Moderate to severe pain has been documented in first three days following TKA (Brander et al., 2003; Salmon et al., 2001; Strassels et al., 2002; Wu et al., 2003) and is consistent with findings of pilot data at the trial site (Wilson et al., 2005). The negative influence of pain on rehabilitative activities after surgery is well established (Harvey et al., 1993; Kurosaka et al., 2002; Laskin et al., 2004; Williams-Russo et al., 1996). A high prevalence of nausea has also been established in the early postoperative period (Wu et al.) and in pilot data (Wilson et al., 2005).

In the symptom status domain of this model, each outcome influences the presence/absence of the other. Pain is known to produce nausea without any other stimulus secondary to sympathetic nervous system activation (Julius et al., 2001; Kandel, Schwartz, & Jessell, 2000). Related to opioid analgesic use, pain also secondarily influences nausea through activation of the chemotrigger zone (Thompson et al., 1999) and is a known predisposing factor for nausea (Gan et al., 2003). Similarly, nausea attenuates the pain experience theoretically through activation of emotional and motivational pain contexts known to shape the perception of pain as unpleasant (Fields, 1999). The tendency for patients to relate nausea to previous opioid analgesic administration also influences pain by reducing the use of interventions such as patient controlled intravenous analgesia.

Functional status.

Activities that promote knee joint mobility are an essential part of rehabilitation in the immediate postoperative period (Laskin & Beksac, 2004). The direct relationship between function and pain following TKA has been documented (Capdevila et al., 1999; Cheville, et al.,

2001; Eggers et al., 1999; Singelyn et al., 1998; Wang et al., 2002) and is a key component of Wilson and Cleary`s (1995) model. Measures of function in this model assess the ability of the individual to perform particular defined activities. Pain-related interference with activity is a measure of functional status that is affected by symptom status. Strassels et al. (2002) found that pain-related interference with activity was in the moderate to severe range prior to hospital discharge in this patient group. Pilot data of pain on movement at the study site are consistent with this finding (Wilson et al., 2005). Usual functional activities measured by the Brief Pain Inventory Interference subscale (BPI-I) (Cleeland et al., 1994) included general activity, movement from bed to chair, walking, mood, relationships with others and sleep in this study. As the goal of TKA postoperative care was early mobility (Laskin & Beksac, 2004) and early hospital discharge (Teeny et al., 2005, for example), inclusion of this outcome on the day prior to expect hospital discharge was appropriate.

Characteristics of the individual.

Individual patient characterizes have been related to different educational needs. Educational background (Jacobs-Lawson et al., 2009) and sex (Chang et al., 2005; Watt-Watson et al., 2004) influenced educational needs prior to procedures. Chang et al. (2004) identified differences in concerns requiring education before TKA between women and men. For example, women reported concerns related to pain after surgery more frequently than men in focus groups in this study. Similarly, Watt-Watson et al. (2004) documented that women have more concerns about seeking help with medications for pain (29.1±18.5 versus 22.4±16.2, p=0.002). This is particularly of concern as TKA patients are predominantly female (Furnes et al., 2002; CIHI, 2009).

Influence of the intervention on symptom and functional status.

Consistent with the findings of Johnson et al. (1978) that demonstrated that providing information about symptom sensations and management and postoperative activity before surgery improved pain distress and mood, this trial investigated the impact of a preoperative education program on function and symptom status outcomes. The benefits of educational interventions in orthopedic patients that include pain-related content on postoperative pain outcomes have been documented (Dillon-McDonald et al., 2001; McDonald & Molony, 2004; Sjoling et al., 2003). Reduction in pain has been related to improved knee function after surgery (Capdevila et al., 1999; Cheville, et al., 2001; Eggers et al., 1999; Singelyn et al., 1998; Wang et al., 2002). Support for an individualized approach recommended in systematic reviews of preoperative educational interventions in surgical patients (Johanssen et al., 2005; McDonald et al., 2006; Shuldham, 1999a; 1999b) was found in trials in cancer patients. DeWit et al. (2001) found that fewer patients reported inadequate pain management following an intervention that individualized pain communication and management information.

Rationale for the educational content provided by the individualized intervention was related to findings of other research and established theory. The inclusion of symptom sensation information, pain communication and management, and the importance of maintaining comfort on movement has been found to reduce pain immediately after surgery (Dillon-McDonald et al., 2001; Johnson et al., 1978; McDonald & Molony, 2004; Sjoling et al., 2003). From a theoretical perspective, the basis for providing education supporting pharmacologic pain management strategies is the reduction of noxious inputs peripherally and in the dorsal horn through the inhibition of the transmission of nociceptive input, and activation of descending inhibitory pathways (Bausbaum et al., 2000). Opioids affect messaging of afferent fibers about tissue damage to cells that transmit pain messages to the

brain (Melzack & Wall, 1996). Similarly, the use of non-pharmacologic analgesic strategies (i.e. ice, relaxation) provided in the intervention were designed to activate non-noxious Aβ afferent fibres, facilitating endogenous opioid-peptide production and enhance inhibitory pain response (Fields, 1999; Fields, 1987; Keltner et al., 2006). Overall, the prevention of central sensitization that accompanies the reduction of nociceptive input may reduce the longer term consequences of persistent pain and central nervous system remodeling (Ji et al., 2001; Woolf, 1983).

An additional benefit of preoperative education on pain is related to reduction in anxiety. The reduction of anxiety has been established as an outcome of preoperative educational interventions (Johansson et al., 2005; McDonald et al., 2006). There is a theoretical link related to the contextual nature of pain perception that is influenced by sensory, emotional, motivational and discrimatory elements of an individual's experience (Melzack & Casey, 1968). Modification of symptoms through the reduction of anxiety and addressing personal barriers to the effective use of pre-emptive strategies for pain and nausea were hypothesized to decrease the magnitude of these symptoms.

Early use of anti-emetics to treat opioid related nausea has been shown to be beneficial in postoperative patients (Chen et al., 1998; Parlow et al., 2004). As intrathecal, parenteral and oral opioids are part of usual pain management at the trial site; content related to the use of anti-emetic early in the nausea experience is supported. In addition, baseline nausea risk reduction associated with hypovolemia was addressed through the introduction of daily fluid intake guidelines for patients preoperatively. Maintenance of an euvolemic state prior to surgery was hypothesized to reduce nausea by reducing the vestibular and vagal impact of blood pressure fluctuation secondary to opioid mediated histamine release (Thompson, 1999) and movement (Pusch et al., 2002a; Pusch et al., 2002b).

Educational content that addresses individual concerns about using analgesics and addiction has been shown to reduce the prevalence of these concerns postoperatively (Watt-Watson et al., 2004). The importance of including information about the need for communicating symptom management needs to health care providers was supported by Watt-Watson et al. (2004) with the finding that most patients did not initiate requests for analgesia before being asked.

In summary, the intervention was designed to reduce pain and nausea and the impact of pain on function through early communication of pain and nausea to health care providers, administration of appropriate analgesics and anti-emetics and the use of non-pharmacologic interventions. Educational content that was individualized to address misbeliefs about symptom management and to provide clarification was hypothesized to improve upon results of previous trials that did not include this approach.

Definitions.

Function in the immediate postoperative period is defined as: a) interference with activity related to pain as measured by the Brief Pain Inventory Interference Subscale which includes pain related interference with general activities, sleep, mood, walking, movement from bed to chair, and relations with others and were measured using the Brief Pain Inventory Interference subscale (Cleeland & Ryan, 1994); and, expected activity as measured by the TKA Activity Questionnaire that includes walking specific distances; walking to the bathroom and shower; sitting at the bedside or in a chair; and, attendance at physiotherapy sessions.

Nausea was defined as an unpleasant subjective and sensory experience that is influenced by a number of differing stimuli and may or may not include vomiting (Huether, 2002). Nausea was measured using the Overall Nausea Index (Melzack, 1989).

Pain was defined by the International Association for the Study of Pain as, “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (IASP, 2003). Pain was measured using the Short Form McGill Pain Questionnaire (Melzack, 1987).

Chapter Three

Methods

Purpose

The purpose of this randomized controlled trial was to investigate the impact of an individually delivered pre-operative educational intervention for patients undergoing total knee arthroplasty (TKA). The primary outcome was pain-related interference with activity and secondary outcomes were pain, nausea, expected postoperative activity and analgesic and antiemetic administration in the early postoperative period.

Research questions

Primary research questions.

1. What is the effect of an individualized pre-operative education intervention for TKA patients on pain-related interference with usual activities on postoperative day three?

Secondary research questions.

1. What is the effect of an individualized pre-operative education intervention for TKA patients on expected activity on postoperative days one, two, and three?
2. What is the effect of an individualized pre-operative education intervention for TKA patients on nausea and pain on postoperative days one, two and three?
3. What is the effect of an individualized pre-operative education intervention for TKA patients on analgesic and anti-emetic administration on postoperative days one, two and three?

Additional questions.

1. What is the effect of an individualized pre-operative education intervention for TKA surgical patients on :
    a. intraoperative fluid administration;

b. transfusion during hospital stay; and,

c. length of hospital stay.

Design

A randomized controlled trial design was used to answer the trial research questions. Outcomes were evaluated on the first, second and third days after TKA surgery.

Sample and setting

This trial was conducted at a two-site, academic health sciences centre in Southeastern Ontario. At the time of the trial, this centre was the sole provider of major orthopedic surgical procedures in this area.

Inclusion and exclusion criteria

Patients were included if they:

1. were booked for elective unilateral primary total knee arthroplasty using planned intrathecal (spinal) anesthetic technique;
2. had grade I-II American Society of Anesthesiologists (ASA) Physical Status Classification (Larson, 1996);
3. were able to speak and understand English;
4. were able to be reached by telephone;
5. were planned for home discharge; and
6. consented to participate in this trial.

Patients were excluded if they:

1. were not expected to be discharged home; and,
2. were booked for hemi, revision or bilateral knee arthroplasty.

Recruitment procedure

Ethics approval was obtained from the University of Toronto Research Ethics Board and the Trial Site Teaching Hospitals Research Ethics Board. Recruitment took place at the weekly outpatient orthopedic preadmission testing clinic at a facility affiliated with the trial centre. Potential participants were identified by clinic staff from published operating room booking lists available at the trial site and its affiliated outpatient facility. Inclusion and exclusion criteria for the trial were posted in the clinic to allow staff the opportunity to identify people meeting these trial criteria. Patients were routinely contacted by telephone by Pre-Surgical Screening Centre (PSS) staff to schedule their pre-anesthetic appointment. Eligible patients for this trial were asked for their permission by PSS staff to release their names to the investigator using a standardized script. All patients who agreed were given a detailed verbal and written explanation of the trial during their preadmission appointment by the trial research assistant. Participant rights, confidentiality, and the risks and benefits of participation were reviewed, questions answered and consent signed (Appendix H). All participants received an additional copy of the consent/trial information form detailing investigator contact information, trial purpose and outline.

Manoeuvre

Once the consent form was signed, baseline data including demographic information were collected by the research assistant using the Baseline Demographics Questionnaire (Appendix I). Participants were randomly assigned to the intervention plus usual care group or the usual care group using a randomization service provided by a research program not connected to this trial. This service provided secure randomization without the possibility of manipulation of group assignment. Personnel at the research office used a computer generated block randomization table provided by statistical services. The research assistant called the

research office number, provided the participant number and received group assignment information. Group assignment was recorded on the Baseline Demographics Questionnaire and was stored in a location separate from all postoperative data collection forms. A notice was included on the Anesthetic Record confirming the patient's participation in the trial. The intervention was initiated immediately following randomization for participants in the experimental group in a private room in the pre-surgical screening area.

Data were collected at midday on each of postoperative days one, two and three by one of three research assistants all blinded to group allocation. This time period was chosen to allow measurements of expected postoperative activity to be reflective of usual morning activities including walking a specific distance, transfer from bed to chair as well as attendance at morning physiotherapy. Patients usually attended physiotherapy once on postoperative day one and twice on each of postoperative days two and three. Mobilization and general activity on postoperative day three have been significant clinical predictors of the individual's ability to manage discharge home on the morning of postoperative day four and pain-related interference has been documented to be in the moderate to severe range in TKA patients (Strassels et al., 2002). Pain on movement at the trial site was found to be moderate to severe on days one, two and three in pilot data (Wilson et al., 2005). Data were collected across the three full in-patient days to understand the impact of the intervention on the outcomes of interest in the acute postoperative period. See Figure 2 for Schema of Trial Design.

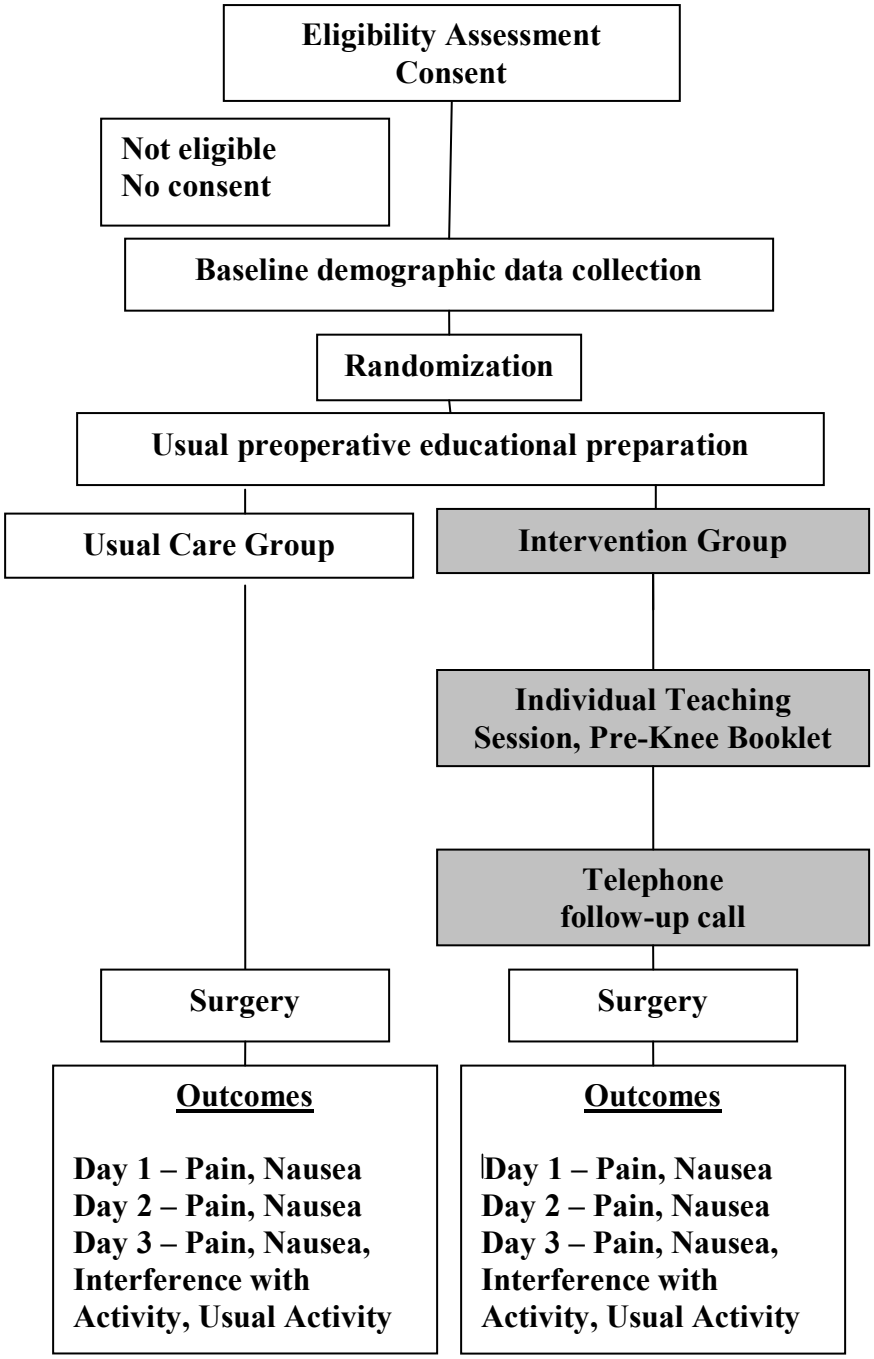


Figure 3. Schema of trial design

Description of usual care

Participants in both groups received usual care. Usual preoperative preparation in the PSS included the following components: an educational session provided by a physiotherapist outlining physiotherapy activities; a 30 minute video explaining the surgical procedure and postoperative orthopedic routines; and, a brief review of the use of PCA-IV by clinic nursing staff. All patients received the following written teaching material that is generic to all postsurgical patient groups: *Pain after surgery: A patient's guide*; and, *About Warfarin: Information for Patients*. An additional booklet, *Elective Knee Arthroplasty: Plan of Care* was also provided. This booklet details the procedure of knee arthroplasty as well as physiotherapy routines and covers issues relating to the physical layout of the in-patient orthopedics unit. Nursing staff do not review this written material provided with patients during this visit. Nursing and clerical staff in the PSS ensure all relevant diagnostic testing is complete and that all specialist consultation is completed if required.

Patients arrived the day of surgery and were admitted to hospital through the Same Day Admission Centre (SDAC). Each was taken directly to the operating room from the SDAC and recovered in the Post-Anesthetic Care Unit (PACU). All patients received intrathecal (spinal) anesthesia and stayed in the PACU until the level of sensory blockade induced by the intrathecal anesthetic was below the umbilicus. Nursing staff in the PACU administered analgesics and anti-emetics intravenously as required and performed sensory block assessments to monitor the rate of sensory return. The usual time for spinal blockade regression was approximately 40 minutes. A proportion of patients also received a single dose of local anesthetic to induce a femoral nerve block prior to leaving the PACU. The effect of this nerve block usually lasted 6-8 hours (Ng et al., 2001). Once the sensory level from the spinal anesthetic receded, PACU patient condition discharge criteria were met and the femoral nerve

block provided, the patient was then discharged by the PACU nursing staff to the in-patient orthopedic care area. Consultation to the Acute Pain Management Service (APMS) was completed in the PACU area and a PCA-IV pump was provided to the patient using morphine or hydromorphone. All patients received PCA-IV teaching by the PACU nursing staff at this time.

Postoperative analgesic management included PCA-IV opioid until the morning of postoperative day two in conjunction with ketoprofen 100 mg PO every twelve hours for two doses until the morning of postoperative day one unless contraindicated. Acetaminophen 650 mg PO was given every four hours until discharge from hospital on the morning of postoperative day four. Oral opioid, administered by the nursing staff when requested (PRN) (e.g. morphine, hydromorphone or oxycodone), replaced the PCA-IV on the morning of postoperative day two. Consistent with published nausea prevention and management guidelines (Gan et al., 2003), all patients who have TKA procedures were followed by the APMS for the first 48 hours and had orders for combination anti-emetic therapy in the perioperative and postoperative settings using routine intravenous ondansetron every eight hours for 24 hours then reassessed and prochlorperazine intravenously for additional nausea.

Activity on the orthopedics unit usually followed the Collaborative Care Plan for Elective Knee Arthroplasty; however; participation in all activities was dependent on the patient's condition. Patients were encouraged by staff to move from bed to chair on the morning of postoperative day one and attend physiotherapy once. On postoperative day two and three, patients are encouraged to move to the chair in both the morning and afternoon prior to transportation to the physiotherapy gymnasium. Patients were assisted to walk on all three days to the bathroom for toileting and bathing. The goal for hospital discharge for patients planning to go home and not to a rehabilitative facility was four days. Hospital length of stay statistics

for the fiscal year 2006 at the trial site showed that although the average length of stay was 6.6 days, the median was 4 days. Again, activity completion and patient condition on the third postoperative day was a key factor in the decision to initiate hospital discharge on the morning of the fourth postoperative day.

Pilot data to support intervention development.

The intervention for this trial focused on important content issues for symptom management after TKA surgery in an individualized approach to meet patient's unique needs. Content use in this intervention is drawn from trials of preoperative education programs in surgical patients (Dillon-McDonald et al., 2001; McDonald et al., 2004; Sjoling et al., 2003; Watt-Watson et al., 2004) and supported by focus groups findings of individual areas of concern for TKA patients (Chang et al., 2005). To ensure concerns found in the literature were consistent with those of TKA patients at the trial site, pilot interviews of ten patients were conducted on day two or three post TKA surgery. Patients were asked to identify potential challenges or areas of concern with the educational content of analgesic and anti-emetic administration and related preoperative fluid consumption. None of the ten patients interviewed had any concerns with an increased need for urination associated with increase fluid consumption. The common concerns that were identified formed the basis for individualizing the intervention content and are provided in Appendix G.

The Pre-Knee Symptom Education intervention

Participants randomized to the experimental group received the intervention in addition to usual preoperative preparation. The Pre-Knee Symptom Education intervention was comprised of three components, the booklet, an individual teaching session and a follow-up support telephone call. The time period between surgery and the face to face intervention varied between 5 days and 4 weeks but previous research found that time frame for

preoperative education did not influence results (Lepczyck et al., 1990) and material was reinforced during the follow-up telephone call in the week prior to surgery. The Pre-Knee Symptom Education Booklet was reviewed with each consenting participant in an individualized teaching session during the preoperative patient visit to the PSS centre. Content provided in the Pre-Knee Symptom Education booklet is outlined in Table 2. The teaching session and booklet review were provided in a quiet examination room. All components were delivered by the investigator during the PSS clinic appointments which was booked within four weeks of surgery.

Table 2.

Pre-Knee Symptom Education Intervention content

Topic	Supporting Evidence
Pain, importance of pain management	Dillon-McDonald et al. (2001); Chang et al. (2005); Johnson et al. (1978); Lin et al. (1997); McDonald et al. (2004); Melzack & Wall (1996); Sjoling et al. (2003); Watt-Watson et al. (2004)
Importance of pain management to promote activity	Dillon-McDonald et al.; Lin et al.; Sjoling et al.; Watt-Watson et al.
Communicating pain to health professionals	Dillon-McDonald et al.; Johnson et al.; McDonald et al.; Sjoling et al.; Watt-Watson et al.
Asking for analgesics	Dillon-McDonald et al.; Johnson et al.; Sjoling et al.; Lin et al.; Watt-Watson et al.
Asking for anti-emetics	Gan et al. (2003); Melzack & Wall
Preventing dehydration (fluids)	Hodgkinson et al. (2003); Phillips, Johnston & Gray (1993)
Misbeliefs about taking medication	Chang et al.; Watt-Watson et al.; Wilson et al. (2005)
Non-pharmacological measures	Melzack & Wall; Watt-Watson et al.

The Pre-Knee Symptom Education Booklet.

The written material in the booklet (Appendix J) provided information on the appropriate use of PCA-IV, oral analgesics, co-analgesics and anti-emetics, strategies for communicating discomfort and nausea to health care professionals as well as tips for movement to decrease activity-induced nausea. In contrast to the generic patient education material provided, the booklet provided information that was specific to TKA postoperative recovery and covered common concerns that people have regarding symptom management after TKA. Communication of pain using numeric rating scales was specifically reviewed and highlighted with participants. Content related to the use of PCA-IV and PRN opioids and anti-emetics focused primarily on encouraging pre-emptive use in the prevention of movement exacerbated pain and nausea. Participants were instructed to use analgesics prior to attempting activities such as transfer from bed to chair and walking to the bathroom. Similarly, requests for anti-emetics were recommended at the first experience of nausea rather than at the point of or after vomiting occur.

The booklet contained hydration information that outlined the recommended daily fluid intake using established guidelines (Hodgkinson, Evans, & Wood, 2003). This section provided the volumes of common commercially prepared and packaged fluids (take-out coffee, pop, juice etc.). As a reminder for the need for fluids, patients were recommended to fill in a chart of their fluid intake the week prior to surgery. The chart also included a section for comments or questions to ask during the telephone follow-up session.

Face and content validity for the Pre-Knee Symptom Education Booklet were examined by 6 experts in orthopedics and pain in nursing, medicine, physiotherapy and pharmacy. Modifications were made to illustrations and layout only. The booklet was pilot tested for readability at the grade 6 level, feasibility and acceptability and for usefulness in a sample of

five TKA in-patients. All patients reported that the booklet was helpful with some editorial and layout changes made in response to comments received.

Individual teaching session.

The investigator reviewed all information contained in the booklet during the individual teaching session. All material from each topic area was reviewed in an interactive manner, eliciting questions and comments throughout. The investigator reinforced the need for good pain control to facilitate activity and the importance of requesting anti-emetics early in the nausea experience. Specific strategies to minimize or prevent pain and nausea were reviewed in detail along with the importance of drinking fluids to maintain appropriate hydration. Methods on how to communicate pain and nausea to caregivers were discussed and the importance of asking for medications when needed was reinforced.

Individualization of educational content was achieved through discussing each participant`s questions and understanding of the information provided. New concerns identified by trial participants as well as strategies presented were recorded on the Individualized Education Content Tool (Appendix J) and used during the follow-up support telephone call. Participants were reminded that the investigator would call them a few days prior to surgery. They were encouraged to record any subsequent questions that arose at home in the space provided in the booklet to discuss during the follow-up support telephone call.

Follow-up support telephone call.

Participants in the intervention group received a follow-up support telephone call during the week prior to their booked surgical date. During this call, participants were asked if they had reviewed the booklet and if they had any questions or comments related to the information provided. Participant's individual topic areas recorded during the teaching session were reviewed and appropriate strategies were reinforced. All were reminded that the trial

research assistant would be collecting information about their activity, pain and nausea after surgery.

Instruments

Baseline demographic data were collected during the preadmission visit prior to surgery. Post-surgical data were collected on days one, two and three between 1100 and 1300 hours to ensure measurements were reflective of mobilization activity, routine in the TKA population. The primary outcome, pain related interference with activity, was measured on day three only. Secondary outcomes of expected postoperative activity, pain and nausea were measured on days one, two and three and days one and two respectively. Data collection commenced January 2008 and was completed in June 2009, an 18 month period.

Summary of instruments.

Table 3 summarizes the trial instruments according to outcome and timing.

Table 3.

Summary of instruments and measurement times

Outcome Measure	Instrument
Baseline Demographic Information *Preoperative*	Baseline Demographics Questionnaire (BDQ)
Primary Outcome	
Day 3: Pain-related interference with activity	BPI-I
Secondary Outcomes	
Day 1: Pain	MPQ-SF
Nausea	ONI
Day 2: Pain	MPQ-SF
Nausea	ONI
Day 3: Pain	MPQ-SF
Nausea	ONI
Expected Postoperative Activity	TKA Activity Questionnaire
Analgesic and Antiemetic administration	Surgical Information Questionnaire

Baseline demographic information

Demographic characteristics and clinical information were collected from each consenting participant prior to randomization. Age, sex, preoperative orthopedic diagnosis, analgesic history and information regarding comorbid conditions were elicited using the BDQ (Appendix I).

Primary outcome

Pain related interference with activity on postoperative day three.

Pain interference was measured using the Brief Pain Inventory, Interference (BPI-I) subscale on postoperative day three (Cleeland et al., 1994). The construct validity and feasibility of use for modified versions of the BPI-I have been well established in several groups of postsurgical patients including coronary artery bypass graft patients (Mendoza et al., 2004b; Mendoza et al., 2004a; Watt-Watson et al., 2004) and those patients with arthritis (Tan, Jensen, Thornby, & Shanti, 2004). The Brief Pain Inventory Short Form (BPI-SF) that contains the BPI-I has well established construct validity (Caraceni et al., 2002; Daut, Cleeland, & Flannery, 1983; Keller et al., 2004; Lai et al., 2004; Tan et al., 2004). Psychometric testing of post-operative use of the BPI-SF demonstrates two factor structure consistency between acute and chronic pain states (Mendoza et al., 2004b; Mendoza et al., 2004a; Watt-Watson et al., 2004; Zalon, 1999) as well as sensitivity to change (Mendoza et al., 2004a) and sex differences (Watt-Watson et al., 2004). Construct validity of the BPI-SF in TKA patients can be generalized both from that established in surgical and arthritis patient populations. The use of the BPI-I in the immediate postoperative period (Zalon, 1997) and beyond post-operative day three has been demonstrated (Mendoza et al., 2004a; Watt-Watson et al., 2004). Use of a measure that addresses the impact pain has on activities is appropriate in this population where goals include early mobilization and activity. In addition, use of this measure with TKA

patients on the day prior to hospital discharge has documented moderate to severe pain-related interference with activity (Strassels et al., 2002).

Two items were deleted; 'normal work' and 'enjoyment of life' as these items were not relevant to the early post-operative period. Items modified in the BPI-I in these studies are relevant to the TKA population. The addition of one item addressing the activity of transferring from bed to chair was added and the modified tool was pilot tested on the third postoperative day in a group of TKA patients (N=14). The additional item, transferring from bed to chair, was easily answered by all participants and similarly judged to be an appropriate item for the administration time. Similar adaptation of the BPI-I items in a study by Watt-Watson et al. (2004) where both 'normal work' and 'enjoyment of life' were deleted and 'deep breathing and coughing' was inserted for use in a postoperative patient population. Chronbach's alpha for this change was reported as 0.71.

The modified BPI-I provided a total score of 0-60 through adding together the six numeric rating scale (NRS) (0-10) scores. The NRS address the degree to which pain interferes with general activities, sleep, mood, walking, transferring from bed to chair and relations with others. The anchors for the NRS items in the BPI-I are 'does not interfere' (0) and 'completely interferes' (10).

Secondary outcomes

Pain.

Pain and pain quality were measured using the Short Form McGill Pain Questionnaire (MPQ-SF) (Melzack, 1987). The MPQ-SF included the Pain Rating Index (PRI), the Present Pain Intensity (PPI) and a Visual Analogue Scale (VAS) for pain rating. The PRI measured pain quality using15 descriptors of both sensory (n=11) and affective (n=4) dimensions. Each adjective that was chosen by patients was ranked on a severity scale from 0= none to 3= severe

(Jensen & Karoly, 2001). Individual PRI subscales were summed to obtain scores for sensory (PRI-S), affective (PRI-A) and total (PRI-T) of 0-33, 0-12 and 0-45 respectively. The PPI was also included as a global pain measure. The PPI included five items that were summed for a total score of zero to five: no pain (0); mild (1); discomforting (2); distressing (3); horrible (4); and, excruciating (5).

Reliability and validity of the MPQ-SF has been well established (Melzack, Abbott, Zackon, Mulder, & Davis, 1987; Melzack, 1987). The MPQ-SF has a high degree of correlation with the major dimensions (sensory, affective, total) of the original MPQ (Melzack et al., 1987) and has demonstrated sensitivity to change in acute and chronic pain interventions. In elderly arthritic patients, the MPQ-SF has been shown to have high internal consistency and intercorrelations (Gagliese & Melzack, 1997; Gagliese & Katz, 2003). This measure takes two to five minutes to complete. Comprehension of items and feasibility of patient completion or assisted completion will be assessed by the investigator during pilot testing of this measure using the trial population.

The NRS was used to rate pain instead of the VAS component of the MPQ-SF. The NRS asked patients to rate their pain from zero to ten where zero equals no pain and 10 is the worst pain possible (Jensen et al., 2001). The NRS has been correlated with VAS pain ratings and found to be easier for older adults to use and has been associated with fewer errors (Gagliese & Melzack, 1997; Jensen, Karoly, & Braver, 1986). As well, the NRS required no special materials and could be used in any clinical setting (Jensen et al.). Patients were asked to rate the pain they had at the time of the interview at rest and with movement. Patients were also asked to rate their worst pain on movement in the previous 24 hours. The MPQ-SF was administered on each of postoperative days one two and three between 1100 and 1300.

Nausea.

Nausea was measured using the Overall Nausea Index (ONI) one component of the Nausea Questionnaire (NQ) (Melzack, 1989) on each of postoperative days one, two and three. The ONI was a six point scale with the following verbal descriptors: No nausea (0); mild (1); discomforting (2); distressing (3); horrible (4); and, excruciating (5). Scoring of the ONI is expressed as a value out of five (Melzack, 1989).

Initial reliability and validity testing of the NQ was done using a sample of chemotherapy patients (Melzack, Rosberger, Hollingsworth, & Thirlwell, 1985). All three indices of the NQ were significantly correlated with physician and nurse estimates of ONI scores and demonstrated the ability to detect a significant difference between patients receiving two different chemotherapy medications (Melzack et al., 1985). The ONI has been used successfully in postoperative populations, demonstrating the ability to detect a difference between the effect of two different anti-emetic medications (Parlow et al., 2004). Sensitivity to change for all components of the NQ has also been established in the perinatal population (Lacroix, Eason, & Melzack, 2000). Nausea was measured between 1100 and 1300 on each of postoperative days one and two at the same time pain measurements were taken to ensure the representation of nausea on movement and at rest. Although pilot data demonstrated 48 hour duration of nausea, measurements were taken on all three post-operative days to determine if nausea was present to any degree on the day prior to expected hospital discharge.

Analgesic and antiemetic administration.

Data for the secondary outcome measures of anti-emetic and opioid administration were recorded from the chart for each of postoperative days one to three using the Surgical and Postoperative Information Questionnaire (Appendix L). Doses were calculated for a 24 hour period using PACU admission time as an anchor. For example, if the PACU admission time

was 1700 hours, antiemetic and opioid administration was calculated from 1700 until 1700 the following day. Opioid analgesic administration data were expressed in oral morphine equivalents (see Appendix O for Opioid Equianalgesia Conversion table). Opioid equianalgesia conversions used in the data analysis were consistent with current practice at the study site.

Expected postoperative activity.

The TKA Activity Questionnaire (TKA-AQ) (Appendix M) was developed by the investigator based on usual post-operative activity protocol in the trial centre. The TKA-AQ contains expected activity items relating to bed-to-chair transfers, physiotherapy attendance, walking, toileting, showering and sitting in the chair/side of bed for meals. These items were based on the set of activities provided in the Collaborative Care Plan for TKA that was previously developed by a team of clinical experts from nursing, medicine, pharmacy, physiotherapy, occupational therapy and social work and used at the trial centre for all primary TKA patients. On postoperative days 1, 2 and 3, between 1100 and 1300, the RA obtained data from the patients about activities completed using the AQ. Scoring of the TKA Activity Questionnaire was calculated as a proportion of activities completed by day and in total. Day one had four items and days two and three had six items each for a total of 16 items.

Additional questions.

Information about hospital length of stay, intraoperative fluid administration, estimated intraoperative blood loss, surgery length and transfusion requirement were collected using the Surgical and Post-operative Information Questionnaire (Appendix L). Hospital length of stay was determined by review of the participant electronic record and was dichotomized to reflect achievement of usual length of stay (4 days) versus longer than usual.

Ethical considerations

Participants were assigned a trial identification number. All contact information was kept in a locked cabinet. Only the trial investigator had access to the master list of participant names and numbers. All data will be destroyed after seven years.

Risks and benefits

The trial intervention was an addition to what is usual postoperative care for the TKA patient population. There were no anticipated risks to participants. No adverse effects occurred that were related to the intervention provided in this trial. Patients in the intervention group may have benefited from an enhanced level of education toward improving the recovery from this procedure. All patients may have potentially benefited from gaining a sense of satisfaction in participating in clinical research and assisting the larger postoperative patient population.

Data analysis

Results were analyzed using an intention to treat approach. As a result, all participants randomized were entered into the analyses to prevent bias introduced by including only participants compliant with the trial protocol. Baseline data were analyzed using descriptive statistics. Descriptive statistics, including mean, median and standard deviation, were used to provide a summary of the data at all collection points. A two-tailed level of significance of 0.05 was used for all analyses. Data were analyzed using the SPSS/PASW software package, version 18.

Primary outcome: Pain related interference with activity on postoperative day three.

Independent samples t-test was used to determine differences in pain-related interference with activity between the intervention and usual care groups on postoperative day three on total and component scores.

Secondary outcomes: Pain, nausea, anti-emetic and analgesic administration and postoperative activity.

Repeated measures ANOVA was used to determine differences between groups and over the measurement periods in pain scores (MPQ-SF, NRS questions), nausea scores (ONI), and total 24 hour analgesic administration. Differences in anti-emetic administration between the two groups were determined using Chi Square. Linear by Linear Chi Square was also used to detect differences in frequency of postoperative activities completed (TKA-AQ). Separate analyses were conducted using participants rating moderate to severe worst pain and nausea [scores of 4 to 10 (Jones et al., 2005)] in the last 24 hours with anti-emetic and analgesic administration.

Additional questions.

Chi Square was used to determine if a difference in the use of transfusion existed between the intervention and usual care groups. An independent samples t-test was used to detect a difference in intraoperative fluids administered. Length of stay was dichotomized as usual (up to four days) or longer than usual and analyzed using Chi Square to detect a difference between the two groups.

Data management.

All data were entered by the research assistant (RA) into a database developed using Microsoft® Access 2002 (Microsoft Corporation 1992-2001) for data management purposes. Duplicate data entry was performed in a second database by a second RA for accuracy monitoring purposes. The duplicate databases were compared for accuracy and adjusted as required. Logic and range checks were performed for all continuous variables (i.e. numeric rating scales) by using validation rules and look-up tables programmed into in the database structure.

Data entry forms were developed in Microsoft® Access 2002 (Microsoft Corporation 1992-2001) for data entry of each measurement tool into the database. These forms were available on a shared, password protected file accessible only by the RA and investigator.

The trial database was backed-up daily onto a second password protected hard drive as well as a portable storage device (i.e. USB Mass Storage Device) located in a separate, locked facility. When the database was complete, the investigator transferred the data to a series of working files for use in statistical analyses to maintain the integrity of the original complete database. All questionnaires, databases, coding information and access codes are kept in a locked file cabinet accessible only by the trial investigator.

Monitoring compliance

Individualization of the intervention and the reinforcement provided along with the telephone follow-up support call served as reminders for education content and suggested activities.

Contamination

Although participants were not blinded to the intervention, the research assistants collecting trial outcome data were blinded to group assignment. All preoperative data collected were kept in a sealed envelope in a separate location from outcome data collection forms in an area not accessible by the research assistants. Intervention components delivered in the PSS Centre were delivered in an area that was physically separate from the usual care areas. Participants in the intervention group were asked not to share trial materials, written or verbal, with other patients. The teaching session and provision of the Pre-Knee Symptom Education Booklet occurred after all usual nursing care activities were completed. Participants had left the communal waiting area at this stage and stayed in individual rooms for the remainder of the PSS visit. This reduced the possibility of contact with participants in the usual care group. The

investigator (as the provider of the intervention) did not participate in the postoperative care of any participant.

Co-intervention

All participants received the usual preoperative educational preparation and usual postoperative care. All usual nursing preoperative preparation was completed prior to intervention delivery. It was not expected that any further contact for the purposes of education by Pre-Surgical Screening staff would occur for participants in either group..

The use of femoral nerve blockade using local anesthetics in some participants may impact postoperative pain and analgesic administration; however; randomization was expected to neutralize the effect of this co-intervention on trial outcomes.

Loss to follow-up

The majority of participants enrolled in this trial and randomized had booked surgery dates. Some surgery dates were altered following the delivery of the intervention, monitoring of operating room booking schedules by the trial RAs ensured dates remained accurate. Loss to follow-up in the postoperative period was minimal (n=3) as all participants remained in hospital for the duration of the data collection period.

All outcome data were collected by the trial research assistants during a face to face interview or data abstraction and as a result, missing questionnaire data were related only to the physical condition of the participant preventing measure completion. Some data were missing on abstraction from the Anesthetic Record; intraoperative fluids administered were not consistently documented.

Sample size

Sample size for this trial was based on group means from another study (N=406) using the BPI-I as a primary outcome. Watt-Watson et al. (2004) measured pain related interference

with activity on day three post-coronary artery bypass graft surgery. Mean BPI-I total scores for this measurement were 16.55±11.88 and 16.06±12.35 for usual care and intervention groups respectively. Although the standard deviation in pilot data for this measure in TKA patients (n=14) is smaller, use of the larger figures provides a more conservative sample size. Using an moderate effect size of 0.5 based on between standard deviation and within standard deviation (Cohen, 1988), the sample size required was 64 per arm (alpha=0.05, power=80%). Use of a moderate effect size was employed as there no studies addressing the size of a clinically significant change in pain-related interference with activity. A reduction of half the standard deviation of the general population, as reported by Watt-Watson et al., is a reasonable estimate of the clinically important effect of this intervention.

Minimal trial attrition was expected as all measurements were taken during the in-patient hospital stay. A conservative estimate of 10% was used. As a result the sample size required for this trial was 140 in total with an alpha level of 0.05 and power of 0.80.

Chapter Four

Results

Results of this trial are presented in this chapter and include a description of the sample, an outline of the implementation of the intervention and an analysis of the primary, secondary and additional research questions.

Sample

Participant flow through the trial is presented in Figure 3. Three hundred and thirty seven patients were screened for participation in this trial. Of these, 175 did not meet eligibility criteria secondary to planned general anesthetic technique, American Society of Anesthesiologists (ASA) Physical Status Classification of unstable comorbid disease and/or booking for hemi, revision or bilateral knee arthroplasty. A small number of patients who were eligible (n=19) declined participation in the trial. Of these, most cited study fatigue as the primary reason for not participating (n=13), several reported anxiety as a factor (n=5), and one felt strongly about the possibility of being randomized to the usual care group and declined to participate. One hundred and forty three patients were enrolled in this trial.

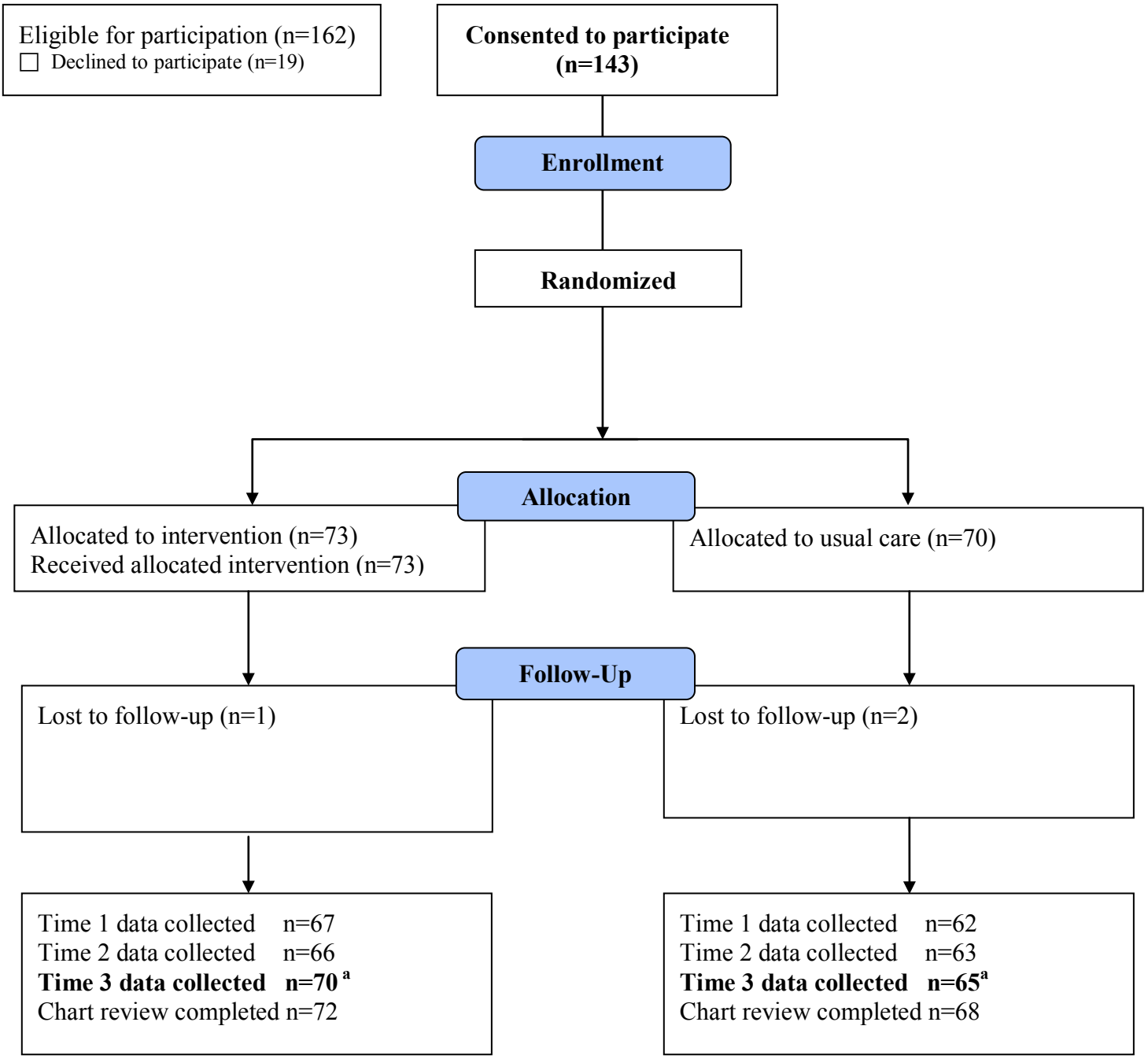


Figure 4. Flow of participants through the trial
[a] Primary outcome

Randomization.

One hundred and forty three participants were randomized following baseline demographic data collection in the pre-admission phase of surgery preparation. One participant in the usual care group did not meet eligibility criteria at the time of surgery as a result of a change of procedure type (bilateral versus unilateral knee arthroplasty) and one participant in each group had the procedure cancelled indefinitely. As a result, the total number for the analysis of baseline characteristics was 143 and 140 for postoperative outcomes.

Attrition.

No participants withdrew from the trial during data collection. Some individual participants were unable to complete questionnaires with the research assistant at one or two data collection periods as a result of sedation or other medical conditions. One participant had a cerebrovascular incident on post-operative day one and as such was unable to complete day two and three measures. Primary outcome data collection was completed on 70 participants in the intervention group and 65 participants in the usual care group.

Baseline characteristics

Baseline demographic data were collected using the self-report Baseline Demographic Questionnaire (Appendix I) and are included in Table 4. The majority of the participants in both groups was female and lived with a partner or family member; 20% of participants in each group lived alone. The mean age of each of the usual care and intervention groups was 67±8 and 66±8 years respectively. The groups were distributed fairly evenly between educational categories of less than high school and completed post-secondary education with 47% of the intervention group and 52% of the usual care group reporting less than high school education. Osteoarthritis was the most common diagnosis for surgery (usual care n=67, 96%; intervention n=70, 96%) and approximately one third of each group required opioid analgesics for pain

management pre-operatively (usual care n=24, 35%; intervention n=21, 29%). Participants who had no other health conditions represented over one third of the sample (usual care n=24, 35%; intervention n=32, 44%). The most common other health condition reported was hypertension (usual care n=31, 44%; intervention n=29, 40%). All other health conditions reported are consistent with American Society of Anesthesiologists I and II classifications of healthy individuals or those with mild systemic disease respectively (Larson, 2007).

Table 4.

Baseline demographics of participants

Demographics	*Intervention (n=73)*	*Usual Care (n=70)*
	n(%)	*n(%)*
Sex		
Female	46(63)	43(61)
Male	27(37)	27(39)
Home status		
Live alone	13(18)	15(21)
Highest education level		
Less than high school	34(47)	36(51)
High school	0	0
Post-secondary	39(53)	34(49)
Home pain medication		
None	13(18)	18(26)
Opioid	21(29)	24(34)
Non-opioid	39(53)	28(40)
Preoperative diagnosis		
Osteoarthritis	70(96)	67(96)
Rheumatoid arthritis	3(4)	3(4)

Intervention

The intervention consisted of a twenty minute individualized education session with the investigator immediately following baseline data collection and randomization, a booklet for review and a follow-up telephone call from the investigator in the week prior to surgery. All

but one of the participants in the intervention group received the education session in the PSS centre during the usual pre-surgical screening visit. One participant received the session at a later date during a subsequent appointment as a result of some diagnostic testing scheduling difficulties. All participants in this group received the educational booklet (Appendix J) immediately following randomization at the start of the individualized education session and the content of the booklet was reviewed. Topics covered followed the content template developed for this trial (Appendix K). Follow-up telephone call contact was made with 65 of the 72 participants in the week prior to surgery. Messages were left as necessary and time for a follow-up call was recommended or number left for return call. Participants missed the telephone call as a result of last minute surgery time change (n=4) or were unable to be reached (n=3).

Participants were encouraged to ask questions about the material provided. Their questions were focused on a) use of the PCA-IV pump, b) concerns about the adverse effects of opioid analgesics, c) physiotherapy timing, d) home discharge analgesia, and e) pre-surgical fasting guidelines and information regarding oral fluid intake. All information provided during the educational session was reinforced during the follow-up telephone call and participants were again encouraged to ask questions and pre-surgical fasting guidelines were reinforced. Calls lasted approximately ten minutes. All participants indicated that they had read the booklet.

Primary research question

The primary research question for this trial was: *What is the effect of an individualized pre-operative education intervention for TKA patients on pain-related interference with usual activities on postoperative day three?* The impact of the intervention on pain related

interference with activity was measured using a modified form of the Brief Pain Inventory-Interference subscale (BPI-I).

Day three measurements of the BPI-I are presented in Table 5. The six items were rated on a scale of 0-10 with higher scores representing greater pain-related interference; total interference subscale score was out of 60. Total scores for the usual care group (22.4±15.1) and the intervention group (24.4±14.4) were not significantly different (P=0.45). Independent sample t-tests were non-significant for all BPI-I items. Highest interference scores for both groups at day three were in the moderate range and included, General Activity (usual care: 5.6±3.2; intervention: 5.8±3.2) and Transfer from Bed to Chair (usual care: 5.0±3.4; intervention: 4.6±2.9). It is important to note that these pain-related interference scores were measured on the third postoperative day, one day prior to the expected discharge date for this group of patients.

Table 5.

Pain related interference with activity on postoperative day three

	Intervention (*n*=70) *M*(*SD*)	Usual Care (*n*=65) *M*(*SD*)
Interference scores		
BPI-I		
Total (scores 0-60) [a]	24.4(14.4)	22.4 (15.1)
Subscales (scores 0-10)		
General Activity	5.6 (3.2)	5.8 (3.2)
Walking	4.8 (3.0)	4.4 (3.5)
Mood	3.3 (3.2)	2.4 (3.2)
Transfer from bed to chair	4.8 (2.9)	5.0 (3.4)
Sleep	3.8 (3.5)	3.3 (3.1)
Relationships with others	1.9 (2.9)	1.6 (2.7)

Note: BPI-I = Brief Pain Inventory – Interference
[a] *t*=-0.76: p=0.45

Secondary research questions

Secondary research questions for this trial was: *What is the effect of an individualized pre-operative education intervention for TKA patients on: expected activities; pain and nausea; and, analgesic and anti-emetic administration on postoperative days one, two, and three?*

Expected postoperative activities.

Activity items were assessed using the TKA Activity Questionnaire (TKA-AQ) (Appendix M) and administered orally by the RA. Table 6 summarizes the frequency of activities completed by participants on each postoperative day. Using Chi Square for each item, none of the items

Table 6.

Frequency of participants completing expected activities on days one, two and three

	Intervention (n=72) n(%)	Usual Care (n=68) n(%)
Postoperative day one		
Up in chair	52(72)	50(74)
Physiotherapy	53(74)	46(68)
Walk 5-10 feet	38(53)	39(57)
Up to bathroom	23(32)	24(35)
Postoperative day two		
Up in chair, morning	61(85)	58(85)
Physiotherapy	62(86)	51(75)
Up in chair, afternoon	46(64)	50(74)
Physiotherapy	37(51)	40(59)
Walk 10-15 feet	60(83)	51(75)
Up to bathroom	45(63)	37(54)
Postoperative day three		
Up in chair, morning	56(78)	49(72)
Physiotherapy	61(85)	56(82)
Up in chair, afternoon	58(81)	52(76)
Walk 20-40 feet	61(85)	51(75)
Shower with assistance	39(54)	27(40)
Up to bathroom	50(70)	48(71)

of the TKA-AQ was significantly different between groups. On postoperative day three, only 38% of the intervention group and 25% of the usual care group participants had engaged in all six of the expected activities for that day (Table 7). Approximately half of each group missed at least one activity per day (intervention group, 56%; usual care group, 44%). Twenty-five percent of the usual care group and 15% of the intervention group did not walk 20-40 feet and 29% and 30% respectively did not get up to the bathroom independently on the day before expected discharge from hospital. Overall, only 4% of the intervention group and 6% of the usual care group completed all activities on all three days and 8% and 7% did not complete any of the activities respectively. Across both groups, 25% (n=35) did not get up to the chair in the morning, 22% (n=31) could not walk the prescribed distance, 32% (n=45) were unable to walk to the bathroom independently on postoperative day three.

Table 7.

Frequency of participants completing expected activities by day[a]

	Intervention (n=72) n(%)	Usual Care (n=68) n(%)
Postoperative day one [b]		
All activities (4/4)	17(24)	17(25)
Some activities (1-3/4)	42(58)	34(50)
No activities (0/4)	13(18)	17(25)
Postoperative day two [c]		
All activities (6/6)	23(32)	22(32)
Some activities (1-5/6)	42(58)	40(59)
No activities (0/6)	7(10)	6(11)
Postoperative day three [d]		
All activities (6/6)	27(38)	17(25)
Some activities (1-5/6)	39(54)	44(65)
No activities (0/6)	6(8)	7(10)

Note: [a] includes physiotherapy
[b] X^2=0.24, p=0.63
[c] X^2=0.02, p=0.90
[d] X^2=2.03, p=0.15

Nausea.

The impact of the intervention on nausea was measured using the six-point Overall Nausea Index (ONI). The ONI measures nausea in the last twenty four hours on a six point intensity scale, with zero being no nausea and five being worst nausea. Frequency of participants reporting moderate to severe nausea (scores of 2-5) are reported in Table 8. There was no difference between groups in nausea scores (previous 24 hours) over time (F=0.02; p=0.88);

however, there was a difference within groups in nausea scores (previous 24 hours) over time ($F=50.9$; $p<0.01$) with nausea decreasing over the three day period.

Table 8.

Frequency of participants who reported moderate to severe nausea on postoperative days one, two and three

Moderate to severe nausea in last 24 hours	Intervention n(%)	Usual Care n(%)
ONI (3-5/5)		
Postoperative Day		
One [a]	31(46)	33(53)
Two [b]	22(33)	30(48)
Three [c]	19(28)	15(24)

[a] $X^2=0.6$, $p=0.43$
[b] $X^2=2.7$, $p=0.1$
[c] $X^2=0.4$, $p=0.5$

Non-parametric analysis of those reporting moderate to severe nausea on each of the three days was similarly non-significant. The frequency of participants in each group reporting moderate to severe nausea on the day prior to expected hospital discharge (postoperative day three) was 28% of the intervention group and 24% of the usual care group. Analysis of participants reporting moderate to severe nausea and commensurate antiemetic use is reported later in this chapter.

Pain.

Postoperative pain was measured using the Short Form McGill Pain Questionnaire (MPQ-SF) (Appendix J) on each of postoperative days one, two and three. The MPQ-SF is comprised of a Pain Rating Index (PRI), 15 descriptors each on an scale of 4 points (0-3), pain

Numeric Rating Scales [NRS(0-10)] for rest pain, pain on movement and worst pain and one six-point global pain rating scale, Present Pain Intensity (PPI). The PRI scores were divided into sensory [PRI-S(0-33)], affective [PRI-A(0-12)] and total dimensions [PRI-T (0-45)]. Means and standard deviations for the NRS, PRI-S, PRI-A, PRI-T and PPI are reported in Tables 9, 10 and 11 respectively.

The frequency of participants in each group reporting moderate to severe, worst pain ratings of each descriptor is described in Appendix N. There were no significant group differences on any of the three postoperative days in either pain right now at rest, pain now with movement or worst pain in last 24 hours. There was however, a significant effect for time in pain right now at rest ($p=0.0002$) and worst pain last 24 hours ($p=0.013$), with pain decreasing over time but not for the item, pain right now when moving ($p=0.06$). Similarly, there was a significant effect for time in the PPI global pain rating (0-5) ($p=0.001$) but no group difference across time ($p=0.70$). As with the NRS and PPI, there was a significant effect of time for both the PRI-S ($p=0.02$), the PRI-A ($p=0.05$) and the PRI-T ($p=0.02$), but there were no significant group differences across the three measurement times. Across both groups, the average rating of worst pain in the last 24 hours was 7±2.4; in the severe range on each of the three postoperative days. Seventy three percent of the total sample reported moderate to severe pain on movement on day three while 81% of the sample reported having experienced moderate to severe pain in the last 24 hours.

The most frequent descriptors rated as moderate to severe by participants on all three postoperative days were aching, heavy and tender, used by approximately one third of participants in each group. Punishing-cruel was also moderate to severe for 13 participants on days one and two and 11 participants on day three. The descriptor ‘sickening’ was also rated as moderate to severe by 17% (n=22) of the total sample on postoperative day one. Additionally,

the proportion of participants in both groups rating global pain with the PPI as either distressing (3/5), horrible (4/5) or excruciating (5/5) was 30% on day one, 17% on day two and 16% on day three.

Table 9.

Pain on postoperative days one, two and three

NRS (0-10)	Intervention (n=62) M (*SD*)	Usual Care (n=55) M (*SD*)
Pain right now at rest [a]		
Postoperative Day		
One	4.1(2.9)	3.7(2.8)
Two	3.3(3.0)	2.9(2.2)
Three	2.8(2.5)	2.8(2.7)
Pain right now when moving [b]		
Postoperative Day		
One	6.4(2.6)	6.4(2.7)
Two	6.2(2.8)	5.9(2.4)
Three	5.4(3.0)	6.1(2.5)
Worst pain last 24 hours [c]		
Postoperative Day		
One	7.5(2.5)	7.2(2.8)
Two	7.7(2.4)	7.5(2.1)
Three	7.0(2.4)	7.0(2.3)

Note: NRS = Numeric Rating Scale
[a] F=0.36, p=0.70
[b] F=1.61, p=0.20
[c] F=0.14, p=0.87

Table 10.

Sensory (PRI-S), Affective (PRI-A) and Total (PRI-T) dimensions, MPQ-SF

	Intervention (*n*=66) *M* (*SD*)	Usual Care (*n*=59) *M* (*SD*)
PRI-S (0-33)		
Postoperative Day [a]		
One	6.6(6.1)	6.7(5.4)
Two	5.7(5.9)	4.9(4.5)
Three	4.9(5.1)	6.0(6.9)
PRI-A (0-12)		
Postoperative Day [b]		
One	2.3(2.8)	1.9(2.4)
Two	2.3(3.2)	1.3(2.2)
Three	1.6(2.9)	1.7(2.7)
PRI-T (0-45)		
Postoperative Day [c]		
One	8.9(8.3)	8.6(7.1)
Two	7.9(8.7)	6.2(5.9)
Three	6.5(7.0)	7.7(9.4)

[a] F=0.001, p=0.98
[b] F=1.21, p=0.27
[c] F=0.89, p=0.74

Table 11.

Present Pain Intensity (PPI) Ratings, MPQ-SF

	Intervention (*n*=66) *M* (*SD*)	Usual Care (*n*=59) *M* (*SD*)
PPI (0-5)		
Postoperative Day [a]		
One	1.9(1.3)	1.9(1.2)
Two	1.8(1.1)	1.7(0.8)
Three	1.4(1.5)	1.6(1.3)

[a] F=0.15, p=0.70

Analgesic and antiemetic administration.

Opioid analgesic administration over postoperative days one, two and three was collected using participant paper chart review and presented in oral morphine equivalents. PCA-IV opioids prescribed for participants were morphine (82%) and hydromorphone (18%). Oral opioids prescribed on day three were morphine, hydromorphone or oxycodone (67%, 14% and 18% of participants respectively) and one participant received oral codeine. The equianalgesia conversion table for opioids used in these calculations can be found in Appendix O. Four outliers were found in the data from the usual care group and one in the intervention group, affecting the means and standard deviation in both groups on all three postoperative days. As a result, median and interquartile ranges (IQR) are presented rather than means and standard deviations and can be found in Table 12. Repeated measures analysis of variance demonstrated a significant main effect for time as total analgesic administration in both groups declined over the three postoperative days (F=36.1, p=0.000). However, there was no difference between the groups over the three days (F=0.99, p=0.36). Removal of the outliers and reanalysis of the data did not materially change the results. There was a significant effect between postoperative days

in terms of opioid analgesic use. Opioid analgesic administration in patients reporting moderate to severe pain shows a similar trend toward declining use over time, despite a consistent report of moderate to severe pain on each day.

Overall, there were 7 participants who did not receive any opioid analgesic doses on postoperative day three; two of these participants did not receive any doses on postoperative day two. One participant did not receive even one dose of opioid over the three day period.

Table 12.

Total opioid analgesic administration in milligrams of oral morphine equivalents for 24 hours on each of the three day trial period

	Intervention (n=72) Median(IQR)	Usual Care (n=68) Median(IQR)
Postoperative day		
One	78(69)	78(87)
Two	62(65)	56(55)
Three	40(45)	40(42)

Anti-emetic administration was also recorded using participant paper chart review. Although there was a trend toward a lower mean number of total anti-emetic doses in the intervention group (1.0±0.2 versus 1.5±0.2, p=0.08), when dichotomized to none or at least one antiemetic dose (Table 13), the trend was no longer apparent (X^2=0.80, p=0.37). Overall, 79 participants were administered at least one dose of antiemetic over the three-day trial period.

Table 13.

Frequency of participations who received at least one anti-emetic dose over the three day trial period

	Intervention (n=72) n(%)	Usual Care (n=68) n(%)
All participants [a]	38(53)	41(60)

[a] $X^2=0.80$, $p=0.37$

There was variability in the number of antiemetic doses received by those participants reporting moderate to severe nausea in the previous 24 hours. For example, 29% of participants in the intervention group and 25% in the usual care group who reported moderate to severe nausea on the first postoperative day received no anti-emetics in the previous 24 hour period. Seventeen percent of participants in each group who reported either no or mild nausea in the previous 24 hours, received at least one dose of antiemetic during the same time period. Routine dosing protocol ordered for all participants reporting even mild nausea involves the administration of three doses of one prescribed antiemetic (ondansetron), but very few participants reporting moderate to severe nausea in the intervention and usual care groups received three doses on any of the three postoperative days (16%, 0%, 13% and 10%, 0%, 0% respectively).

Additional research questions.

The Surgical Information Questionnaire (SIQ) was again used to answer the following question: *What is the effect of an individualized pre-operative education intervention for TKA surgical patients on: intraoperative fluid administration; transfusion; and, length of hospital stay?*

Intraoperative fluid administration, transfusion and length of hospital stay were measured using participant paper and electronic chart review. There were no significant differences in any of these variables between groups. Intraoperative fluid administration was not documented in the paper chart in 10% of cases in the intervention group and 8% of cases in the usual care group. The range in volume of fluids administered intraoperatively was 600 mL to 3000 mL across both groups. There was a trend toward a lower transfusion frequency (11.1% versus 20.6%, p=.12) and shorter mean length of hospital stay (3.7±1.6 versus 4.5±3.0 days, p=0.06) in the intervention group compared to usual care. Means and standard deviations for intraoperative fluids administered and transfusion are presented in Tables 14 and 15. The trend toward shorter length of stay in the intervention group was not apparent when this variable was grouped in consideration of expected length of stay (Table 16). Participants who were transfused tended to have a longer length of stay with 75% of those transfused in the intervention group and 64% in the usual care group staying longer than the expected four days postoperatively.

Table 14.

Intraoperative fluids administered

	Intervention (*n*=65) *M* (*SD*)	Usual Care (*n*=63) *M* (*SD*)
Total intraoperative administration of fluids (mL) [a]	1878(509)	1703(507)

[a] *t*=-1.12, p=0.27

Table 15.

Transfusions on postoperative days one to three

	Intervention (n=72) n(%)	Usual Care (n=68) n(%)
Total number of participants requiring transfusion [a]	8(11)	14(21)

[a] $X^2 = 2.4$, p=0.12

Table 16.

Length of stay beyond four days

	Intervention (n=72) n(%)	Usual Care (n=68) n(%)
Participants with length of stay > 4 days [a]	29(40)	23(34)

[a] X^2=0.19, p=0.22

Chapter 5

Discussion

This chapter will focus on the strengths and limitations of this trial, procedural issues in the conduct of this trial, a discussion of the conceptual framework used and the results in the context of available evidence.

Strengths

This trial was designed to address the methodological limitations of other studies of preoperative education for orthopedic surgery (Johansson, Nuutile, Virtanen, Katajisto & Salantera, 2005; McDonald, Green & Hetrick, 2004; McDonald & Molony, 2004; Stern & Lockwood, 2005) and to address recommendations for education content and delivery methods (McDonald, Green & Hetrick; Stern & Lockwood; Shuldham, 1999a; Shuldham 1999b; Watt-Watson et al., 2004;). A pragmatic and cost effective intervention was developed. The trial employed a rigorous randomized controlled design. Adherence to trial methods and blinded data collection minimized bias. In addition, use of expert guidance in the development and adaptation of educational materials and establishment of content validity of the intervention components ensured the strength of the content was not a factor in the outcome of the trial. The use of a randomization method that was centrally controlled and concealed added to the rigor of the design, preventing selection bias. As only three participants randomized were lost to follow-up, attrition bias is not of concern.

Only those participants randomized to the intervention group received the components of the intervention from the investigator in the pre-operative setting. Participants in the usual care group had no contact with the investigator at any time nor did the investigator engage in any aspect of the postoperative care of any participant in this trial. Although participants could not be unaware of group allocation, the research assistants collecting postoperative outcome

data were blinded to group allocation, reducing the potential for co-intervention or the introduction of bias by trial personnel during data collection.

Reliable and valid measures that were appropriate to TKA patients were used in data collection and measurements were taken each day at the same time by the same research assistant. Although the Activity Questionnaire that was developed using the existing CCP for primary TKA patients was not pilot tested prior to use in this trial, the components included are part of usual care and were assessed as completed or not completed. This care plan was the guiding framework for the postoperative care of TKA patients and the activities were clinical benchmarks for the measurement of a successful postoperative stay. The CCP for Primary TKA was developed by a team of interdisciplinary experts at the trial centre.

Limitations

Limitations of this trial are primarily related to support for the implementation of the educational material in the postoperative setting. As the intervention for this trial was directed only at the participants, with no component of staff education, protocol development or monitoring, the influence of the health care environment on the ability of the participants to engage in the associated behaviours was not reinforcing. Systems issues such as staff lack of adherence to established protocols for symptom management may have resulted in more pain and nausea and greater functional interference. This is addressed later in the chapter.

One limitation of this trial was the potential contamination of the usual care group by participants in the intervention group in the postoperative setting. Participants in the intervention group could have shared accommodations with participants in the usual care group, raising the possibility that educational material was shared between roommates. Segregation of participants in the intervention group postoperatively was not feasible for this

trial. However, as the majority of the educational intervention was provided preoperatively, it is unlikely that this had much of an effect on trial results.

Procedural issues in the conduct of the trial

The procedural issues of participant recruitment and the delivery of the intervention will be reviewed as related to recruitment and intervention delivery.

Recruitment.

The physical space in the PSS area proved to be challenging for the research assistant in terms of accessing patients waiting for appointments and maintaining patient confidentiality. Review of the patient list for the PSS centre occurred at the beginning of the clinic day. The environment was typical of usual health care environments, very busy with limited space. As a result, trial explanation was often done as the opportunity arose to use vacant rooms, or when potential participants were between provider appointments. Recruitment of even a small number of participants took a full morning, increasing the cost and time to recruitment completion. Patient recruitment in outpatient clinics not associated with PSS activities (i.e. surgeon office) may have been a better option, as patients would then have only one appointment to attend rather than four or five in a limited period of time. However, identification of patients willing to speak to the research assistant was seamless as a result of the high level of communication between the PSS booking office and its unit clerk and nursing staff.

Intervention delivery.

The intervention for this trial included the provision of the Pre-Knee Symptom Education Booklet, a twenty minute related individualized session to discuss content and questions and a follow-up telephone call pre-surgery to reinforce booklet and education session content. The individual session and booklet were delivered following baseline data collection

and randomization in the PSS clinic. Again, lack of physical space and the activity-intense schedule for each patient made arranging space to conduct the session a logistical challenge. For a number of participants, sessions were held after the physiotherapy class was completed in the early afternoon. At this stage in the day, some participants had been in the PSS clinic for more than five hours.

During the educational session, the investigator individualized educational material according to questions asked and comments made by participants. This is consistent with educational recommendations reported elsewhere (Watt-Watson et al, 2004; Johansson et al, 2006; McDonald, Green & Hetrick, 2004). In general, participants were receptive to the material and verbalized understanding of the content provided. Participants indicated during the follow-up telephone call that they had reviewed the booklet again at home, prior to surgery.

Time between PSS clinic visits and surgery dates varied from five days to four weeks based on operating room scheduling times, PSS testing outcomes and other unforeseen surgical administration issues. Access to these patients in any forum other than PSS is very difficult secondary in part to the large catchment area for the trial centre and to mobility issues requiring surgery. The use of the PSS clinic was a practical choice. There is evidence that the timing of educational interventions that include verbal and written instruction does not make a difference in knowledge uptake (Lepczyk, Raliegh & Rowley, 1990). In a trial of 76 cardiac surgery patients, Lepczyk et al found there was no difference in postoperative knowledge scores between groups given a teaching program at three weeks preoperatively as an outpatient or one day preoperatively as an inpatient. Additionally, educational material was reinforced during the follow-up telephone call, in the week prior to surgery.

Telephone follow-up calls were investigator-initiated in almost all cases. Younger participants who were employed were more difficult to reach and often required multiple

attempts and/or messages left with requests for return calls at a prescribed time. Participants provided contact numbers for follow-up calls during the education session in PSS but it may have been advantageous to seek alternate telephone numbers such as cellular or other home numbers. The use of a password-protected database to organize and store participant contact and surgery information that was accessible to both the investigator and research assistants proved to be an effective means of tracking the telephone component of the intervention delivery and any fluctuations in booked surgery times.

Review of trial findings

There were no significant group differences in any of the outcomes in this trial. However, the results of the total sample are important to highlight. Findings from both groups and the total sample will be discussed with respect to four main sections: participant characteristics; pain-related interference, pain and nausea; system issues affecting symptom management; and, expectations for activity and hospital discharge.

Participant characteristics.

Baseline characteristics of the trial sample were similar between groups with a mean age of 67±8 years in the intervention group and 66±8 in the usual care group, consistent with many studies of TKA patients and national TKA data. In 2007, the average age of patients undergoing TKA in Canada was 68 years (CIHI, 2009). The primary diagnosis requiring surgery was osteoarthritis in both groups with approximately one third of participants requiring opioid analgesics for arthritic pain preoperatively. Beaupre, Lier, Davies and Johnston (2004) reported similar demographics, with mean age in years of 67±7 and 67±6 and diagnosis of osteoarthritis in 96% and 97 % in intervention and usual care groups respectively in a trial of a preoperative physiotherapy intervention for TKA patients.

Eighteen and twenty-two percent of intervention and usual care groups respectively reported living alone, a factor for consideration in the expected discharge of patients to home by postoperative day four. Patients who had primary TKA were not transferred to a rehabilitative facility, required out-patient physiotherapy and received minimal homecare. Out-patient physiotherapy was conducted at a rehabilitation facility, requiring travel by car. Very few individuals in the general group of orthopedics patients had enough private medical coverage to support physiotherapy visits at home. As a result, any rehabilitation at home or as an out-patient that required support and assistance from extended family members or friends would have been problematic and would have lengthened hospital stay. De Pablo and colleagues (2004), in a trial of 1276 patients with total joint replacement, found that participants that lived alone were more likely to have delayed discharge or be discharged to a rehabilitation facility (RR1.23, 95% CI 1.0-1.5). Participants who were not discharged to a facility needed to remain in hospital beyond the expected discharge date until appropriate functional independence could be achieved.

Pain-related interference with activity, pain and nausea.

There were no differences in total or component scores for pain-related interference with activity as measured by the BPI-I. A major emphasis of the education content within all three components of intervention delivery was the importance of appropriately timed analgesic use to increase opioid administration and improve pain and pain-related interference with activity. In the context of similar opioid use on postoperative day three in both groups [median daily oral morphine equivalents: intervention 40mg (IQR=45mg), usual care 40mg (IQR=42mg)], moderate to severe BPI-I scores in the intervention group illustrate that placing the focus on the patient alone to ensure pre-activity analgesia administration is not sufficient to improve pain related interference. Watt-Watson and colleagues (2004) reported that only 33%

of prescribed analgesics were administered in 53% of patients reporting moderate to severe pain in their study of 406 cardiac surgery patients. These authors identified a lack of understanding of opioid analgesia among health professionals and recommended future trials include focus groups with staff to discuss issues affecting pain management in the postoperative setting. A discussion of factors affecting opioid administration is presented later in this chapter.

The influence of individual characteristics and the biologic and physiologic impact of this type of surgery on the BPI-I for all patients should be considered. Although standardized mean response scores for the BPI-I have been reported (Keller et al, 2004), no normative data exist for BPI-I for postoperative orthopedic pain, and no trials using the BPI-I for early postoperative outcome measurement in total knee arthroplasty were found for comparison. Mean total BPI-I scores (0-60) for postoperative cardiac surgery patients have been reported to be 16.6±11.9 and 16.1±12.4 for usual care and intervention groups in a trial by Watt-Watson et al (2004) while total scores in this trial were 22.4±15.1 and 24.4±14.4 respectively. Comparison of these findings demonstrates the predisposition of postoperative total knee arthroplasty patients to have more physical disability as a result of incident pain.

BPI-I data were collected on day three after surgery, one day before expected discharge from hospital following TKA procedures. On day three, participants in both groups had mean interference scores in General Activity and Transfer from Bed to Chair components that were in the moderate to severe range. This finding was particular concerning for the roughly one-fifth of each group that reported living alone, as TKA patients were discharged directly home from the trial centre with minimal homecare assistance.

Lower average scores in the components Mood, Relationships with Others and Sleep suggests that overall, activities that were not associated with movement were not affected by

this type of postoperative pain in the time prior to discharge home. However, standard deviations for these scores were large. Individual characteristics and biological and physiological variables in the conceptual model may again explain these findings (Wilson & Cleary, 1995). The predisposition of this group of patients to have persistent pain prior to surgery may have created an adaptive response for these components. Persistent pain conditions have a known impact on mood, relationships and sleep (Chapman, 2009).

The education provided by all three components of the intervention that focused on strategies to prevent resting and pain on movement, including appropriate communication of pain to health care providers, failed to produce a difference in pain ratings and qualitative aspects of pain description. Although resting pain ratings on postoperative day three were in the mild range (intervention 2.8±2.5: 2.8±2.7), pain ratings on movement were in the moderate range (intervention 5.4±3.0: usual care 6.1±2.5) and 81% of the total sample reported experiencing moderate to severe pain in the previous 24 hours. Fifteen participants reported moderate to severe 'sickening' pain on postoperative day three. In comparison, Wu and colleagues (2003) reported average pain at rest to be 2.2±2.1 and pain on movement to be 3.8±2.1 on postoperative day three. Participants in this trial had more pain on movement than reported by Wu and colleagues but interpretation of the difference is difficult as no information was provided about physiotherapy activities in this comparison study.

Moderate to severe pain, in the context of declining and inadequate opioid analgesic administration, is troubling and raises important questions about the postoperative environment in terms of clinical care. Components of the intervention that reinforced analgesic use prior to movement in an interval appropriate to the type of analgesic administered were intended to maximize pain relief and improve mobility to prevent further complications, but the intervention focused on the patients and ignored the roles of the care providers.

The discrepancy between pain ratings at rest or with movement is problematic given the requirement for postoperative activity. Carli et al. (2010) reported median day two knee flexion pain of 8 (range 6-9) in the periarticular injection group and 7 (range 5.5-8) in the femoral nerve block group in a study of 40 TKA patients. Consistent with our trial site, both groups in this study were receiving oral opioids, routine acetaminophen and routine NSAIDs by this time period. The relationship between knee flexion and pain has been established (Laskin & Beksac, 2004). Huang and colleagues (2008) reported an increase in knee range of motion (78±15 degrees versus 64±17 degrees, p=0.0004) in a trial of the addition of celecoxib to PCA in 80 TKA patients. Pain on movement was not presented by these authors, but average pain at rest was significantly different (1.8±1.7 versus 3.17±2.0, p=0.02).

The need for aggressive analgesia to facilitate knee flexion and joint rehabilitation is clear but was not a feature of the findings of this trial. Opioid analgesic administration declined over the three-day study period (F=36.1, p=0.000), while pain ratings on movement stayed in the moderate range in both groups across all three postoperative days. Day three median opioid administration in oral morphine equivalents was 40 mg (IQR=45) in the intervention group and 40 mg (IQR=42) in the usual care group, less than reported in the pilot work for this trial (55mg, IQR=89) (Wilson et al., 2005). There were no differences in day two median opioid administration in both groups [intervention 62 mg (IQR=65); usual care 56mg (IQR=42mg)], similar to the usual care group (68±60 mg) in a study of 65 total joint replacement patients that investigated the impact of a non-pharmacological intervention kit which included relaxation breathing and distraction techniques (Pellino et al., 2005).

It is important to note that median oral morphine equivalent administration of 40 mg for both groups in this trial on postoperative day three translates to only two or three doses in 24 hours at the most commonly prescribed dose of 10 to 15 mg of oral morphine equivalents

every three hours. As a result, participants in both trial groups received, at best, only one third of the opioid doses that were prescribed. This finding is strikingly similar to the 33% of prescribed doses administered in the study by Watt-Watson and colleagues (2004). It is common practice at the trial site to base oral opioid prescription on the previous 24 hours of PCA-IV administration. Opioid conversion from intravenous to oral at the trial site follows figures provided in Appendix O. Although there is much controversy surrounding what is appropriate intravenous to oral dose conversion (Anderson, Saiers, Abram & Schlicht, 2001), it is clear that regardless of conversion practices, patients are not receiving the analgesia that is prescribed and administration is not related to pain ratings. The use of longer acting, sustained release opioids may have been an option to address the need for better analgesia with fewer dosing intervals and less requirement for intervention by nursing staff. Cheville and colleagues (2001) compared twice-daily doses of sustained release oxycodone plus usual analgesia to placebo and usual analgesia in a study of 59 TKA patients. Patients who received the long acting opioid had lower pain scores on active knee movement than placebo ($p<0.001$) and stayed 2.3 fewer days in a rehabilitation facility ($p=0.013$).

As the trial included opioid tolerant participants, there should have been some overall average increase in opioid consumption in the sample, as 29% of the intervention group and 35% of the usual care group used opioids for pain prior to surgery. The expected usual practice at the study site to resume chronic opioid doses at the preoperative level immediately postoperatively and provide patients who were on chronic opioids with higher PCA-IV boluses (e.g. morphine 2 mg, hydromorphone 0.4 mg). However, this did not occur as median opioid administration was lower in this trial than in the pilot study and was not particularly high in either study.

Pain quality ratings using the MPQ-SF, provided verbal descriptors and Pain Rating Indices (PRI) for sensory, affective and total dimensions. All PRI scores decreased over time, but no significant differences were found between the intervention and usual care groups. Descriptors rated as moderate to severe by the greatest proportion of participants included gnawing, aching, heavy and tender on postoperative day one, and aching, heavy and tender on postoperative days two and three (Appendix N). The descriptors 'aching', 'tender' and 'heavy' have been reported by patients with disc disease pain while 'gnawing' and 'aching' have been reported by patients with arthritic pain (Dubuisson & Melzack, 1976) and are consistent with both nociceptive and neuropathic pain. The affective descriptor 'sickening' was also rated moderate to severe by many participants on each of the postoperative days.

Unrelieved pain and stress response as a result of acute, surgical injury can have psychological and physiological consequences for patients (Apkarian, Bushnell, Treede & Zubieta, 2005; Carr & Thomas, 1997; Kehlet, 1997). The phenomenon of central sensitization of dorsal horn neurons by prolonged and repetitive nociceptive input can create the physiology for a longer term pain problem (Bausbaum & Jessell, 2000) predisposing patients to related comorbidities. TKA patients with persistent, unrelieved pain are less likely to do specific physiotherapy activities (i.e. range of motion, weight-bearing) that may result in delayed rehabilitation and knee stiffness.

Concomitant moderate to severe nausea rates in this trial reflect the established interrelationship between pain and nausea. Twenty-eight percent of the intervention and 24% of the usual care groups reported experiencing moderate to severe nausea in the previous 24 hours on postoperative day three. The results are similar to the rate of 28% reported by Huang et al (2008). The attenuation of the pain experience by the presence of nausea and the production of nausea by the pain experience (Fields, 1999; Julius et al., 2001; Kandel,

Schwartz, & Jessell, 2000) reinforces the need to address both of these symptoms simultaneously. Opioid sparing techniques have minimal effect on nausea incidence as nausea in TKA patients in multifactorial.

The education provided, which aimed at reducing nausea through the regular use of anti-emetics, maintaining good oral hydration and movement to reduce vestibular activation, was not sufficient to produce a difference in the incidence of nausea in the intervention group. Encouragement of preoperative hydration to meet usual body requirements to prevent inadvertent perioperative dehydration did not influence outcomes. Inconsistencies were relayed to the investigator about the operating room instructions regarding fasting requirements that may have negated the effects of related intervention education. Participants reported having been told by operating room clerical staff to maintain "nothing by mouth after midnight," regardless of surgery booking time. This information was contradictory to the fasting guidelines in place for the trial site that allow clear fluids up to four hours before surgery. It is possible that some participants who followed this direction would have been without fluid for 12-18 hours if booked for surgery later in the day. A 70 kilogram participant who had been without fluids for 12 hours would have been in a baseline deficit of 1050 millilitres (Hodgkinson, Evans & Wood, 2003) prior to experiencing surgical blood loss and up to 600 millilitre sequestration of fluid in the lower limbs as a result of spinal anesthesia (Drobin, 2006). Overall, mean documented intraoperative fluid administration was conservative (intervention 1803±529 mL; usual care 1700±505 mL) despite the absence of risk factors for fluid overload in this relatively healthy sample.

Although it was suggested to participants to record fluid consumed, diary review was not a method of data collection to assess adherence with this information. Participants were reminded to consume fluids during the follow-up telephone call, and most indicated that they

were attempting to do so but confirmation of this effort was not possible. As a result, the potential for oral hydration to prevent postoperative nausea is unknown in the absence of any significant reduction in nausea in the intervention group.

Future studies designed to address the effects of this approach to nausea prevention in TKA patients should include either the provision of the easily monitored, weight-based intraoperative intravenous fluids (Yogendran, Asokumar, Cheng & Chung, 1995) or more closely monitored preoperative hydration (Adanir, Aksun, Ozgurbuz, Altin & Sencan, 2008) as has been shown to reduce nausea following other surgical procedures. Adanir and colleagues demonstrated a reduction in postoperative nausea in a trial of 210 elective surgery patients following preoperative intravenous fluid replacement calculated to replace individual fasting related fluid deficits (48% versus 64%, p=0.019). Intraoperative fluids administered to participants in this trial were far from standardized, ranging from 600mL to 3000mL in the total sample.

Overall, the incidence of transfusion was fairly low and not different between groups (intervention group 11%, usual care group 21%: p=0.12) despite the fact that symptomatic anemia includes nausea, a finding present in one third to one half of all participants on postoperative days one and two. The findings in our trial are lower than reported elsewhere. Bierbaum and colleagues (1999) found that 36% of 4642 primary TKA patients had postoperative transfusion in a descriptive study of the blood management requirement of 9482 total joint replacement patients. It is possible that infrequent nausea assessment in the context of assessment for symptomatic anemia may have contributed to a lower incidence of transfusion, but given the current trend toward rationalization of transfusion (Tinmouth et al., 2005), clinicians may be reluctant to transfuse even if patients are symptomatic.

Anti-emetic use followed a similar pattern to that of analgesic use. Anti-emetic administration did not differ significantly between groups; 61% of the intervention group and 60% of the usual care group had at least one dose of antiemetic in the three day period. However, of those participants reporting moderate to severe nausea on any of the three days, 25% had no anti-emetics administered at all, while 17% of those who reported having mild or no nausea received at least one dose. Education regarding the appropriate use of anti-emetics and pre-existing standard orders for all patients to receive 24 hours (3 doses) of a routinely administered anti-emetic at first report of nausea should have ensured the proportion of participants reporting moderate to severe nausea received appropriate therapy. However, very few of the participants in either group reporting this degree of nausea received all three doses in the 24 hours prior to data collection on any of the three days. Interestingly, all that was required by this protocol to receive the three doses is a single report of nausea. Ondansetron in prophylactic routine dosing has been shown to reduce postoperative nausea (Hahm et al., 2010) and has been used at the trial centre for many years. It is not clear why this protocol was not followed.

The importance of early physiotherapy and resumption of usual activities after orthopedic surgery is essential to the achievement of optimal functional improvement following total knee arthroplasty surgery. Increasing pain impacts rehabilitation by interfering with general movement and knee joint flexion and induces nausea as a factor impairing postoperative activity. In this trial, moderate to severe pain-related interference with general activity and moving from bed to chair, moderate to severe nausea and moderate to severe pain on postoperative day three in TKA patients is a disturbing finding in the context of less than adequate analgesic and anti-emetic administration. The impact of pain and nausea on the

completion of expected activity was not moderated by education addressing analgesic and anti-emetic administration.

Conceptual framework

The conceptual framework used in this trial was an adaptation of Wilson and Cleary's Health Outcomes Model (Wilson & Cleary, 1995). The primary purpose of this model was to delineate the relationship between a continuum of biologic, physiologic and psychosocial variables on health status and health related quality of life (Wilson & Cleary). Individual characteristics, biological and physiological variables and symptom and functional status domains of the original model were used to provide direction in the development of the intervention and measurement of its impact on TKA patients. The parts of the model selected for use in this trial were relevant to the TKA postoperative experience and provided practical direction for intervention delivery and measurement. In the adapted model, education aimed at addressing knowledge deficits, barriers, individual values and preferences in the use of analgesics, anti-emetics and non-pharmacologic therapies and the reduction of symptom status factors (e.g. nausea and pain-related nausea) was hypothesized to reduce pain-related interference with activity. Environmental characteristics were intentionally not considered in the adapted model for the purpose of determining if an intervention with participants alone would affect postoperative outcomes. The continuum of domains and their interrelationship were generic to the larger spectrum of human experience and not necessarily well-contained in the institutional setting.

The exclusion of environmental characteristics in the conceptual model for this trial probably contributed to the lack of a significant effect of the intervention on the outcomes measured. Findings in this trial show that usual symptom management practices were inadequate and that appropriate medication procedures and protocols in place were not

followed. The impact of the intervention on symptom and functional status of this model was not supported by trial findings, as there were no differences in total or component scores for pain-related interference with activity as measured by the BPI-I. The influence of the educational intervention being provided only to participants without targeting the characteristics of the environment increased the likelihood that factors outside the domains of interest affected the outcome (Brenner, Curbow & Legro, 1995).

System issues related to symptom management

This trial presents clear evidence that there are significant system issues influencing postoperative symptom management after total knee arthroplasty. Participants in both groups who were reporting moderate to severe nausea or pain frequently did not receive the anti-emetic therapy or analgesics ordered. Evidenced-based protocols for nausea management were in place at the trial site but data show that they were not followed consistently and in some cases, not at all. Anti-emetic agents used in these protocols, ondansetron and prochlorperazine, are effective for postoperative nausea when given appropriately (Dzwonczyk, Weaver, Puente & Bergese, 2010). Using 'as needed' orders for anti-emetics creates a condition where the patient must have nausea to receive treatment. Standing orders for three routine doses of ondansetron at first incidence of nausea were designed to ensure patients would receive consistent treatment without having to experience on-going nausea. In this trial, 25% of participants who reported moderate to severe nausea had no anti-emetics administered at all. Similarly, participants who reported moderate to severe pain received approximately one third of the prescribed doses of oral analgesic on postoperative day three despite hospital-wide programs that support the need for effective pain management (e.g. Pain, the 5th Vital Sign). Other research has suggested that this is not an unusual finding; staff education and attitude may be contributing factors. Gordon and colleagues (2008), in a study of practice associated

pro re nata (PRN) administration of opioids in 602 registered nurses, found that comfort with dose titration was directly and positively related to years of practice experience. Nurses with less than 5 years of experience had more discomfort with titration ($p<0.05$). Only 50% of nurses in this study reported pain ratings as an important consideration in choosing to administer PRN opioids, and only 22% would consider the pharmacodynamics of the opioid. The most commonly chosen consideration prior to opioid administration was the patient's current level of sedation (66%).

At the trial site, the APMS is available for consultation by the nursing staff at all times to modify or increase analgesic doses. Although patients reporting scores in the moderate to severe range on pain assessment should, by institutional policy, be reviewed either by the attending service or the APMS, they were not. Although an inadequate explanation for deficiencies in care, staffing resources and patient acuity may have contributed to fewer pain and nausea assessments, placing the onus on the patient to report symptoms requiring treatment. The frequency of pain assessments performed by the nursing staff was not measured in this trial, but usual practice is to assess and document pain, sedation and PCA-IV administration every four hours.

It appears that the current postoperative environment does not support best practice in terms of symptom management regardless of measures put in place. This finding is not unique to orthopedic patient care. In a systematic review of 16 trials of labour support during childbirth in institutional settings, Hodnett, Gates, Hofmeyr and Sakala (2009) concluded that the effectiveness of labour support interventions was mediated by the environment in which the interventions were provided. Although this clinical group has different requirements than TKA patients, findings of the review in terms of environmental factors were similar. The ability of

interventions with patients to overcome barriers present in the environment is limited if strategies to address these barriers are not also included.

Collaborative care path activities and hospital discharge

There were no differences between groups in the proportions of participants completing expected activities on postoperative days one, two and three. Postoperative expected activities were milestones for successful navigation of the CCP. The finding that only 4% of the intervention group and 6% of the usual care group completed all activities outlined on the CCP, and approximately half of each group missed at least one activity each day indicates that deviation from the path is common.

Participants in the intervention group attended physiotherapy more often on all three postoperative days and reached walking milestones on days two and three although these differences were not statistically significant. Review of the need for the use of anti-emetics and analgesics before physiotherapy and other activity during the intervention in preparation for activity may have contributed to this trend, as the postoperative activity schedule was indirectly reinforced. In a trial of 143 TKA patients and 177 total hip arthroplasty patients, Mancuso and colleagues (2008) found that preoperative education regarding postoperative recovery milestones produced a difference in the recovery expectations when compared to usual care ($p=0.008$). A systematic review of preoperative education for orthopedic patients identified expectations and understanding of postoperative orthopedic routines as contributors to better adherence to rehabilitation and willingness to perform exercises (Johansson et al., 2005).

Activity limitations as a result of the presence of debilitating pain and nausea are a primary consideration, but resource issues at the trial centre may also have been a factor. Physiotherapy and assistive personnel were less available on weekends despite a usual

orthopedic operative room list on Fridays. Twenty-two percent of the sample did not walk the prescribed distance on the day before expected hospital discharge, and 32% did not go to the bathroom independently. These patients require physiotherapy and nursing assistance to gather supplies (walker etc.) and for ambulation. Timing of surgery with respect to day of the week may have been a factor. In spite of this, many participants in both groups were up to the chair at least once each day despite moderate pain with movement. For example, on the morning of postoperative day two, 85% of participants in both groups were up in the chair. As well, 75% of the usual care group and 85% of the intervention group were able to walk 20-30 feet on the third postoperative day.

Activity findings of this trial were slightly better than reported elsewhere. In a recent comparison of periarticular infiltration and femoral block in 40 TKA patients, only 49% of the total sample walked the prescribed distance on the third postoperative day (Carli et al., 2010). Regardless, both this comparison study and our trial illustrate the relative lack of functional independence, specifically walking, on the day prior to expected discharge.

There were no differences in hospital length of stay between groups. Forty three percent of the intervention group and thirty-two percent of the usual care group stayed longer than the expected four days. These findings are in contrast to a recent study of preoperative education for 261 total joint arthroplasty patients (Yoon et al., 2010). Yoon and colleagues reported a significant difference in length of stay between participants who received a standardized program (booklet and telephone call) that reviewed postoperative routines and those who received usual care. Length of stay for the two groups in this comparison study were 3.1±0.9 days and 4.1±1.9 days ($p=0.001$) for intervention and usual care groups respectively. Participants had comparable preoperative comorbid conditions and sex distribution to those in

this trial. Average length of stay of all patients following primary TKA at the trial centre was 5.8 days in 2009, similar to the national average for 2007 of 6 days.

Length of stay is likely to have been negatively influenced by all other outcomes measured within symptom and function status domains in this trial and indirectly influenced by environmental and individual characteristics. Achievement of milestone activities and optimal pain and nausea management are necessary for discharge from hospital. Given the large proportion of participants in both groups that had moderate to severe pain and nausea on postoperative day three and the relative inability of a similar proportion of participants to engage in independent activities of daily living, the finding that over one-third of participants in this trial stayed beyond the CCP prescribed length of stay is not surprising and is of significant concern. It is difficult to interpret activity completion and length of hospital stay in the context of unrelieved pain and nausea. An examination needs to be done of whether or not activity and discharge goals are realistic for patients with pain and nausea that interferes with activity. The national average length of stay in TKA patients is 6 days, suggesting that a discharge goal of 4 days may not be appropriate for all patients having this surgery. It is likely that system issues affecting optimal symptom management may be a factor in the larger TKA population.

In summary, the intervention designed for this trial did not have a direct effect on symptoms of nausea and pain, pain-related interference with activity or performance of expected postoperative activities. Individualizing the educational content to address participant's pre-existing knowledge and understanding did not improve upon results from other trials that did not include this approach (McDonald & Molony, 2004; McDonald et al., 2001; Sjoling et al, 2002). Although the importance of achieving optimal pain management for the facilitation of activity was stressed in all three components of the intervention, participants

in the intervention group did not demonstrate a more effective use of analgesics than the usual care group. While recommendations of systematic reviews of patient education prior to orthopedics surgery support using multiple components for material delivery concurrently (Johansson, Nuutila, Virtanen, Katajisto & Salantera, 2005; Stern & Lockwood, 2005), Johansson and colleagues suggest structuring preoperative education to be 'empowerment-oriented' is key in helping patients to become more responsible for their care although no examples of strategies are provided in this review. Educational content that directly addresses patient empowerment may have improved this outcome of this trial but it appears that addressing system issues would have had the greatest effect.

A large number of participants across both groups had significant pain and nausea, were frequently unable to complete prescribed postoperative rehabilitative and self-care activities, did not receive prescribed analgesics and anti-emetics and stayed in hospital beyond the four-day discharge target. The influence of environmental factors such as staff attitudes and knowledge, staffing resources and staff understanding of postoperative routines on the outcomes of this trial is not known. The intervention was designed to focus education efforts on the individual patient and did not include elements of the health care environment.

Chapter Six

Summary, Implications for Practice and Research, Conclusion

Trial summary

Arthritis is the third most common diagnosis affecting Canadians (CIHI, 2009). Nation-wide, 31% of women and 19% of men over 40 years of age have been diagnosed with the disease, a proportion that rises to half the population of people older than 55 years. Total Knee Arthroplasty (TKA) is an established surgical treatment for osteoarthritis and rheumatoid arthritis, improving joint function in terms of pain and mobility and overall quality of life (Weiss et al., 2002). Consistent with the trend toward an aging population, the need for TKA surgery in Canada has increased by 140% and 159% in Ontario from 1994 to 2004 (CIHI).

Early physiotherapy following TKA surgery is essential to achieving optimal joint function (Laskin & Beksac, 2004). Unfortunately, evidence indicates that patients experience moderate to severe pain after surgery in both resting and on movement, impairing mobility in the first three postoperative days (Brander et al., 2003; Crutchfield, Zimmerman, Nieveen, Barnason & Pozehl, 1996, Wu et al., 2003). The goal of early hospital discharge on or before postoperative day four necessitates aggressive and comprehensive planning that must begin in the preoperative setting that includes pain and symptom management strategies (Cook, Warren, Ganley, Prefontaine & Wylie, 2008).

The two previous preoperative education programs that employed a variety of different educational delivery methods did not show any significant benefit in terms of pain, hospital length of stay or functional performance (Johansson et al., McDonald, Green & Hetrick, 2004; Shuldham, 1999a; Shuldham, 1999b). No study was found that addressed the impact of preoperative education preparation on postoperative nausea or assessed an individually delivered preoperative preparation program.

The trial was a single site randomized controlled trial that compared an individualized preoperative preparation program delivered to participants undergoing primary total knee arthroplasty that employed face to face, telephone and written methods of information delivery. The primary outcome for this trial was pain related interference with activity and the conceptual model used to guide intervention development and delivery and outcome measurement was an adaptation of the health outcomes model by Wilson and Cleary (1995).

This trial is unique in its approach to preoperative patient education and is the first trial that included an individualized face to face and telephone follow-up approach to pain and nausea management education combined with the more conventional method of providing written material. There were 143 patients randomized in the PSS centre preoperative to either usual care group or the intervention group (usual care plus the Pre-Knee Symptom Education Program). One hundred and forty participants participated in the trial (intervention group n=72; usual care group n=68). Most participants were female, did not live alone and had a pre-surgical diagnosis of osteoarthritis. The average age of the sample was 67±8 years. Participant characteristics were similar at baseline. All outcomes measures were collected postoperatively on days one, two and three after surgery

There were no differences between groups for any of the variables assessed during this trial. Overall, the information provided about the postoperative experience of the sample in this trial was fairly sobering. Participants in the sample experienced moderate to severe pain with activity on all three postoperative days (intervention group 94%; usual care group 95%) and moderate to severe nausea on postoperative day three (intervention group 30%; usual care group 24%), the day prior to expected discharge from hospital. Despite reporting moderate to severe pain and nausea, participants in both groups received only a fraction of the prescribed

doses of analgesics or anti-emetics. A portion of the total sample was unable to complete expected postoperative activities on the day prior to expected discharge from hospital.

Implications for practice

Pain and nausea were serious problems for the trial participants. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO, 2005) has identified pain as an avoidable symptom that has major physiological and psychological effects on individuals in hospitals, slowing recovery and increasing cost to the health care system. The relationship between pain and resulting joint stiffness after TKA and the need for revision arthroplasty has been well established (Furnes et al., 2002). The recent trend toward 'fast-track' arthroplasty surgery as a strategy to decrease waiting lists means that more patients are discharged earlier from hospital to home with pain that interferes with rehabilitation. Barriers to the provision of appropriate and timely symptom management interventions must be addressed before 'fast-track' programs can be successful. The presence of pain and nausea following early discharge may result in increased use of emergent care facilities and may affect the successful completion of outpatient rehabilitation. The cost to the system related to untreated pain and nausea warrants a large scale approach. This trial has shown that putting evidenced based procedures and protocols in place in not sufficient. Institutional management must monitor procedure and protocol use and take steps to ensure the staff has the resources and education for appropriate implementation.

Ultimately, involving front-line staff members of all disciplines will be the key to changing practice. Presentation of the findings to the staff of the orthopedic unit at the trial site will be important for illustrating the problem and will provide a starting point for discussion. Nurses, physicians, occupational therapists and physiotherapists should be engaged in determining what needs to be addressed in the practice environment to support the use of

effective symptom management techniques and protocols in intraoperative and postoperative settings. Communication of these protocols needs to be consistent at all staff levels. Similarly, interdisciplinary staff should contribute to preoperative and postoperative educational content for orthopedic patients. Nursing staff, in particular, should be asked what they think patients need to know for successful symptom management after surgery. Perioperative education for total joint replacement patients need to be more clearly and systematically established with this staff input. Educational strategies need to be implemented and monitored throughout the preoperative to postoperative transition and should incorporate communication of instructions from all hospital personnel.

In light of the demand on the system for short-stay procedures, it is recommended that interdisciplinary teams re-examine the feasibility of expected postoperative activities and length of stay for certain patients after TKA once symptom management practices have been addressed. Twenty nine percent of participants in the intervention group and 23% of participants in the usual care group had length of stay beyond the projected four day period outlined in the CCP at the trial site. For certain individuals, the goals of usual postoperative activity and length of stay may not be appropriate. When a quarter of patients cannot walk the prescribed distance on the day before hospital discharge, expectations for activity level may not be realistic. This may particularly be the case if assistive personnel are not available. If it is not possible to reorganize operative days to coincide with optimal staff levels (e.g. earlier in the week), then some modifications must be made for those patients who require more postoperative assistance. The lack of ability to perform rehabilitative activities will result in greater length of stay, more patient morbidity and increased cost to the health care system. Stratification of patient groups to have different activities to establish where it is feasible to

follow a short-stay or four-day stay path and where it is not, may be an effective method for appropriately allocating resources.

Patient characteristics that are predisposing factors for complicated postoperative rehabilitation should be indentified preoperatively, and a coordinated approach put in place to ensure these individuals have the necessary supports to meet rehabilitation goals appropriate to their condition. For example, the 32% of participants in this trial who had pre-existing use of opioid analgesia and were opioid tolerant needed to have different pain management requirements than the 68% who did not. Additionally, patients who lived alone or were without home support would have difficulties with the achievement of early discharge given the pain-related interference with activities and relative lack of functional independence.

Overall, institutional accountability reflecting hospital accreditation standards in the clinical environment for the provision of symptom management and early identification and investigation of activity and mobility concerns needs to be established. A consistent approach used by disciplines involved in the care of TKA patients needs to span from initial assessment for surgery to postoperative care and include all points of contact between.

Implications for research

This trial demonstrates that the delivery of individualized educational content with reinforcement provided by booklet and telephone follow-up was not sufficient to impact postoperative symptoms after total knee arthroplasty surgery. Further trials that also include standardizing information provided to patients by preadmission, surgical booking and postoperative nursing and medical staff would be beneficial in supporting learned behaviours and knowledge uptake. Consistent with the recommendations of Watt-Watson and colleagues (2004), a qualitative research approach using focus groups of orthopedic nursing, medical and physiotherapy staff should be undertaken to determine the environmental and patient-related

characteristics affecting the provision of analgesics and anti-emetics and the relationship to postoperative activity. A similar approach should be taken with patients to determine if there are particular resources that are needed on the nursing units to support self-care in requesting symptom management interventions. In addition, a descriptive study of nursing and physiotherapy staffing patterns and patient acuity should be conducted to determine if there is a relationship between nursing workload and symptom management and postoperative activity. The contribution of research of this type to the body of knowledge supporting the postoperative care of orthopedic patients will strengthen the impact of the recommendations for practice change made in the previous section of this chapter.

Examination of the group of TKA patients that experience persistent pain preoperatively is warranted. An investigation of these patients that describes the characteristics of their home environments, the impact of painful osteoarthritis on function before surgery and successful home strategies for symptom management would provide helpful information to inform program development and evaluation. Description of the preoperative and postoperative experiences of patients with persistent pain and comparison with those who do not will help to determine where additional resources are required to meet recovery milestones for these individuals.

Future trials of goal-directed preoperative or intraoperative intravenous fluid delivery for the prevention of postoperative nausea in total joint replacement patients are needed. Nausea prevalence reported in this trial has illustrated the need for preventative approaches that are part of standard care in addition to postoperative treatment. Support for intraoperative fluid replacement in other patient groups has been successful in reducing postoperative nausea (Gan et al., 2002; Mythen & Webb, 1995; Pusch et al., 2002a; Pusch et al., 2002b). A trial of the impact of intraoperative fluid replacement calculated to address fluid deficits that are a result

of fasting times on postoperative nausea would establish the role of fluids in nausea prevention in this group. In addition, physiologic studies of blood pressure variation in the immediate postoperative period, blood loss and the impact of volume replacement on blood pressure and nausea are needed as no conceptual model that explains the multifactorial causes of postoperative nausea in patients after total joint replacement surgery exists. A model would support the identification of patient risk factors and inform appropriate prevention and treatment.

Comparison of the findings of this trial with outcomes in similar groups of total joint replacement patients in terms of length of stay would be helpful in interpreting if postoperative activities and discharge goals are realistic. In particular, comparison of findings and patient characteristics with characteristics and outcomes in established short-stay joint replacement programs with low hospital re-admission rates would provide essential information for future program development and reinforce practice change. Descriptive studies that include patient follow-up should be done to ensure patients are not disadvantaged by hospital discharge practices. These follow-up studies should include three phases in patients' recovery: time of hospital discharge; postoperative at-home rehabilitation; and, longer term functioning. The examination of discharge medications, pain and nausea, analgesic and anti-emetic use, out-patient physiotherapy attendance and functional ability would provide important patient-focused indicators of the success of usual and short stay programs. Qualitative exploration of patients' experiences in the first few weeks after surgery would assist in the illustration of any barriers present that impact rehabilitative activities and symptom management.

Conclusion

The numbers of Canadians requiring primary total knee arthroplasty has increased 140% over the last ten years (CIHI, 2009). The highest rate of TKA surgery is in the 75-84

year age range (65%).There are no published guidelines for the preoperative preparation or postoperative care of these relatively older aged patients in spite of the thousands of these procedures that are done each year. The absence of a clear understanding of characteristics affecting the incidence of symptoms in the early postoperative period as well as those affecting the provision of appropriate analgesia and anti-emetic therapy will result in increased morbidity for patients and increased for the health care system. The purpose of the trial was to examine the impact of individualizing preoperative patient education as a means to address postoperative symptoms affecting functional status after TKA.

Providing information to patients alone is not sufficient to address the need for postoperative symptom prevention and management after TKA. A broader, consistent approach that includes health care providers at all levels of patient contact is required to support recovery and rehabilitation after this type of surgery. Further research is required to delineate the barriers in the health care environment to appropriate pain and nausea management and to provide more evidence for the relationship between pain and nausea and functional outcomes for patients who have had total knee arthroplasty surgery.

References

Ali, S. L., Taguchi, A., Holtmann, B., & Kurz, A. (2003). Effect of supplemental pre-operative fluid on post-operative nausea and vomiting. *Anaesthesia, 58,* 780-789.

Anderson, L. & Gross, J. B. (2004). Aromatherapy with peppermint, isopropyl alcohol, or placebo is equally effective in relieving postoperative nasuea. *Journal of PeriAnesthesia Nursing, 19,* 29-35.

Anderson, R., Saiers, J., Abraham, S & Schlicht, C. (2001). Accuracy in equianalgesic dosing. Conversion dilemmas. *Journal of Pain and Symptom Management, 21*(5), 397-406.

Antall, G. F. & Kresevic, D. (2004). The use of guided imagery to manage pain in an elderly orthopedic population. *Orthopedic Nursing, 23,* 335-340.

Apkarian, A., Bushnell, M., Treede, R. & Zubieta, J. (2005). Human brain mechanisms of pain perception and regulation in health and disease. *European Journal of Pain, 9*(4), 463-484.

Bardsley, M. & Cleary, R. (1999). Assessing the outcomes of total knee replacement. *Journal of Evaluation in Clinical Practice, 5,* 47-55.

Barrington, M. J., Olive, D., Low, K., Scott, D. A., Brittain, J., & Choong, P. (2005). Continuous femoral nerve blockade or epidural analgesia after total knee replacement: A prospective randomized controlled trial. *Anesthesia and Analgesia, 101,* 1824-1825.

Bausbaum, A. I. & Jessell, T. M. (2000). The perception of pain. In E.Kandel, J. Schwartz, & T. Jessell (Eds.), *Principles of neural science* (4th ed., pp. 472-491). New York: McGraw-Hill.

Beard, H. S., Murray, D. W., Rees, J. L., & Choong, P. F. (2002). Accelerated recovery for unicompartmental knee replacement - a feasability study. *Knee, 9,* 221-224.

Beaupre, L. A., Lier, D., Davies, D. M., & Johnston, D. B. C. (2004). The effect of a preoperative exercise and education program on functional recovery, health related quality of life, and health service utilization following primary total knee arthroplasty. *Journal of Rheumatology, 31,* 1166-1173.

Ben-David, B., Schmalenberger, K., & Chelly, J. E. (2004). Analgesia after total knee arthroplasty: Is continuous sciatic blockade needed in addition to continuous femoral blockade? *Anesthesia and Analgesia, 98,* 747-749.

Benor, D.E., Delbar, V. & Krulik, T. (1998). Measuring the impact of nursing interventions on cancer patients`ability to control symptoms. *Cancer Nursing, 21*, 320-334.

Bianconi, M., Ferraro, L., Traina, G., Zanoli, G., Antonelli, T., Guberti, A., Ricci, R., & Massari, L. (2003). Pharmacokinetics and efficacy of ropivacaine wound instillation after joint replacement surgery. *British Journal of Anaesthesia, 9*1(6), 830-835.

Bierbaum, B., Callaghan, J., Galante, J., Rubash, H., Tooms, R., & Welch, R. (1999). An analysis of blood management in patients having a total hip or total knee arthroplasty. *Journal of Bone and Joint Surgery, 81,* 2-10.

Bondy, L. R., Sims, N., Schroeder, D. R., Offord, K. P., & Narr, B. J. (1999). The effect of anesthetic patient education on preoperative patient's anxiety. *Regional Anesthesia and Pain Medicine, 24,* 158-164.

Brander, V. A., Stulberg, S. D., Adams, A. D., Harden, N., Bruehl, S., Stanos, S. P. et al. (2003). Predicting total knee replacement pain. *Clinical Orthopedics and Related Research, 416,* 27-36.

Brenner, M., Curbow, B. & Legro, M. (1995). The proximal-distal continuum of multiple health outcome measures: The case of cataract surgery. *Medical Care, 33*(4 Suppl), AS236-AS244.

Browne, C., Copp, S., Reden, L., Pulido, P., & Colwell, C. (2004). Bupivacaine bolus injection versus placebo for pain management following total knee arthroplasty. *Journal of Arthroplasty, 19,* 377-380.

Canadian Institute for Health Information (2005). Age standardized acute care hospitalization rate per 100,000 population by surgery type and region. Canadian Institute for Health Information. Retrieved from http://www.cihi.ca.

Canadian Institute for Health Information (2009). *Hip and knee replacements in Canada - Canadian Joint Replacement Registry 2008-2009 Annual Report*. Ottawa: CIHI 2009.

Capdevila, X., Barthelet, Y., Biboulet, P., Ryckwaert, Y., Rubenovitch, J., & d'Athis, F. (1999). Effects of perioperative analgesia technique on the surgical outcome and duration of rehabilitation after major knee surgery. *Anesthesiology, 91,* 8-15.

Caraceni, A., Cherny, N., Fainsinger, R., Kaasa, S., Poulain, P., Radbruch, L. et al. (2002). Pain measurement tools and methods in clinical research in palliative care: recommendations of an expert working group of the European Association of Palliative Care. *Journal of Pain and Symptom Management, 23,* 239-255.

Carli, F. Clemente, A., Asenjo, J., Kim, D., Mistraletti, G., Gomarasca, M., Morabito, A., & Tanzer, M. (2010). Analgesia and functional outcome after total knee arthropalsty: Periarticular infiltration vs continuous femoral nerve block. *British Journal of Anaesthesia, 105*(2), 185-195.

Carr, E. & Thomas, V. (1997). Anticipating and experiencing post-operative pain: the patient's perspective. *Journal of Clinical Nursing, 6,* 191-201.

Chang, H.J., Mehta, P., Rosenberg, A. & Scrimshaw, C.R. (2004). Concerns of patients actively contemplating total knee replacement: Differences by race and gender. *Arthritis and Rheumatism, 51*(1), 117-123.

Chapman, C.R. (2009). Psychophysiological aspects of pain. In, J. Ballantyne, S. Fishman and J. Rathmell (Eds.), *Bonica's management of pain* (4th ed.). (pp. 375-386). Baltimore: Lippincott, Williams & Wilkins.

Chelly, J. E., Greger, J., Gebhard, R., Coupe, K., Clyburn, T. A., Buckle, R. et al. (2001). Continuous femoral blocks improve recovery and outcome of patients undergoing total knee arthroplasty. *Journal of Arthroplasty, 16,* 436-445.

Chen, J., Frame, D., & White, J. (1998). Efficacy of ondansetron and prochlorperazine for the prevention of post-operative nausea and vomiting after total hip replacement or total knee replacement procedures: A randomized double-blind comparative trial. *Archives of Internal Medicine, 158,* 2124-2128.

Cheville, A., Chen, A., Oster, G., McGarry, L., & Narcessian, E. (2001). A randomized trial of controlled release oxycodone during inpatient rehabilitation following unilateral total knee arthroplasty. *Journal of Bone and Joint Surgery, 83-A,* 572-576.

Choi, P. T., Bhandari, M., Scott, J., & Douketis, J. (2003). Epidural analgesia for pain relief following hip or knee replacement (Cochrane Review). *The Cochrane Library,* 1-35.

Cleeland, C. & Ryan, K. (1994). Pain assessment: global use of the Brief Pain Inventory. *Annals of Academic Medicine Singapore, 23,* 129-138.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences*. (2nd ed.) Hillsdale: Earlbaum Associates.

Cole, P. J., Craske, D. A., & Wheatley, R. G. (2000). Efficacy and respiratory effects of low-dose spinal morphine for postoperative analgesia following knee arthroplasty. *British Journal of Anaesthesia, 85,* 233-237.

Cook, J., Warren, M., Ganley, K., Prefontaine, P. & Wylie, J. (2008). A comprehensive joint replacement program for total knee arthroplasty: A descriptive study. *BMC Musculoskeletal Disorders, 19*(9), 154. doi:10.1186/1471-2474-9-154.

Crowther, C. L. & Mourad, L. A. (2002). Alterations of musculoskeletal function. In K.L.McCance & S. E. Huether (Eds.), *Pathophysiology: The biologic basis for disease in adults & children* (pp. 1364-1408). St. Louis: Mosby.

Crutchfield, J., Zimmerman, L., Nieveen, J., Barnason, S., & Pozehl, B. (1996). Preoperative and postoperative pain in total knee replacement patients. *Orthopedic Nursing, 15,* 65-72.

Daut, R. L., Cleeland, C. S., & Flannery, R. (1983). Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. *Pain, 17,* 197.

Dennis, D. A. (2001). The stiff total knee arthroplasty: Causes and cures. *Orthopedics, 24,* 901-902.

De Pablo, P. Losina, E., Phillips, C., Fossel, A. Mahomed, N., Lingard, E. & katz, J. (2004). Determinants of discharge destination following elective total hip replacement. (2004). *Arthritis and Rheumatology, 51*(6), 1009-1017.

de Wit, R, & van Dam, F. (2001). From hospital to home care: a randomized controlled trial of a Pain Education Programme for cancer patients with chronic pain. Journal of Advanced Nursing, 36(6), 742-754.

Drobin, D. (2006). A single-model solution for volume kinetic analysis of isotonic fluid infusions. *Acta Anaesthesiologica Scandinavica, 50*(9), 1074-1080.

Duibuisson, D. &Melzack, R. (1976). Classification of clinical pain descriptions by multiple group discriminant analysis. *Experimental Neurology, 51*(2), 480-487.

Dzwonczyk, R., Weaver, T., Puente, E. & Bergese, S. (2010). Postoperative nausea and vomiting prophylaxis from an economic point of view. *American Journal of Therapeutics*, Advance online publication.

Eipe, N. & Penning, J. (2010). Opioid conversions and patient-controlled analgesia parameters in opioid-dependent patients. *Canadian Journal of Anesthesia, 57*(12), 1129-1130.

Eggers, K. A., Jenkins, B. J., & Power, I. (1999). Effect of oral and i.v. tenoxicam in postoeprative pain after total knee replacement. *British Journal of Anaesthesia, 83,* 876-881.

Esler, C., Blakeway, C., & Fiddian, N. (2003). The use of a closed-suction drain in total knee arthroplasty. *Journal of Bone and Joint Surgery, 85-B,* 215-217.

Fields, H. (1999). Pain: an unpleasant topic. *Pain, Supplement 6,* S61-S69.

Fields, H. L. (1987). *Pain*. New York: McGraw-Hill.

Forster, J. G. & Rosenberg, P. H. (2004). Small dose clonidine mixed with low-dose ropivacaine and fentanyl for epidural analgesia after total knee arthroplasty. *British Journal of Anaesthesia, 93,* 670-677.

Furnes, O., Espehaug, B., Lie, S., Vollset, S., Engesæter, L., & Havelin, L. (2002). Early failures among 7,174 primary total knee replacements: a follow-up study from the Norwegian Arthroplasty Register 1994-2000. *Acta Orthopedica Scandinavica, 73,* 117-129.

Gagliese, L. & Katz, J. (2003). Age differences in postoeprative pain are scale dependent: A comparison of measures of pain intensity and quality in younger and older surgical patients. *Pain, 103,* 11-20.

Gagliese, L. & Melzack, R. (2003). Age related differences in the qualities but not the intensity of chronic pain. *Pain, 104,* 597-608.

Gan, T. J., Meyer, T., Apfel, C., Chung, F., Davis, P. J., Eubanks, S. et al. (2003). Consensus guidelines for managing postoperative nausea and vomiting. *Anesthesia and Analgesia, 97,* 62-71.

Ganapathy, S., Wasserman, R. A., Watson, J. T., Bennett, J., Armstrong, K. P., Stockall, C. A. et al. (1999). Modified continuous femoral three-in-one block for postoperative pain after total knee arthroplasty. *Anesthesia and Analgesia, 89,* 1197-1208.

Gordon, D., Pellino, T., Higgins, G., Pasero, C. & Murphy-Ende, K. (2008). Nurses' opinions of administration of PRN range opioid oral orders for acute pain. *Pain Management Nursing*, 9(3), 131-140.

Grattidge, P. (1998). Nausea and vomiting after major arthroplasty with spinal anaesthesia including morphine: A randomized trial of subhypnotic propofol infusion as prophylaxis. *Acta Anesthesiologica Scandinavica, 42,* 124-127.

Hahm, T., Ko, J., Choi, S. & Gwak, M. (2010). Comparison of prophylactic anti-emetic efficacy of ramosetron and ondansetron in patients at high-risk for postoperative nausea and comiting after total knee replacement. *Anaesthesia, 65*(5), 500-505.

Harvey, I. A., Barry, K., Johnson, R., & Elloy, M. A. (1993). Factors that affect the range of motion of total knee arthroplasty. *Journal of Bone and Joint Surgery, 75,* 950-958.

Heck, D., Robinson, R., Partridge, C., Lubitz, R., & Freund, D. (1998). Patient outcomes after knee replacement. *Clinical Orthopedics, 356,* 93-110.

Himmelseher, S., Ziegler-Pithamitsis, D., Argiriadou, H., Martin, J., Jelen-Esselborn, S., & Kochs, E. (2001). Small-dose S(+) Ketamine reduces postoperative pain when applied

with ropivacaine in epidural anesthesia for total knee arthroplasty. *Anesthesia and Analgesia, 92,* 1290-1295.

Hodnett, E., Gates, S., Hofmeyr, G.J. & Sakala, C. (2009). Continuous support for women during childbirth. *Cochrane Database of Systematic Reviews, 3*, CD003766.

Hodgkinson, B., Evans, D., & Wood, J. (2003). Maintaining oral hydration status in older adults: A systematic review. *International Journal of Nursing Practice, 9,* S19-S28.

Hoppenfeld, S. & deBoer, P. (1994). The knee. In S.Hoppenfeld & P. deBoer (Eds.), *Surgical Approaches in Orthopedics: The Anatomical Approach* (2nd ed., pp. 429-482). Philadelphia: Lippincott.

Horlocker, T., Wedel, D., Rowlingson, J., Enneking, F., Kopp, S., Benzon, H., Brown, D., Heit, J, Mulroy, M., Rosenquist, R., Tryba, M & Yuan, C. (2010). Regional anesthesia in the patient receiving antithrombotic or thrombotic therapy: American Society of Regional Anesthesia and Pain Medicine evidence-based guidelines (3rd ed.). *Regional Anesthesia and Pain Medicine, 35*(1), 64-101.

Huang, Y., Wang, C., Wang, L., Lin, W., Hornq, L. & Jiang, C. (2008). Perioperative celecoxib administration for pain management after total knee arthroplasty: A randomized controlled study. *BMC Musculoskeletal Disorders, 9*:77.

Hubbard, R. C., Naumann, T. M., Traylor, L., & Dhadda, S. (2003). Parecoxib sodium has opioid-sparing effects in patients undergoing total knee arthropalsty under spinal anaesthesia. *British Journal of Anaesthesia, 90,* 166-172.

Huether, S. E. (2002). Alterations of digestive function. In K.L.McCance & S. E. Huether (Eds.), *Pathphysiology: The biologic basis for disease in adults and children* (4th ed., pp. 1191-1313). St. Louis: Mosby.

IASP (2003). Pain terms. Retrieved from http://www.iasp-pain.org/terms-p.html#Pain.

Isaac, D., Falode, T., Liu, P., L'Anson, H., Dillow, K., & Gill, P. (2005). Accelerated rehabilitation after total knee replacement. *Knee, 12,* 346-350.

Jacobs-Lawson, J., Schumacher, M. Huighes, T. & Arnold, S. (2009). The relationship between lung cancer patients` educational level and evaluation of their treatment information needs. *Journal of Cancer Education, 24*(4), 346-350.

Jensen, M. P. & Karoly, P. (2001). Self-report scales and procedures for assessing pain in adults. In D.C.Turk & R. Melzack (Eds.), *Handbook of Pain Assessment* (2nd ed., pp. 15-34). New York: Guilford Press.

Jensen, M. P., Karoly, P., & Braver, S. (1986). The measurement of clinical pain intensity: A comparison of six methods. *Pain, 27,* 117-126.

Ji, R. R., Kohno, T., Moore, R. A., & Woolf, C. J. (2003). Central sensitization and LTP: do pain and memory share similar mechanisms? *Trends in Neuroscience, 26,* 696-705.

Ji, R. R. & Woolf, C. J. (2001). Neuronal plasticity and signal transduction in nociceptive neurons: Implications for the initiation and maintenance of pathological pain. *Neurobiology of Disease, 8,* 1-10.

Johansson, K., Nuutila, L., Virtanen, H., Katajisto, J., & Salantera, S. (2005). Preoperative education for orthopaedic patients: systematic review. *Journal of Advanced Nursing, 50,* 212-223.

Johnson, J.E., Fieler, V., Jones, L., Wlasowicz, G. & Mitchell, M. (1997). *Self-regulation theory: Applying theory to your practice*. Pittsburgh: Oncology Nursing Press.

Johnson, J., Rice, V., Fuller, S. & Endress, P. (1978). Sensory information, instruction in a coping strategy, and recovery from surgery. *Research in Nursing and Health, 1*(1), 4-17.

Joint National Pharmaceutical Council and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (2005). *Pain: Current Understanding of Assessment,*

Management, and Treatments. Retrieved from http://www.jointcommission.org/standards_information/standards.aspx.

Jones, D., Westby, M., Griedanus, N., Johanson, N., Krebs, D., Robbins, L. et al. (2005). Update on hip and knee arthroplasty: Current state of the evidence. *Arthritis and Rheumatism, 53,* 772-779.

Julius, D. & Bausbaum, A. (2001). Molecular mechanisms of nociception. *Nature, 413,* 203-210.

Kandel, E., Schwartz, J., & Jessell, T. (2000). The perception of pain. In *Principles of neural science* (4th ed., pp. 472-491). New York: McGraw-Hill.

Kaye, A. D. & Kucera, I. J. (2005). Intravascular fluid and electrolyte physiology. In R.D.Miller (Ed.), *Miller's anesthesia* (6th ed., pp. 1763-1790). Philadelphia: Churchill Livingstone.

Kehlet, H. (1994). Postoperative pain relief: What is the issue? *Anaesthesia, 72,* 375-378.

Kehlet, H. (1997). Multimodal approach to control postoperative pathophysiology and rehabilitation. *British Journal of Anaesthesia, 78,* 606-617.

Keller, S., Bann, S., Dodd, S., Schein, J., Mendoza, T., & Cleeland, C. S. (2004). Validity of the Brief Pain Inventory for use in documenting the outcomes of patients with non-cancer pain. *Clinical Journal of Pain, 20,* 309-318.

Klasen, J., Optiz, S. A., Melzer, C., Theil, A., & Hempelman, G. (1999). Intraarticular, epidural and intravenous analgesia after total knee arthroplasty. *Acta Anesthesiologica Scandinavica, 43,* 1021-1026.

Kopacz, D., Sharrock, N., & Allen, H. (1999). A comparison of levobupivacaine 0.125%, fentanyl 4 ug/mL, or their combination for patient-controlled epidural analgesia after major orthopedic surgery. *Anesthesia and Analgesia, 89,* 1297-1305.

Kumar, J., McPherson, E., Dorr, L., Wan, Z., & Baldwin, K. (1996). Rehabilitation after total knee arthroplasty: A comparison of 2 rehabilitation techniques. *Clinical Orthopedics, 331,* 93-101.

Kurosaka, M., Yoshiya, S., & Mizuno, K. (2002). Maximizing flexion after total knee arthroplasty. *Journal of Arthroplasty, 14,* 59.

Lacroix, G., Lessard, M. R., & Trepanier, C. A. (1996). Treatment of postoperative nasuea and vomiting: Comparison of propofol, droperidol and metoclopramide. *Canadian Journal of Anesthesia, 43,* 115-120.

Lacroix, R., Eason, E., & Melzack, R. (2000). Nausea and vomiting during pregnancy: A prospective study of its frequency, intensity, and patterns of change. *American Journal of Obstetrics and Gynecology, 182,* 931-937.

Lai, Y., Guo, S., Keefe, F., Tsai, S., Chien, C., Sung, Y. et al. (2004). Effects of brief pain education on hospitalized cancer patients with moderate to severe pain. *Supportive Care in Cancer, 12,* 645-652.

Larson, C. P. (1996). Evaluating the patient and preoperative preparation. In P.G.Barash, B. F. Cullen, & R. K. Stoelting (Eds.), *Handbook of clinical anesthesia* (2nd ed., pp. 3-15). Philadelphia: Lippincott-Raven.

Laskin, R. & Beksac, B. (2004). Stiffness after total knee arthroplasty. *Journal of Arthroplasty, 19,* 41-46.

Lepczyk, M., Raliegh, E. & Rowley, C. (1990). Timing of preoperative teaching. *Journal of Advanced Nursing, 15*(3), 300-306.

Lin, P. C., Lin, L. C., & Lin, J. J. (1997). Comparing the effectiveness of different educational programs for patients with total knee arthroplasty. *Orthopedic Nursing, 16,* 43-49.

Lingard, E. A., Katz, J., Wright, E. A., Sledge, C. B., & Kinemax Outcomes Group (2004). Predicting the outcome of total knee arthroplasty. *Journal of Bone and Joint Surgery American Edition, 86-A,* 2179-2186.

Loewen, P. S., Marra, C. A., & Zed, P. J. (2000). 5-HT3 receptor antagonists vs traditional agents for the prophylaxis of post-operative nausea and vomiting. *Canadian Journal of Anesthesia, 47,* 1008-1018.

Lorenzini, C., Moriera, L. B., & Ferreira, M. B. C. (2002). Efficacy of ropivacaine comapred with ropivacaine plus sufentanil for post-operative analgesia after major knee surgery. *Anaesthesia, 57,* 424-428.

Lotke, P., Faralli, E., Orenstein, E. M., & Ecker, M. I. (1991). Blood loss after total knee replacement. Effects of tourniquet release and continuous passive motion. *Journal of Bone and Joint Surgery, 73,* 1037-1040.

Macalou, D., Trueck, S., Meuret, P., Heck, M., & Vial, F. et al. (2004). Postoperative analgesia after total knee replacement: The effect of an obturator nerve block added to femoral 3in1 nerve block. *Anesthesia and Analgesia, 99*(1), 251-254.

Marcinkowski, K., Wong, V.G. & Dignam, D. (2005). Getting back to the future: A grounded theory study of the patient perspective of total knee joint arthroplasty. *Orthopedic Nursing, 24*, 202-209.

Martin, J. H. & Larsen, P. D. (1994). Dehydration in the elderly surgical patient. *AORN Journal, 60,* 666-671.

McDonald, D. D., Freeland, M., Thomas, G., & Moore, J. (2001). Testing a preoperative pain management intervention for elders. *Research in Nursing & Health, 24,* 402-409.

McDonald, D. D. & Molony, S. L. (2004). Postoperative pain communication skills for older adults. *Western Journal of Nursing Research, 26,* 836-852.

McDonald, S., Green, S. E., & Hetrick, S. (2004). Pre-operative education for hip and knee replacement (Review). *Cochrane Database of Systematic Reviews, 1*, CD003526.pub2.

McNamee, D. A., Parks, L., & Milligan, K. R. (2002). Postoperative analgesia following total knee replacement: an evaluation of the addition of an obturator nerve block to combined femoral and sciatic block. *Acta Anesthesiologica Scandinavica, 46,* 95-99.

Melzack, R. (1989). Measurement of Nausea. *Journal of Pain and Symptom Management, 4,* 157-160.

Melzack, R. (1987). The short form McGill Pain Questionnaire. *Pain, 30,* 191-197.

Melzack, R., Abbott, F., Zackon, W., Mulder, D., & Davis, W. (1987). Pain on a surgical ward: a survey of the duration and intensity of pain and the effectiveness of medication. *Pain, 29,* 67-72.

Melzack, R. & Casey, K. L. (1968). Sensory, motivational and central control determinanats of pain: A new conceptual model. In D.Kenshalo (Ed.), *The Skin Senses* (pp. 423-443). Springfield: Charles C. Thomas.

Melzack, R., Rosberger, Z., Hollingsworth, M. L., & Thirlwell, M. (1985). New approaches to measuring nausea. *Canadian Medical Association Journal, 133,* 755-758.

Melzack, R. & Wall, P. (1996). *The challenge of pain*, (2nd ed.). London: Penguin.

Melzack, R. & Wall, P. (1965). Pain mechanisms: A new theory. *Science, 150,* 971-979.

Mendoza, T., Chen, C., Brugger, A., Hubbard, R., Snabes, M., Palmer, S. et al. (2004a). The utility and validity of the modified Brief Pain Inventory in a multiple dose postoperative analgesic trial. *Clinical Journal of Pain, 20,* 357-362.

Mendoza, T., Chen, C., Brugger, A., Hubbard, R., Snabes, M., Palmer, S. et al. (2004b). Lessons learned from a multiple-dose post-operative analgesic trial. *Pain, 109,* 103-109.

Mont, M., Lee, C. W., Sheldon, M., Lennon, W. C., & Hungerford, D. S. (2002). Total knee arthroplasty in patients <50 years old. *Journal of Arthroplasty, 17,* 538-543.

Moon, L. & Backer, J. (2000). Relationships among self-efficacy, outcome expectancy, and postoperative behaviors in total joint replacement patients. *Orthopedic Nursing, 19,* 77-85.

Moore, K. L. (1985). *Clinically Oriented Anatomy*. (2nd ed.) Baltimore: Williams & Wilkins.

Moran, C. & Horton, T. (2000). Total knee replacment: The joint of the decade. *British Medical Journal, 320,* 820-821.

Morsi, E. (2002). Continuous flow colf therapy after total knee arthroplasty. *Journal of Arthroplasty, 17,* 718-722.

Muller, U., Exadaktylos, A., Roeder, C., Pisan, M., Eggli, S., & Juni, P. (2004). The effect of a flowchart on use of bood transfusions in primary total hip and total knee replacements: Prospective before and after study. *British Medical Journal, 328,* 934-938.

Murdoch, J., Dickson, U., Wilson, P., Berman, J., Gad-Elrab, R., & Scott, N. (2002). The efficacy and safety of three concentrations of levobupivacaine administered as continuous epidural infusion in patients undergoing orthopedic surgery. *Anesthesia and Analgesia, 94,* 438-444.

Myles, P. S., Williams, D. L., Hendrata, M., Anderson, H., & Weeks, A. M. (2000). Patient satisfaction after anesthesia and surgery: Results of a prospective survey of 10811 patients. *British Journal of Anaesthesia, 84,* 6-10.

Mythen, M. G. & Webb, A. R. (1995). Perioperative plasma volume expansion reduces the incidence of gut mucosal hyperperfusion during cardiac surgery. *Archives of Surgery, 130,* 423-429.

Ng, H. P., Cheong, K. F., Lim, A., Lim, J., & Puhaindran, M. E. (2001). Intraoperative single-shot "3in1" femoral nerve block with ropivacaine 0.25%, ropivacaine 0.5% or bupivacaine 0.25% provides comparable 48-hr analgesia after unilateral total knee replacement. *Canadian Journal of Anesthesia, 48,* 1102-1108.

Parentis, M., Rumi, M., Deol, G., Kothari, M., Parrish, W., & Pellegrini, V. (1999). A comparison of the vastus splitting and median parapatellar approach in total knee arthroplasty. *Clinical Orthopedics, 367,* 107-116.

Parlow, J., Costache, I., Avery, N., & Turner, K. (2004). Single-does haldoperidol for the prophylaxis of post-operative nausea and vomiting after intrathecal morphine. *Anesthesia and Analgesia, 98,* 1072-1076.

Patanwala, A., Duby, J., Waters, D. & Erstad, B. (2007). Opioid conversions in acute care. *Annals of Pharmacotherapy, 41*(2), 256-266.

Pellino, T., Gordon, D. B., Engelke, Z. K., Busse, K. L., Collins, M. A., Silver, C. E. et al. (2005). Use of nonpharmcologic interventions for pain and anxiety after total hip and total knee arthroplasty. *Orthopedic Nursing, 24,* 182-190.

Phillips, P. A., Johnston, C. I., & Gray, L. (1993). Disturbed fluid and electrolyte homeostasis following dehydration in elderly people. *Age and Aging, 22,* S26-S33.

Pusch, F., Berger, A., Wildling, E., Tiefenthaler, W., & Krafft, P. (2002a). The effects of systolic arterial blood pressure variations onpostoperative nausea and vomiting. *Anesthesia and Analgesia, 94,* 1652-1655.

Pusch, F., Berger, A., Wildling, E., Zimpfer, M., Moser, M., Sam, C. et al. (2002b). Preoperative orthostatic dysfunction is associated with an increased incidence of postoperative nausea and vomiting. *Anesthesiology, 96,* 1381-1385.

Rathmell, J. P., Pino, C. A., Taylor, R., Patrin, T., & Viani, B. A. (2003). Intrathecal morphine for post-operative analgesia: A randomized, controlled, dose-ranging study after hip and knee arthroplasty. *Anesthesia and Analgesia, 97,* 1452-1457.

Reynolds, L., Hoo, R., Brill, R., North, J., Recker, D. & Verburg, K. (2003). The COX-2 specific inhibitor, valdecoxib, is an effective, opioid-sparing analgesic in patients undergoing total knee arthroplasty. *Journal of Pain and Symptom Management, 25*(2), 133-141.

Roach, J. A., Tremblay, L. M., & Bowers, D. L. (1995). A preoperative assessment and education program: implementation and outcomes. *Patient Education and Counseling, 25,* 83-88.

Salmon, P., Hall, G., Perrbhoy, D., Shenkin, A., & Parker, C. (2001). Recovery from hip and knee arthroplasty: Patients' perspective on pain, function, quality of life, and well-being up to 6 months post-operatively. *Archives of Physical Medicine and Rehabilitation, 82,* 360-366.

Schultz, A. A., Andrews, A., Goran, S. F., Mathew, T., & Sturdevant, N. (2003). Comparison of acupressure bands and droperidol for reducing postoperative nausea and vomiting in gynecologic surgery patients. *Applied Nursing Research, 16,* 256-265.

Sherwood, P., Given, B., Given, C., Champion, V., Doorenbos, A. & Azzouz, F. et al. (2005). A cognitive behavioural intervention for symptom management in patients with advanced cancer. *Oncology Nursing Forum, 32*, 1190-1198.

Shuldham, C. (1999a). A review of the impact of pre-operative education on recovery from surgery. *International Journal of Nursing Studies, 36,* 171-177.

Shuldham, C. (1999b). Pre-operative education - a review of the research design. *International Journal of Nursing Studies, 36,* 179-187.

Silvasti, M. & Pitkanen, M. (2001). Patient-controlled epidural analgesia versus continuous epidural analgesia after total knee arthoplasty. *Acta Anesthesiologica Scandinavica, 45,* 471-476.

Sinclair, S., James, S., & Singer, M. (1997). Intraoperative intravascular volume optimization and length of stay after repai of proximal femoral fracture: Randomized controlled trial. *British Medical Journal, 315,* 909-912.

Singelyn, F., Deyaert, M., Joris, D., Pendeville, E., & Gouverneur, J. (1998). Effects of intravenous patient-controlled analgesia with morphine, continuous epidural analgesia, and continuous three-in-one block on post-operative pain and knee rehabilitation after unilateral total knee arthroplasty. *Anesthesia and Analgesia, 87,* 88-92.

Sites, C., Beach, M., Biggs, R., Rohan, C., Wiley, C., Rassias, A. et al. (2003). Intrathecal clonidine added to bupivacaine-morphine spinal anesthetic improves post-operative analgesia for total knee arthroplasty. *Anesthesia and Analgesia, 96,* 1083-1088.

Sjoling, M., Nordahl, G., Olofsson, N., & Asplund, K. (2003). The impact of preoperative information on state anxiety, postoeprative pain and satisfaction with pain management. *Patient Education and Counseling, 51,* 169-176.

Smith, J., Stevens, J., Taylor, M., & Tibbey, J. (2002). A randomized, controlled trial comparing compression bandaging and cold therapy in post-operative total knee replacement surgery. *Orthopedic Nursing, 21,* 61-66.

Stern, C. & Lockwood, C. (2005). Knowledge retention from preoperative patient information. *International Journal of Evidence Based Healthcare, 3,* 45-63.

Strassels, S. A., Chen, C., & Carr, D. (2002). Postoperative analgesia: Economics, resource use, and patient satisfaction in an urban teaching hospital. *Anesthesia and Analgesia, 94,* 130-137.

Strebel, S., Gurzeler, J. A., Schnieder, M. C., Aeschbach, A., & Kindler, C. H. (2004). Small-dose intrathecal clonidine and isobaric bupivacaine for orthopedic surgery: A dose-response study. *Anesthesia and Analgesia, 99,* 1231-1238.

Tan , G., Jensen, M. P., Thornby, J. L., & Shanti, B. F. (2004). Validation of the Brief Pain Inventory for chronic nonmalignant pain. *Journal of Pain, 5,* 133-137.

Teeny, S. M., York, S. C., Benson, C., & Perdue, S. T. (2005). Does shortened length of hospital stay affect total knee arthroplasty rehabilitation outcomes? *Journal of Arthroplasty, 20,* 39-45.

Tennant, A., Fear, J., Pickering, A., Hillman, M., Cutts, A., & Chamberlain, M. A. (1995). Prevalence of knee problems in the population aged 55 years and over: Identifying the need for knee arthroplasty. In (310 ed., pp. 1291-1293).

Thompson, H. (1999). The management of post-operative nausea and vomiting. *Journal of Advanced Nursing, 29,* 1130-1136.

Tinmouth, A., McDougall, M., Fergusson, D., Amin, M., Graham, I., Hebert, P. et al. (2005). Reducing the amount of blood transfused. A systematic review of behavioral

interventions to change physicians' transfusion practices. *Archives of Internal Medicine 165*(8), 835-852.

Velji, K. (2006). Effect of an individualized symptom education program on the symptom distress of women receiving radiotherapy for gynecological cancer. Available from ProQuest database (AAT NR21992).

Venn, R., Steele, A., Richardson, P., Polonieki, J., Grounds, M., & Newman, P. (2002). Randomized controlled trial to investigate influence of the fluid challenge on duration of hospital stay and perioperative morbidity in patients with hip fractures. *British Journal of Anaesthesia, 88,* 65-71.

Wang, H., Boctor, B., & Verner, J. (2002). The effect of single-injection femoral nerve block on rehabilitation and length of hospital stay after total knee replacement. *Regional Anesthesia and Pain Medicine, 27,* 139-144.

Wall, P.D. (1995). Independent mechanisms convergent on pain. *Nature Medicine, 1*(8), 740-741.

Waterman, H., Leatherbarrow, B., Slater, R., & Waterman, C. (1999). Post-operative pain,nausea and vomiting: qualitative perspectives from telephone interviews. *Journal of Advanced Nursing, 29,* 690-696.

Watt-Watson, J., Stevens, B., Katz, J., Costello, J., Reid, G., & David, T. (2004). Impact of pre-operative education on pain outcomes after coronary artery bypass graft surgery. *Pain, 109,* 73-85.

Weale, A. E., Halabi, O. A., Jones, P. W., & White, S. H. (2001). Comparisons of outcomes after unicompartmental and total knee arthroplasty. *Clinical Orthopedics and Related Research, 382,* 143-153.

Weiss, J., Noble, P., Conditt, M., Kohl, H., Roberts, S., Cook, K. et al. (2002). What functional activities are important to patients with knee replacements? *Clinical Orthopedics and Related Research, 404,* 172-188.

White, C., McPherson, A., McCann, M., Sadler, A. & Fyvie, J. (2006). Prolongued extrapyramidal side effects after discontinuation of haldoperidol as an anti-emetic. *Palliative Medicine, 20*(3), 215-216.

Williams-Russo, P., Sharrock, N., Haas, S., Insall, J., Windsor, R., Laskin, R. et al. (1996). Randomized trial of epidural versus general anesthesia: Outcomes after primary total knee replacement. *Clinical Orthopedics, 331,* 199-208.

Wilson, I. B. & Cleary, P. D. (1995). Linking clinical variables with Health-Related Quality of Life: A conceptual model of patient outcomes. *Journal of the American Medical Association, 273,* 59-65.

Wilson, R., Goldstein, D., VanDenKerkhof, E., & Rimmer, M. (2005). APMS clinical dataset. October 1, 2004-October 1, 2005. Kingston, Ontario, Unpublished.

Woolf, C. J. (1983). Evidence for a central component of post-injury pain hypersensitivity. *Nature, 306,* 686-688.

Wu, C., Naqibuddin, M., Rowlingson, A., Lietman, S., Jermyn, R., & Fleisher, L. (2003). The effect of pain on health-related quality of life in the immediate postoperative period. *Anesthesia and Analgesia, 97,* 1078-1085.

Yashar, A., Venn-Watson, E., Welsh, T., Colwell, C., & Lotke, P. (1997). Continuous passive motion with accelerated flexion after total knee arthroplasty. *Clinical Orthopedics and Related Research, 1,* 38-43.

Yates, P., Edwards, H., Nasha, R., Arenda, S., Purdie, D. & Najmond, J. et al. (2004). A randomized controlled trial of a nurse administered educational intervnetion for improving

cancer pain management in ambulatory settings. *Patient Education and Counseling, 53*, 227-237.

Yogendran, S., Asokumar, B., Cheng, D., & Chung, F. (1995). A prospective randomized double-blinded study of the effect of intravenous fluid therapy on adverse outcomes on outpatient surgery. *Anesthesia and Analgesia, 80,* 682-686.

Yoon, R., Nellans, K., Geller, J., Kim, A., Jacobs, M., & Macaulay, W. (2010). Patient education befoe hip and knee arthroplasty lowers length of stay. Journal of Arthroplasty 25[4], 547-551.

Zalon, M. (1997). Pain in frail, elderly women after surgery. *Image: Journal of Nursing Scholarship, 29,* 21-26.

Zhou, T., Tang, H., & White, P. (2001). Propacetamol versus ketorolac for treatment of acute post-operative pain after total hip or knee replacement. *Anesthesia and Analgesia, 92,* 1569-1575.

Appendices

Appendix A

Total Knee Arthroplasty Descriptive Studies

Total Knee Arthroplasty Descriptive Studies

Author	Study Design	Sample Characteristics, Response rate, setting	Outcome Concepts and Definitions	Measures	Outcomes/Limitations
Brander, Stulberg, Adams, Harden, Bruehl, Stanos and Houle (2003)	Descriptive	Elective total knee replacement Age=66 (10.5) years 55.2% female n=116 patients	Pain: Mood state Knee function	Short Form McGill Pain Questionnaire (MPQ SF), Visual Analogue Scale Beck Depression Inventory, State Trait Anxiety Index, Perceived Stress Scale Western Ontario and McMaster University Osteoarthritis Index (WOMAC), Knee Society knee and function scores.	Results for one month postoperative measurement only included. <u>Pain</u> VAS 52.6(24.4) 44.4% patients reported VAS >40 No differences in findings relative to anesthesia type, weight, gender or age MPQ-SF, Knee function items and mood state items not reported beyond preoperative values
Crutchfield, Zimmerman, Nieveen, Barnason and Pozehl (1996)	Descriptive	Elective total knee replacement Age: 70(8.8) years 71% female n=120 patients	Pain	Long Form McGill Pain Questionnaire (MPQ LF)	Data collected preoperatively, and at 1600 postoperative days one and three. Frequency data provided of sensory, affective, evaluative and miscellaneous descriptors chosen by patients <u>Sensory</u> >40% chose throbbing, sharp, tender on day 1 >40% chose sharp, tender on day 3 <u>Affective</u> >40% chose tiring on both days 1 and 3 <u>Evaluative</u> >40% chose annoying on both days 1 and 3

Author	Study Design	Sample Characteristics, Response rate, setting	Outcome Concepts and Definitions	Measures	Outcomes/Limitations
					Miscellaneous >40% chose tight on both days 1 and 3 MPQ Subscales were as follows: Sensory: F=7.39, p<.001 Day 1 mean=17.73 Day 2 mean=15.68: NS Affective: F=5.72, p<.01 Day 1 mean=3.33 Day 2 mean=3.00: NS Evaluative: F=5.64, p<.01 Day 1 mean=2.31 Day 2 mean=2.25: NS Present Pain Index: F(2,228)=4.35, p<.05 Day 1 mean=1.98 Day 2 mean=1.58, F=9.68, p<.01
Strassels, Chen and Carr (2002)	Descriptive	Elective total knee replacement Age=63(53-80) years 70% female n=10 patients	Pain Pain interference	American Pain Society Quality Improvement Patient Outcome Questionnaire	Data was collected within 24 hours before hospital discharge Descriptive data regarding pain experience only presented Mean current pain: 2.0(1.7) Mean worst pain (last 24h): 5.5(2.7) Avg pain postoperative day 1=5.4(2.7) Avg pain postoperative day 2=5.4(2.7) Avg pain postoperative day 3=4.0(2.1) Avg pain postoperative day 4=1.4(1.7) Avg pain postoperative day 5=1.0 Mean % relief from

Author	Study Design	Sample Characteristics, Response rate, setting	Outcome Concepts and Definitions	Measures	Outcomes/Limitations
					medications=60%(40) <u>Mean pain related interference</u> General activity=5.3(4.4) Mood=4.1(3.8) Walking ability=6.8(3.5) Relations with other people=3.3(2.8) Sleep=4.9(3.8) Other activities=2.1(2.1)
Salmon, Hall, Peerbhoy, Shenkin and Parker (2001)	Descriptive, comparative	Elective total knee replacement Age=66(11.1) 57% female n=53 Elective total hip replacement Age=69(11) n=107	Functional impairment Pain intensity Mood Quality of Life Life evaluation	WOMAC VAS Profile of Mood States (POMS) SF 36 Cantril's Life satisfaction ladder (1-10)	Results for POD 1, 3, 7 and one month measurements only included. Worst pain POD 1 TKA pain worse than THA pain at all measurement times, $p<.01$ TKA pain and role limitation worse than THA at 1 month, $p<.01$ TKA fatigue more than THA POD 3, $p<.05$ TKA vigor, energy and fatigue lower than baseline until POD 7 $p<.01$ Subjective health lower than baseline at one month, $p<.01$
Moon & Becker (2000)	Descriptive, correlational	Elective total knee replacement n=36 Elective total hip replacement n=14 Age=67.5(45-85) 62% female	Self efficacy and outcome expectancy Ambulation	Preoperative self efficacy scale – modified to suit postoperative activity distance measured in feet	Measurements taken on POD 1 Distance ambulated: 47.8(31.8) feet Self efficacy sole predictor of postoperative exercise ability accounting for 8-33% variance directly related to frequency and number of repetitions of exercises ($p<.01, .05, .001$)

Author	Study Design	Sample Characteristics, Response rate, setting	Outcome Concepts and Definitions	Measures	Outcomes/Limitations
Wu, Naqibuddin, Rowlingson, Lietman, Jermyn and Fleisher (2003)	Descriptive, correlational	Elective total knee replacement Elective total hip replacement Age=67.8(8.4) 49% female n=37	Pain intensity Nausea HRQOL	VAS pain - rest, activity VAS nausea SF-12 – modified to reflect postoperative time frame	Measurements taken every evening during in-patient stay (VAS pain, nausea), Preoperatively and in the evenings of POD 1-5, 7 and 14 (SF-12) VAS Pain Intensity Day Rest M(SD) Activity M(SD) POD 1 3.4(2.6) 5.0(2.7) POD 2 3.1(2.3) 4.8(2.2) POD 3 2.2(2.1) 3.8(2.1) POD 4 2.2(2.0) 3.2(2.2) POD 5 2.1(2.0) 3.2(2.2) Nausea severity was worst on POD 1: 1.3(2.0) and was significantly positively related to mental component scores (MCS) $r2=0.53$, $p<0.01$ Pain at rest and with activity positively correlated with physical component scores (PCS) on POD 1, 2, 4, 5, 7 & 14 and MCS on POD 2, 3, 4, 5 & 7 at rest only ($p<0.01$-0.05).

Appendix B

Total Knee Arthroplasty Analgesic Interventions

Table 1.
Total knee arthroplasty analgesic interventions

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Bogoch, Henke, MacKenzie, Olschewski and Mahomed (2002)	Randomized Controlled Trial	Total knee and total hip replacement patients N=115 Acute care hospital, in-patient orthopedics	Pain (4,8,24h post-op) Satisfaction with pain management Opioid consumption via PCA-IV	VAS pain VAS satisfaction Morphine equivalents	Single-shot lumbar paravertebral nerve block immediately after surgery	Intervention group used less opioid in first 4 hours only (p<.0001) No difference in pain or satisfaction No differentiation between resting and pain on movement ratings Ethical issues with placebo block No physiotherapy information
Macalou, Trueck, Meuret, Heck, Vial, Ouloguem, Capdevila, Virion & Bouaziz (2004)	Randomized Controlled Trial	Total knee arthroplasty patients N=90 Acute care hospital, in-patient orthopedics	Pain (hourly until 7 hours post-op) Opioid consumption Adverse effects including nausea, sedation (0-2 scale), vomiting, hypotension requiring intervention, respiratory depression (RR<10/min), bradycardia (<40 bpm)	VAS pain Morphine equivalents Adverse effect incidence	Obturator and femoral nerve block before induction of general anesthesia	Addition of obturator block reduced morphine consumption (P<0.0001) Lower VAS in intervention group (p=0.0003) Less nausea in intervention group (p=0.01) No information on movement status of participants when VAS measures done. Brief study period
Murdoch, Dickson, Wilson, Berman, Gad-Elrab, Scott (2002)	Randomized Controlled Trial	Total joint replacement patients N=91	Sensory and motor blockade Pain Vital signs (HR, RR,	Assessment VAS pain Assessment	Continuous epidural analgesia with three concentrations of levobupivacaine for 24h after surgery	14 patients withdrawn due to treatment failure No clinically significant differences in vital signs between groups

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
		Acute care hospital, in-patient orthopedics	BP, O2Sat) Opioid consumption	 Morphine equivalents All measurements taken intensity q1h x 4 hours then q2h x 8 hours then q6h until 24 hour study period reached		Higher concentration group had more motor blockade (p=0.002), lower VAS (p=0.0008, p<0.0001) No difference in opioid consumption between groups No information on movement status of participants when VAS measures done.
Zhou, Tang & White (2001)	Randomized controlled trial	Total joint replacement patients N=164 Acute care hospital, in-patient orthopedics	Pain intensity Pain relief – time to onset of analgesia Adverse events	VAS pain Verbal rating scale (0=none, 1=mild, 2=moderate, 3=severe) Global pain evaluation (0=poor, 1-fair, 2=good, 3=excellent) (at T6 only) 5 point categorical scale (0=none, 1=a little, 2=moderate, 3=a lot, 4=complete) Nausea and sedation Measurements at 1,2,3,4,5,6 hours post administration	Intravenous ketorolac or intravenous propacetamol verses placebo	No reliability or validity information on verbal descriptor scales used Reported pain intensity, relief data as differences Better pain relief with both ketorolac and propacetamol compared with placebo (p<0.0001) until 5 hour measurement Greater pain intensity difference in both groups compared with placebo (p<0.05) Ethical issues with treating moderate to severe pain with placebo. Short study period

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Eggers, Jenkins, & Power (1999)	Randomized controlled trial	Total knee replacement patients N=101 Acute care hospital, in-patient orthopedics	Pain intensity Opioid consumption Knee mobility (flexion)	VAS pain, rest and activity Morphine equivalents Manual gonimeter Measurements at 1, 2, 12, 24 hours then daily for a total of 8 days	Oral or IV tenoxicam before surgery, then OD for 8 days postoperatively: Oral or IV tenoxicam after surgery, then OD for 8 days postoperatively: Placebo dosing	No differences in opioid consumption, VAS pain, knee mobility Reported as two-phase study: perioperative versus postoperative days 2-8.
Browne, Copp, Reden, Pulido & Colwell (2004)	Randomized Controlled Trial	Total knee replacement patients N=60 Acute care hospital, in-patient orthopedics	Pain Opioid consumption	SF-MPQ Morphine equivalents Measurements at 0, 1, 2, 4, 8, 12 & 24 hours post surgery	Intra-articular bupivacaine injection or placebo before knee capsule closure	No differences in pain, opioid consumption. Stated SF-MPQ use but only VAS pain intensity data reported No information on data collection or randomization methods
Klasen, Opitz, Melzer, Thiel & Hempelmann (1999)	Randomized Controlled Trial	Total knee replacement patients N=37: Protocol violation in 7/37 cases Acute care hospital, in-patient orthopedics	Pain Opioid consumption Stress hormone serum levels Adverse effects ROM	VAS pain, rest and activity Morphine equivalents Concentrations of adrenaline, noradrenaline, adrenocorticotropic hormone, antidiuretic hormone, & β-endorphin levels	Epidural morphine or intraarticular morphine or usual care (PCA-IV)	No difference in pain, opioid consumption or stress hormones between all three groups. Trend for improved ROM IA/Usual care. β-endorphin levels reduced at 8h only in epidural morphine group ($p<0.001$) Very small sample size per group: sample size calculation based on 50% in opioid consumption

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
				Measurements at 4,8,12 & 24 hours after the initiation of subarachnoid block		Groups not blinded. No information on randomization or data collection procedures
Cole, Craske & Wheatley (2000)	Randomized Controlled Trial – Double-blinded	Total knee replacement patients N=38 Acute care hospital, in-patient orthopedics	Pain intensity Opioid consumption Oxygen saturation/hypoxemia : mild = SP02 <94%/12 minute interval; moderate = SP02 <90%/12 minute interval; severe = SP02 <85%/6 minute interval	VAS pain, rest and activity Morphine equivalents VAS measurements at 1,2,3,4, 8, 12, 16, 20 & 24 hours after surgery Oxygen saturation measured continuously for 14 hours after surgery	Intrathecal morphine or placebo	Lower pain intensity and opioid consumption in intervention group at all measurement times ($p<0.05$) No differences in SP02. No cases of moderate or severe hypoxemia in either group
Lorenzini, Moreira & Ferreira (2002)	Randomized Controlled Trial	Total knee replacement and anterior cruciate ligament repair patients N=115: protocol violation in 1/115 cases Acute care hospital, in-patient orthopedics	Pain intensity Opioid consumption Sensory and motor blockade Adverse effects	VAS pain, rest & activity: Simple descriptor scale (none, mild, moderate, severe) Morphine equivalents Assessment/Bromage scale Incidence of nausea, vomiting and pruritus	Epidural ropivacaine and sufentanyl or ropivacaine alone	Lower pain at 12 and 24 hours in intervention group ($P=0.009$) More adverse effects in intervention group ($p<0.01$) Poorly designed study – all data reported in consideration of pervious 6 hour interval Two surgical groups: TKA and anterior cruiciate repair. Data reported together

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
				Measurements at 6, 12, 24 hours – each measurement compilation of review of previous interval		
Sites, Beach, Biggs, Rohan, Wiley, Rassias, Gregory & Fanciullo (2003)	Randomized Controlled Trial – Double Blinded	Total knee replacement (unilateral and bilateral) patients N=81 Acute care hospital, in-patient orthopedics	Pain intensity Opioid consumption Adverse effects: nausea, hypotension, dry mouth	VAS pain Morphine equivalents Verbal descriptor scale for each symptom: 1=no; 2=mild; 3=moderate; and, 4=severe Measurements at 1,2,4,6,12,& 24 hours after surgery	Two dosages of intrathecal clonidine + bupivacaine/morphine spinal anesthetic	Opioid consumption decreased in both clonidine groups (p=0.028). Pain decreased in both clonidine groups (p=0.047) however, small mean decrease (1.3) – not clinically significant. Very detailed explanation of study protocol Small sample size – 20/group: calculation based on reduction in opioid consumption Inclusion of bilateral TKA - accounted for 25% of sample size
Tan, Chia, Lo, Liu, Yang & Lee (2001)	Randomized Controlled Trial – double blinded	Total knee replacement patients N=62: 2/60 withdrawn secondary to requirement for general anesthetic Acute care hospital, in-patient orthopedics	Pain intensity Duration of sensory and motor blockade: time when able to lift both legs against gravity Duration of analgesia: time of drug administration to first report of VAS >0	VAS pain Assessment: Bromage scale Measurements at 4,8,12,16 & 24 hours	Intrathecal bupivacaine alone, with morphine or neostigmine	Morphine group had longer duration of analgesia ($p<0.05$), Overall 24 hour pain intensity higher in bupivacaine alone group ($p<0.05$). Motor blockade lasted longer in neostigmine group ($p<0.05$). No information about randomization or data collection procedures

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Kopacz, Sharrock & Allen (1999)	Randomized Controlled Trial – stratified for surgery type	Total joint replacement patients N=68: 3/68 withdrawn Acute care hospital, in-patient orthopedics	Pain intensity Overall pain satisfaction Adverse effects: hypotension (<30% reduction from baseline), nausea, Time to first request for analgesia: from epidural placement to first use of patient controlled epidural analgesia (PCEA)	VAS pain, rest and activity VAS satisfaction with pain care overall Incidence of adverse effects Measurements at 6,12 & 24 hours after surgery	Epidural levobupivacaine, epidural fentanyl or epidural levobupivacaine and fentanyl combination	Combined group had longer interval to request for analgesia than either single agent group (p=0.007) Combined group had lower pain scores at 6, 12 and 24 hours than either single agent group (p=0.0022, 0.036). No difference in adverse effects No information about randomization or data collection procedures
Himmelseher, Ziegler-Pithamitsis, Martin, Jelen-Esselborn & Kochs (2001)	Randomized Controlled Trial – Double blinded	Total knee replacement patients N=42: 5/42 withdrawn secondary to catheter displacement (2), early removal (1), anaphylaxis (1), inability to place epidural (1) Acute care hospital, in-patient orthopedics	Pain intensity Sensory and motor blockade Overall quality of pain Time to first request for analgesia: from epidural placement to first use of patient controlled epidural analgesia (PCEA)	VAS pain, rest and activity Assessment: Bromage scale Verbal descriptor scale: 1=poor; 2=fair; 3=good; and, 4=excellent Measurements at 2,4, 6, 8, 24 & 48 hours after surgery	Epidural ketamine and ropivacaine or ropivacaine alone	Ketamine group less pain at 24 and 48 hours both at rest and with activity (p<0.05) Ketamine group used less PCEA ropivacaine (p<0.01) Overall quality of pain not reported Small sample size – calculation based on 20% reduction in ropivacaine usage via PCEA

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Strebel, Gurzeler, Schnieder, Aeschbach & Kindler (2004)	Randomized Controlled Trial – Double blinded	Total joint replacement patients N=80: 5/80 withdrawn Acute care hospital, in-patient orthopedics	Pain intensity Duration of pain relief: time from intrathecal administration of clonidine to first request of patient controlled analgesia (PCA) Duration of motor blockade: time to achievement of Bromage score of 0/4	VAS pain Measurements at 15,30,45,60 minutes, 2,3,4,5,6,7,8,12,16, 20 & 24 hours after surgery	Intrathecal clonidine (3 doses) and bupivacaine or bupivacaine alone	Pain lower in higher dose clonidine group compared with bupivacaine alone group at 6,7&8 hours ($p<0.05$) Dose-dependen t increase in duration of pain relief in all clonidine groups ($p=0.0001$) and in duration of motor blockade ($p<0.05$) Based sample size calculation on an increase of 30% in time interval to first PCA request
Capdevila, Barthelet, Biboulet, Ryckwaert, Rubenovitch & d'Athis (1999)	Randomized Controlled Trial	Total knee replacement patients N=56 Acute care hospital, in-patient orthopedics	Pain intensity Opioid consumption Adverse effects: nausea, sedation, hypotension (<20% baseline mean blood pressure), urinary retention, pruritus, dysesthesias Joint mobility: maximal amplitude of knee flexion on 5th day after surgery and on discharge	VAS pain, rest and activity Morphine equivalents Incidence Sedation: 0=awake; 1=sleepy but awaked by oral order; 2=sleepy but awakened by nocicpetive stimulation; 3=not awakened Universal manual goniometer Measurements at 1,6,12,24 & 48 hours after surgery	Continuous epidural infusion, continuous femoral nerve block infusion or patient controlled intravenous analgesia (PCA)	Epidural and femoral nerve block groups had less pain at rest and with activity than PCA group ($p<0.01$). PCA group had less knee flexion on discharge than either of the other two groups ($p<0.05$). Length of stay in subsequent rehabilitation facility were longer for PCA group ($p<0.05$)

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Silvasti & Pitkanen (2001)	Randomized Controlled Trial	TKA inpatients Age:71(11), 74(8) 83% female N=49	Pain Sensory/Motor block Patient satisfaction Adverse effects: Nausea, vomiting, anti-emetic usage, urinary retention	Pain: VAS, Verbal rating score (VRS) Sensory block: pinprick Motor block: Bromage scale Measurements at 3,9 & 20 hours	Patient controlled epidural analgesia (PCEA) versus continuous epidural analgesia (CEA)	No difference in any outcomes between groups
Singelyn, Deyart, Joris, Pendiville & Gouverneur (1998)	Randomizaed Controlled Trial	TKA inpatients Age and sex not reported N=45	Pain: at rest and with activity Degree of flexion Adverse effects: Nausea, vomiting, hypotension, urinary retention, catheter problems	Pain: VAS, postoperative pain score (PPS) Flexion: recorded by physiotherapist – method not reported	Patient controlled intravenous analgesia (PCA-IV) versus continuous femoral nerve block (CFNB) versus continuous epidural analgesia (CEA)	Lower VAS in CFNB group ($p<0.0001$) and CEA group ($p<0.0001$) at rest and with activity compared with PCA-IV group Better knee flexion in CFNB group ($p<0.001$) and CEA group ($p<0.001$) No difference in adverse effects between groups Small sample sizes in each group. No information about postoperative activity regimen
Bogoch, Henke, MacKenzie, Olschewski & Mahomed (2002)	Randomized Controlled Trial	THA and TKA inpatients Age: 64(12), 65(14) 63% female N=115	Analgesic consumption: Morphine equivalents Pain: at rest and with activity Length of stay	Pain: VAS Measurements at 4, 8, 12, 24 hours	Lumbar paravertebral nerve block (PVNB) versus PCA-IV	No differences in outcomes between groups No information about postoperative activity regimen

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Hubbard, Naumann, Traylor & Dhadda (2003)	Randomized Controlled Trial	TKA inpatients Age: 68.2(34-89), 70(42-86), 68.6(43-83) 72% female N=195	Analgesic consumption: Morphine equivalents Pain Adverse effects: Hypertension, hypotension, fever, nausea, anaemia, urinary retention	Pain: VAS – no information if measurements taken at rest or with activity Measurements at 6, 24 & 48 hours	Placebo versus two doses of parecoxib sodium	Patients in both parecoxib groups used less morphine (43.5 mg versus 36.7, 31.4 mg: $p<0.05$) Patients in both placebo groups had lower VAS at 6, 24, 48 hours ($P<0.05$)
McNamee, Parks & Milligan (2002)	Randomized Controlled Trial	TKA inpatients Age: 66(58-74), 68.9(51-78) 63% female N=51	Analgesic consumption: Morphine equivalents, time to first request for analgesic Pain	Pain: VAS - no information if measurements taken at rest or with activity Measurements every four hours until 48 hours postoperatively	Femoral/sciatic nerve block versus femoral/sciatic nerve block plus obturator nerve block	Combined group had longer time to first request for analgesia (433.6 (120-1680) versus 257 (105-900): $p<0.05$) No information about randomization procedures Small sample size
Ng, Cheong, Lim, Lim & Puhaindran (2001)	Randomized Controlled Trial	TKA inpatients Age: 65.3(14), 64.3(8.6), 64.8(5.2), 62.8(7.9) 83% female N=45	Pain Analgesic consumption: Morphine equivalents	Pain: Verbal pain score (VPS) – four point scale, no validity information provided	Femoral nerve block using A: ropivacaine 0.25%, B: ropivacaine 0.5%, C: bupivacaine 0.25% versus sham block	No differences in VPS between treatment groups but difference when compared to sham block group ($p<0.05$) No differences in analgesic consumption between treatment groups but difference when compared to sham block group ($p<0.01$)

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Barrington, Olive, Low, Scott, Brittain & Choong (2005)	Randomized Controlled Trial	TKA inpatients Age: 69(10), 71(9) 53% female N=108	Pain: at rest and with activity (at physiotherapy and during continuous passive motion use) Analgesic consumption: Morphine equivalents Quadriceps strength Adverse effects: Nausea, vomiting, hypotension, urinary retention, catheter problems	Pain: VAS Quadriceps strength assessed by physiotherapy using 6 point scale – no validity information reported	Continuous femoral nerve block (CFNB) versus continuous epidural analgesia (CEA)	More nausea in CEA group ($p<0.005$) No difference in VAS between groups CFNB group received more analgesics ($p=0.005$) Analgesic usage includes both non-opioid and opioid analgesics: difficulty in comparison of analgesics used
Bianconi, Ferraro, Traina, Zanoli, Antolelli, Ricci & Massari (2003)	Randomized Controlled Trial	TKA and THA inpatients Age: 66(35-81), 64(38-80) 81% female N=37	Plasma concentrations of ropivacaine Pain: at rest and with activity Rescue medication requirements Adverse Effects: Local anesthetic toxicity, nausea, vomiting, dsypnea, headache, sedation, seizures, agitation	Pain: VAS Measurements taken at 4, 8, 12, 24, 48, 72 hours after surgery	Continuous ropivacaine wound instillation	Significantly lower VAS at rest and with activity at all measurement times in the treatment group ($p<0.05$; $p<0.01$) Lower opioid and non-opioid rescue analgesia in treatment group ($p<0.01$) No differences in adverse effects between groups (high incidence of nausea: 53%, 44%)
Cheville, Chen, Oster, McGarry & Narcessian	Randomized Controlled Trial	TKA inpatients Age: 65(46-85) 51% female	Pain: at end of physiotherapy, worst during physiotherapy,	Pain: VAS – used also for interference question – no	Controlled release oxycontin in postoperative analgesic	No differences in adverse effects between two groups ($p=0.83$)

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
(2001)		N=59	degree of interference with physiotherapy Functional status: passive and active knee range of motion, knee extension torque, transfers, walking, climbing Length of stay Discharge plan: no physiotherapy, outpatient or home physiotherapy , transfer to rehabilitation facility Adverse Effects	validity provided for the use with this question Functional status: manual goniometer, dynamometer and Functional Independence Measure (FIM) – no validity information provided Adverse effects: Memorial Symptom Assessment Scale – no validity information provided Measurements taken during each of eight physiotherapy sessions – timing not reported	regimen versus placebo	VAS lower in treatment group at the eighth physiotherapy session (5.9(1.5), 4.8(1.7): $p<0.012$) – differences not clinical significant. No differences in passive knee range of motion but active range of motion better in treatment group ($p<0.001$) Treatment group discharged 2.3 days earlier (13 versus 15.3 days, $p=0.013$)
Rathmell, Pino, Taylor, Patrin & Viani (2003)	Randomized Controlled Trial	TKA and THA inpatients Age: reported by group 44% female N=80	Analgesic consumption: Morphine equivalents Adverse effects: Nausea, vomiting, pruritus, desaturation, no or poor pain relief	Measurements at 0, 12 and 24 hours post-discharge from recovery room	Three doses of intrathecal morphine versus placebo	More nausea in all treatment groups compared to placebo ($p<0.05$) TKA treatment groups required more analgesia than placebo group ($p<0.0001$) Very small sample size, 10 participants per group, 8 groups in total

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Ben-David, Schmalenberger. & Chelly (2004)	Non-experimental	TKA inpatients Age and gender not reported N=12	Pain: no information about movement status during measurement Lower limb motor function Requirement for addition of sciatic nerve block	Pain: VAS Motor function: Bromage score Measurements in recovery room only, times not provided	Addition of sciatic nerve block following femoral nerve block	10/12 patients required the addition of sciatic nerve block Mean VAS changed from 7.3 to 2.4 No statistics performed, small sample size, no ethics approval. Non-random, not controlled. Published as a Brief Report
Wang, Boctor & Verner (2002)	Randomized Controlled Trial	TKA inpatients Age: 66(10), 67(8) 63% female N=30	Pain: at rest and during rehabilitation Analgesic consumption: Morphine equivalents Ambulation distance: defined as pre-set distance goals Knee flexion Length of stay: days, early (on or before day 3) versus late (on or after day 5) discharge from hospital	Pain: VAS Knee flexion: manual goniometer Measurements in recovery room, on day 1, 2 & 3 after surgery	Single injection femoral nerve block	VAS lower in treatment group in recovery room and on day 1: 7.8(1.6) versus 4.2(2.9); and 5.5(2.1) versus 2.7(2.6) respectively ($p<.01$) No difference in VAS at other time points Analgesic consumption lower in treatment group in recovery room and on day 1 ($p<0.01$, $p<0.05$) Knee flexion greater in treatment group (70 versus 60 degrees, $p<0.05$). No difference at discharge (76.7 versus 71 degrees, $p<0.09$) Shorter length of stay in treatment group: 3 (3-5) versus 4(3-6) days ($p<0.05$)
Chelly, Greger, Gebhard, Coupe, Clyburn,	Cohort study	TKA inpatients Age: 65(57-73), 66(60-74), 70(65-	Analgesic consumption: Morphine equivalents	Incidence and pharmacologic requirements	Continuous femoral nerve block following single shot femoral and	Epidural and femoral nerve block groups needed less morphine, fentanyl and

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Buckle & Criswell (2001)		74) Sex not reported N=92	Intraoperative isoflurane, morphine and fentanyl requirements Intraoperative cardiovascular complications: tachycardia, bradycardia, hypotension, hypertension Postoperative complications: pain, nausea, cardiovascular, urinary retention	reported Measurements in operating room, recovery room, and on days 1, 2 & 3	sciatic nerve block Continuous epidural analgesia Patient controlled intravenous analgesia	isoflurane intraoperatively ($p<0.05$) and had fewer 'pain complications' ($p<0.05$) and less opioid in recovery room, on day 1,2 and total ($p<0.05$) Femoral nerve block group had less intraoperative bradycardia and hypotension ($p<0.05$), less nausea ($p<0.05$) and less opioid on day 3 ($p<0.05$) Epidural and femoral nerve block groups had less nausea, pruritus, dizziness and urinary retention ($p<0.05$) No randomization, no information on method of group assignment. Data presented in chart form only. Pain assessment data not presented
Forster & Rosenberg (2004)	Randomized Controlled Trial	TKA inpatients Age: 70(9), 68(11) 68% female N=69	Pain: rest and with activity Painful episodes at rest Patient satisfaction Need for rescue analgesia	Pain: VAS Adverse effects: motor block – Bromage scale; sedation – Ramsay scale. Satisfaction: overall satisfaction 0-10 numeric rating scale	Clonidine/ropivacaine/fentanyl epidural infusion versus ropivacaine/fentanyl epidural infusion alone	Treatment group needed less rescue analgesic overall: 0(0-7)mg versus 7(0-12)mg ($p=0.027$) No other differences between groups Standardized measurement times – may introduce bias for surgeries at difference

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
			Adverse effects: hypotension, bradycardia, sedation, nausea, pruritus, motor block	Measurements at 1800 and 2400, days of surgery and 0600 and 1200 on day 1		times of the day

Appendix C

Total Knee Arthroplasty Non-pharmacological Interventions

Table 1.
Total Knee Arthroplasty Non-pharmacological Interventions

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Smith, Stevens, Taylor & Tibbey (2002)	Randomized Controlled Trial	TKA patients Age: 72.4 years 50% female N=84	Pain intensity Opioid consumption: morphine equivalents Knee mobility: joint flexion only	Length of stay Knee swelling Knee flexion Wound drainage Transfusion Hemoglobin Pain intensity (VAS) Opioid requirements	Cold therapy pad over operative site for first 24 hours after surgery Usual care in this study was use of a compression bandage for an equivalent period of time	No statistically significant differences between groups found Mean opioid use/48 hours in intervention group was 0.421 (0-1.01) mg/kg versus 0.322 (0-.99) mg/kg (NS)
Shultz, Andrews, Goran, Mathew & Sturdevant (2003)	Randomized Controlled Trial	Inpatient gynecological patients Age: 46.6 (SD=10.8) All female N=103	Postoperative nausea and vomiting Pain Sedation	Nausea: self report 4-point scale – 0=no nausea, 3=severe nausea Vomiting: number of episodes of vomiting or retching Pain: NRS 0-10 Sedation: Sedation-Agitation Scale (minimal validity information provided)	Acupressure bands +/- antiemetic drug or placebo band or drug	Less nausea in antiemetic drug plus placebo band group (X2=8.58, *df* 3, p=0.0355) More rescue antiemetics in acupressure band/antiemetic drug group (X2=9.282, *df* 3, p=0.026) No information on randomization procedures – authors comment on non equivalent groups despite randomization
Anderson & Gross (2004)	Randomized Controlled Trial	Outpatient general, orthopedic and gynecological surgery patients Age: 29(3), 42(6), 44(5)	Nausea Need for rescue antiemetics Patient satisfaction	Nausea: VAS 0-100mm Antiemetics: proportion requesting rescue at 2 minutes	Aromatherapy with alcohol, peppermint or placebo	No difference between groups in either nausea, satisfaction or antiemetic rescue (statistic not provided). Overall nausea in all

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
		63% female		post intervention Satisfaction: VAS 0-100mm		groups decreased after intervention (60.06(4.3) versus 43.1(4.9), p<0.00001) Small sample size, no information about randomization procedures. Patients randomized upon first experience of nausea in recovery room. Sample may have bias toward patients with increased risk for postoperative nausea as a result.
Morsi (2002)	Cross-over trial – non randomized	Bilateral TKA patients having TKA of each knee on separate occasions – inpatient orthopedics unit Age: not reported Sex: not reported N=60	Pain Analgesic consumption Hemovac (drain) output Knee range of motion Wound healing Complications	Pain: VAS 0-10 Analgesic consumption: not clear – recorded as number of pills	Investigator devised continuous flow cold therapy apparatus – participants had cold therapy for first knee and usual care for second knee	Pain decreased in cold therapy sample overall (4.2(0.74) versus 6.3(1.3) p<0.001) Less drainage in cold therapy sample (503(116) mL versus 810(209) mL, p<0.001) More flexion in cold therapy sample at 1 week and 2 weeks (p<0.01) Participants were own control group. Internal consistency bias related to testing effect. Non random.

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
						No information about sample characteristics. Very limited reporting of analgesic consumption.
Antall & Kresevic (2004)	Pilot study: two group experimental repeated measures design Randomized to two groups	THA and TKA patients Age: 67.86 years All male N=13	Pain at rest and with activity Mood Physical functioning	Pain: VAS 0-10 – self reported using journal Mood: Profile of Mood States Physical Functioning: SF-12	Cassette tape of guided imagery suggestion twice a day beginning the evening of surgery until discharge	Trend toward higher anxiety (POMS), pain and longer hospital length of stay in control group Very small sample size – pilot study. Poor compliance with self report journal (64%).
Pellino, Gordon, Engelke, Busse, Collins, Silver & Norcross (2005)	Randomized controlled trial	THA and TKA patients Age: 63.25(10.30): 59.56(15.41) 63% female N=65		Pain and interference (BPI – modified) Anxiety (STAI) Coping (Coping Strategies Questionniare) Opioid requirements	Provision of a non-pharmacological interventions kit	Intervention group used less opioid on POD 2 (33.67(29.51) versus 19.06(12.89), $p<0.05$) No other statistically significant results found.

Appendix D

Total Knee Arthroplasty Anti-emetic Interventions

Table 1.
Total Knee Arthroplasty Anti-emetic Interventions

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Lacroix, Lessard & Trepanier (1996)	Randomized Controlled Trial	Multiple surgery types. Recovery room only. Age: 46.5 (14), 42.7(14), 43.3(11) 67% female N=78	Incidence of treatment failure: recurrence of retching or vomiting during the 60 minutes after administration of the study drug	Nausea: VAS 0-10 Nausea, vomiting and retching: incidence	Three antiemetic agents: metoclopramide, droperidol or propofol IV given after first complaint of nausea lasting at least 10 mintues	No differences in nausea severity between the three groups (p=0.07) Highest incidence of nausea recurrence in propofol group (RR=54, 95% CI 33,73: P<0.001) Mostly female sample – different baseline nausea risk. Diverse sample population.
Chen, Frame & White (1998)	Randomized Controlled Trial	THA & TKA inpatients Age: 62.5(12.3), 62.5(12.5) 63% female N=78	Incidence and severity of postoperative nausea and vomiting Need for rescue antiemetics Need for physiotherapy cancellations Length of hospital stay	Nausea: 0-4 verbal rating scale – no psychometric properties reported Chart review	Ondansetron IV plus IM placebo or Prochlorperazine IM with IV placebo at the end of the surgical procedure	Prochlorperazine group had fewer nausea episodes (RR 3.4, 95% CI 1.2, 9.4 P=0.02) Women had more nausea (RR 9.5 95% CI 2.2, 40.8) and vomiting (RR 5.5 95% CI 1.0, 29.5) with prochlorperazine than men
Parlow, Costache, Avery & Turner (2004)	Randomized Controlled Trial	Inpatients having elective lower limb orthopedic or endoscopic urologic	Treatment failure: nausea score of 1 or more, any episodes of	Melzack Overall Nausea Index Episodes of vomiting, use of antiemetics	Two doses of haldoperidol or placebo IM after spinal block established	Less nausea in haldoperidol groups regardless of dose (76% versus 64% and 55%

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
		procedures Age: 63(11), 67(8), 69(6) 45% female N=122	vomiting, or request for antiemetic at any time			P=0.03)
Grattidge (1998)	Randomized Controlled Trial	THA and TKA in patients Age: 64(12), 65(13) N=82	Nausea, vomiting and pruritus prophylaxis	Incidence of nausea, vomiting or pruritic episodes	Propofol infusion for 20 hours postoperatively or placebo	No significant difference in nausea, or vomiting incidence (40% versus 59%, P=0.1) No information about randomization procedures.
Loewen, Marra & Zed (2000)	Review – structure abstract	All surgical populations N=41 studies n=6638 participants, 2855 receiving 5-HT3 antagonists and 3783 receiving traditional agents	Nausea, vomiting, adverse events	Review of results Investigator input where possible	Prophylactic 5-HT3 receptor antagonists versus traditional antiemetic agents	46% reduction in OR of postoperative nausea and vomiting in 5HT3 groups (OR 0.54, 95% CI 0.42, 0.71. P<0.001) 38% reduction in the odds of vomiting alone in the 5HT3 groups (OR 0.62, 95% CI 0.48-0.81, p<0.001; number need to treat (NNT) 16, 95% CI, 10, 44)

Appendix E

Hydration Interventions

Table 1.
Hydration Interventions

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Yogendran, Buvanendran, Cheng & Chung (1995)	Randomised Contolled Trial	Ambulatory surgery patients Age 29(10), 29(8) 92.5% female N=200	Vital signs – BP standing and sitting Adverse effects – nausea, vomiting, thirst, dizziness, time to first void Postanesthetic discharge time	Heart rate; Blood pressure (standing, sitting); incidence of nausea and vomiting; thirst; dizziness; drowsiness; time to first void; discharge readiness. Postanesthesia discharge scoring system (PADSS) Telephone administered questionnaire	<u>High infusion group</u> Plasmalyte solution IV bolus 20 mL/kg 30 minutes preoperatively <u>Low infusion group</u> Plasmalyte solution IV bolus 2 mL/kg 30 minutes preoperatively	Thirst, dizziness, and drowsiness lower in high infusion group at 30 & 60 minutes and at discharge ($P<0.05$) Nausea less in high infusion group 24 hours postoperatively ($p<0.05$). No difference in discharge readiness
Muller, Exadaktylos, Roeder, Pisan, Eggli & Juni (2004)	Prospective before and after trial	Total joint replacement patients Age 69.9(1.4), 71(1.4) 50.6, 56.7% female N=425	Need for blood transfusion over hospital stay	Incidence of transfusion	Guidelines for the perioperative management of volume status – one page flowchart for use by physicians and nurses	Incidence of transfusion decreased by 15.2% during the intervention period.
Sinclair, James & Singer (1997)	Randomized controlled trial	Patients undergoing proximal femoral fracture repair Age 45% female N=40	Hospital discharge readiness Length of hospital stay	Discharge readiness; duration of hospital stay; mortality, perioperative hemodynamic changes	Repeated colloid fluid challenges to meet maximal stroke volume (measured with Doppler ultrasonography) during operative period	Intervention group had 39% reduction in hospital stay ($p<0.05$) and shorter time to discharge readiness ($p<0.05$)

Author	Study Design	Sample characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Ali, Taguchi, Holtmann & Kurz (2003)	Randomized controlled trial	Laparoscopic/gyn ecologic surgery patients N=80	Nausea and vomiting overall	Incidence of nausea and vomiting	IV fluid (Hartmann's solution) 15 mL/kg Prior to induction of anesthesia	Nausea incidence in intervention group 23% versus 73% in usual care group ($p<0.01$). 20% of intervention group required IV ondansetron versus 50% of usual care group (NS)
Venn, Steele, Richardson, Poloniecki, Grounds & Newman (2002)	Randomized controlled trial	Patients undergoing proximal femoral fracture repair Age 84.5(9.3), 85(6.2), 82(8.7) 82.2% female N=90	Hospital discharge readiness, length of hospital stay	Postoperative morbidity events, length of hospital stay, discharge readiness	Repeated colloid fluid challenges guided by central venous pressure or Doppler ultrasonography intraoperatively	Intervention groups had shorter time to discharge readiness (P=0.035) and length of stay (p=0.008)
Kee, Khaw, Lee, Ng, & Wong (2001)	Randomized controlled trial	Patients undergoing caesarian section All female N=68	Vital signs – blood pressure, heart rate Nausea after procedure and during hospital stay Fetal recovery	Systolic arterial pressure (SAP); heart rate; nausea incidence; APGAR scores	Colloid IV bolus 15 mL/kg prior to spinal induction	Nausea incidence 6% in intervention group versus 24% in control group (P=0.04) 64% control group had greater than 20% decrease in SAP versus 31% in intervention group (p=0.01)
Gan, Soppitt, Maroof, El-Moalem, Robertson, Moretti, Dwane & Glass (2002)	Randomized controlled trial	General, Gynecological and urologic surgery patients Age 56(13); 59(12) 43% female N=100	Nausea and vomiting overall Length of hospital stay Time to oral intake	Length of hospital stay; incidence of nausea and vomiting; time to tolerance of oral intake	Goal directed colloid IV fluids intraoperatively (algorhythm used)	Length of stay shorter in intervention group 5(3) versus 7(3) (p=0.03). Time to oral intake shorter in intervention group 3(0.5) versus 4.7(0.5) (p=0.01). Less nausea requiring antiemetics in intervention group (36% versus 14%: $p<0.05$)

Appendix F

Total Knee Arthroplasty: Educational Interventions

Table 1.
Total Knee Arthroplasty: Educational Interventions

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
Dillon-McDonald, Freeland, Thomas & Moore (2001)	Randomized Controlled Trial	THA or TKA patients Demographics not reported N=31	Postoperative pain	Pain: SF-MPQ	Preoperative pain management education: pain communication; pharmacologic and non-pharmacologic pain management – standard approach	No statistically significant differences between groups found in pain intensity, sensory or affective dimensions Small interaction effect for time and group ($F(2, 24)=2.49$, $p<0.05$) (ES .38) showing a small decrease in pain over time in intervention group
McDonald & Molony (2004)	Randomized Controlled Trial	THA and TKA inpatients Age: 71.8 (5.41) 66% female N=41	Postoperative pain Delirium: measurements taken prior to pain measures. Patients with delirium were removed from the study	Pain: SF-MPQ Delirium: NEECHAM Confusion Scale – validity established	Pain communication education via video and booklet	No significant group differences ($F(6,112) = 0.58$, $p<0.75$) or gender differences ($F(3,55) = 1.44$, $p<0.24$) in affective pain and pain intensity across two postoperative days. Significant group difference in sensory pain only on postoperative day 1: Effect Size 1.3 ($F(4,70) = 2.50$, $p<0.05$) Unequal and small sample sizes in groups. More women in standard care group. Acknowledgement of participant difficulty in completing the MPQ-SF. Used random numbers table – not centrally controlled and concealed
Sjoling, Nordahl, Olofsson & Asplund (2002)	Randomized Controlled Trial	TKA inpatients Age and sex not reported N=60	Experience of postoperative pain: an index of extreme pain intensity measurements from every 3	Pain: Daily Pain Index (DPI)– mean of highest 3 VAS scores on each day; Overall Pain Index (OPI)–	Specific information provided verbally and in booklet using Orem's supportive-educative nursing	No differences in DPI on any postoperative day or OPI between two groups (p=0.6-0.98) No differences in analgesic consumption between groups

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
			hourly measurements Analgesic consumption: number of doses and amount of analgesics used in morphine equivalents Length of hospitalization	mean of highest 3 VAS scores over all measurement times No reliability or validity associated with this method of pain measure reporting	systems	Intervention group had lower degree of state anxiety (M-W test: $p<0.05$). No differences in length of hospitalization Intervention group had higher level of satisfaction (X2 test: $p<0.05$). Reported state anxiety and patient satisfaction without reviewing measures. Measures reported without any reliability or validity information. No information about randomization or demographics.
Roach, Tremblay & Bowers (1995)	Nonrandom quasi experimental design	TKA and THA inpatients Age and sex not reported N=300	Length of Hospital Stay	Length of stay calculated into cost savings based on reduction in patient days per year	Preoperative Assessment and Education Program – interdisciplinary program of education involving the use of booklets, classroom teaching, video, and slide presentations	Length of stay was reduced slightly during the intervention time period (8.7 days versus 8.0 days) – no statistical analysis performed Compared length of stay to previous time period as well as to smaller, non-equivalent group of non-participants (N=163) Poorly reported study
Bondy, Sims, Schroeder, Offord & Narr (1999)	Randomized Controlled Trial	TKA and THA inpatients N=134	Anxiety: state and trial anxiety	State Trait Anxiety Index – validity well established	Education regarding anesthesia using video and two pamphlets	Intervention group had less state anxiety ($p=0.035$) from baseline to immediately prior to surgery No information about randomization procedures
Beaupre, Lier, Davies & Johnston (2004)	Randomized Controlled Trial	TKA inpatients Age: 67(7); 67(6) 55% female N= 131	Pain, stiffness, knee function Knee range of	WOMAC Index – validity well established	4 week treatment/education program involving preoperative	No differences found in any measure between the two groups. Significant difference found in all

Author	Study Design	Sample Characteristics, Response Rate, Setting	Outcome Concepts, Definitions	Measures	Intervention	Outcomes/Limitations
			motion (ROM) Overall health status	ROM – manual goniometer SF-36 – validity well established Measurements taken at 3, 6 & 12 months post surgery	exercise instruction	measures over time ($p<0.05$) except the SF-36
Lin, Lin & Lin (1997)	Randomized Controlled Trial	TKA inpatients N=60	Anxiety Knee range of motion Knowledge of information provided	State Trait Anxiety Index: validity well established ROM – manual goniometer No information about knowledge questionnaire	Preoperative education program using booklet preadmission and video once admitted to hospital	No difference in state or trait anxiety between groups. Significant difference in knowledge and correct exercise performance in intervention group. Greater knee flexion in intervention group. Small sample size. No information about randomization procedures

Appendix G

Pilot Data

Table 1.

Pilot Data (N=16) Pain Intensity over Four Postoperative Days

	Postoperative Day							
	1		2		3		4	
	M(SD)	Median	M(SD)	Median	M(SD)	Median	M(SD)	Median
Rest	2.6(1.9)	2	1.8(1.4)	2	2.7(1.6)	3	2.1(1.8)	2
Active	5.3(2.4)	5.5	4.6(2.5)	4	5.5(2.1)	5	4.1(1.5)	5

Table 2.

Pilot Data (N=10) Concerns with analgesic and anti-emetic administration and preoperative fluid intake.

Educational Content	Identified Concern
Analgesic administration	fear of addiction
	fear of nausea
	concern about bothering nurses
	remembering to use before activity
Anti-emetic administration	concern about sedation
	concern about bothering nurses
Preoperative fluid intake	dislike of plain water
	remembering to drink fluids

Appendix H

Consent/Information Form

Consent Form

[HOSPITAL LETTERHEAD]

Total Knee Arthroplasty Preparation Study

PATIENT INFORMATION AND CONSENT

Start Date: January 2008

Primary Investigator: Dr. Judy Watt-Watson

Co-Investigators: Rosemary Wilson, Dr. Ellen Hodnett, Dr. Joan Tranmer

This research is being lead by Dr. Judy Watt-Watson, Associate Professor, University of Toronto, Faculty of Nursing.

Purpose and Background
People who have had knee replacement surgery usually expect to have pain and nausea in the days right after surgery. Sometimes this pain and nausea prevents people from moving around and doing physiotherapy activities. The purpose of this study is to examine whether or not a program of education provided to people before surgery will make movement and activity easier and less painful in the first three days after surgery.

Procedures

I understand if I agree to participate in this study, the following things will happen:

1. I will be asked to answer a number of questions about myself and my health background by the study investigator during my pre-admission testing visit. Although I will be encouraged to answer all the questions but I am under no obligation to do so.

2. I will be assigned to one of two groups by chance (random assignment). If I am assigned to the one group (the usual care group), I will receive all the current teaching and written information for usual preparation for knee replacement surgery. If I am assigned to the other group (the experimental group), I will receive the TKA Symptom Management Booklet and attend a teaching session with the study investigator that will last about

twenty (20) minutes. During this session, the investigator will provide me with tips for talking to my nurses and doctors about my pain and nausea, review the use of pain management medications and techniques including use of the patient-controlled analgesia pump as well as the use of anti-nausea medications and my fluid intake before surgery. The study investigator will also call me 2-3 days before my surgery to answer any questions I might have. Regardless of the group I am assigned to, I will receive all the usual care for people who are having knee replacement surgery.

3. I understand that on the first, second and third days after surgery, I will be visited by a research assistant who will ask me questions about my pain and nausea and assist me to fill out questionnaires that will take me around 10 minutes to complete. I am under no obligation to answer all the questions posed to me although I understand I will be encouraged to do so.

Potential Benefits
I understand there are two major potential benefits to my participation in this study. By participating in this study, I may learn different ways of dealing with my pain and nausea after surgery that may benefit my recovery. The results of this study may also help health care professionals better understand the affect of what people know before surgery has on activity during the recovery period.

Potential Risks
I understand there are no risks to participating in the study. If I find that any of the information presented is upsetting to me, I can call the nurses in the Pre-admission Testing centre, the researchers that are conducting this study, or my doctor, to discuss this problem.

Cost
I understand there is no charge for the information I will receive if I am assigned to the experimental group.

Financial Compensation
I understand there is no financial compensation to participate in this study.

Confidentiality
I understand that information about individuals participating in this study will be kept strictly confidential and will not be available to anyone but the study researchers. Only an identification number will appear on the questionnaires, and therefore all my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked file drawer in the researcher's office. All information obtained in this study will be used for research purposes only. If I wish, the researchers will send me a copy of the results of the study once it is completed.

I understand that I must respect the privacy and confidentiality of other study participants. The names of others involved in this study and any other personal information I may learn from other people participating in this study must be kept strictly confidential.

Contact

I understand that if I have any questions about the study, I can contact Rosemary Wilson [redacted] extension [redacted], Dr. Judy Watt-Watson [redacted], or Lenora Duhn extension [redacted]. If I have any concerns about my treatment and rights as a research participant, I can call Dr. Diane Doran, Associate Dean of Research at the University of Toronto, Faculty of Nursing [redacted]. If I have any questions about my rights as a research participant, I can call Dr. Albert Clarke, Chair of the Queen's University Affiliated Health Sciences Centre Research Ethics Board at [redacted]. This person is not affiliated with the research project in any way and calling him will not affect my participation in the study.

For further information on my rights as a research participant, I can visit the following web links:

1. Queen's University Affiliated Health Sciences Centre Research Ethics Board: http://www.queensu.ca/vpr/policies/committee.html

2. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada (1988). Tri-Council Policy Statement-Ethical Conduct of Research Involving Humans. Health Canada. http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm

Right to Refuse or Withdraw

I understand that my participation in this study is voluntary and I am free to refuse to take part or to withdraw from the study at any time without affecting my health or medical care.

Consent

My signature on this form indicates that I have understood to my satisfaction the information regarding my participation in the research project and that I agree to participate. In no way does this waive my legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities.

I_____, the undersigned, agree to my participation in the research study described. Any questions I had have been answered and I understand what is involved in the study. I realize that participation is voluntary and that there is no guarantee that I will benefit from my involvement. I acknowledge that a copy of this form has been offered to me.

_____ _____

(Signature of Participant) (Date)

To be signed by the Study Investigator:

To the best of my ability I have fully explained to the participant the nature of this research study. I have invited questions and provided answers. I believe that this individual fully understands the implications and voluntary nature of the study. I have provided the participant with a copy of this consent form for her/his own reference.

_____ _____

(Signature of the Study Investigator) (Date)

Appendix I

Baseline Demographics Questionnaire

Pre-Knee Study

Participant number ☐☐☐☐

Participant's Date of Birth ☐☐☐☐ ☐☐ ☐☐
year month day

ENTRY FORM

BASELINE DEMOGRAPHICS QUESTIONNAIRE

BASELINE INFORMATION AT RANDOMIZATION (Complete immediately before randomization)

1. **Preoperative diagnosis**: (Mark all that apply)
○ Osteoarthritis ○ Rheumatoid arthritis ○ Other

2. **Pain medication at home**: (Mark all that apply)
○ None ○ Hydromorphone ○ Morphine ○ Oxycodone
○ Codeine ○ Meperidine ○ Acetaminophen ○ NSAID

3. **Other health concerns**: (Mark all that apply)
○ Cardiac ○ Respiratory ○ Renal ○ Hepatic
○ Neurologic ○ Dermatologic ○ Genitourinary ○ Other

4. **Date of surgery booking**: (If unknown mark *unknown*)
☐☐☐☐ ☐☐ ☐☐ ○ Unknown
year month day

5. **Highest level of education completed**: (mark one only)
○ Less than high school/secondary school ○ University/4 year college
○ High school/secondary school ○ Postgraduate education/graduate school or higher
○ Community college/junior college ○ Unknown/not completed

6. **Gender**: (mark one only)
○ Male ○ Female ○ Other

7. **Home status**: (mark one only)
○ Live with partner, friend, other relative ○ Live alone

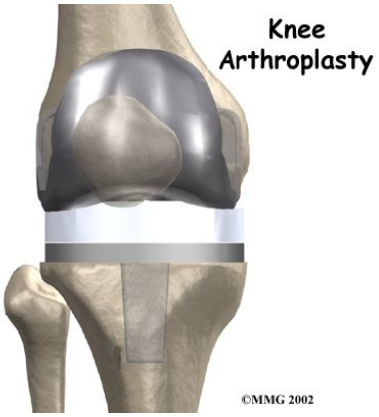
8. **ASA physical classification**: (from front page of completed Anesthetic Record)
○ I ○ II Eligible for study
○ III ○ IV Ineligible for study – do not fill in any more sections

For office use only
RANDOMIZED ○ **yes** ○ **no**

Appendix J

Pre-Knee Symptom Education Booklet

Pre-Knee Symptom Education Booklet[1]



Pre-knee symptom education study

September 2007

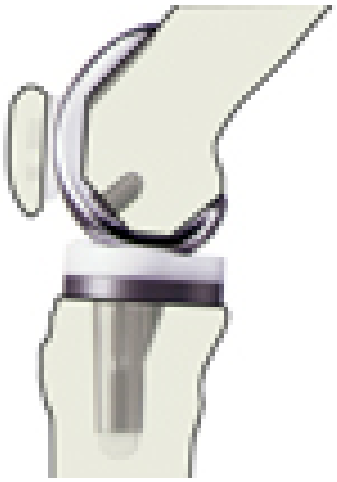
Kingston, Ontario

This booklet has been adapted from Watt-Watson et al (2004) with permission from the authors.

1. Watt-Watson, J., Stevens, B., Katz, J., Costello, J., Reid, G., & David, T. (2004). Impact of pre- operative education on pain outcomes after coronary artery bypass graft surgery. *Pain, 109,* 73-85.

Introduction

This booklet discusses the symptoms you may experience after your total knee arthroplasty surgery, how and when to ask for help with your symptoms and some strategies to help with symptoms such as pain and nausea.



What is pain?

Pain is an unpleasant sensation that is different for each person. Some people describe it as ‘soreness’ or ‘discomfort’. Other people use words like ‘aching’ and ‘tender’ to describe pain. Even people who have the same surgery can feel pain differently.

Surgery for a total knee arthroplasty can be painful because it involves skin, bone and muscle. Movement of your new knee in the days right after your surgery usually causes some pain but good treatments are available to help you.

After your surgery, nurses and doctors will ask you about your pain and will ask you to rate it. It is very important for you to tell them about the pain you are having. This booklet will teach you how to tell to nurses and doctors about your pain and how to use pain medicines and other methods to manage your pain.

Why is pain relief so important?

Moderate to severe pain can stop you from moving around, feeling resting and can cause complications that make your hospital stay longer. Pain can also make it difficult for you to do your physiotherapy. Bad pain can also cause or make nausea worse. It is important for you to have as little pain as possible so that you can get moving and get better faster.

There are many good treatments that can help to relieve pain in your knee after surgery, such as medications and ice. It is important for you to choose what works best for you.

People used to think that they had to be “tough” and “put up with severe pain”. Now nurses and doctors know that having bad pain can slow your recovery. Good pain relief is possible with your help.

How and when do I ask for help with pain?

It is very important for you to tell the nurses and doctors how much pain you are having, what it feels like and if the treatments are working. If your pain prevents you from moving your new knee, please tell your nurse.

A rating scale helps us to understand how much you hurt. You need to tell the nurse your pain rating when you are still and also when you move your knee.

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
No Pain	Mild Pain			Moderate Pain				Severe Pain		Worst Pain

For the first two days after your surgery, a special pump will let you give yourself small doses of pain medicine through your intravenous line. This is called a Patient Controlled Analgesia pump or PCA (see picture below).

You do not need to call your nurse to use the PCA pump.

When you have pain, press the PCA button and the pump will give you your dose. Even if you have only a little pain when you are still, be sure to press the PCA button 5-10 minutes BEFORE you plan to move. This will give the medication a chance to work and will prevent the pain you

have when you move. Having less pain will help you to move around better.

In the afternoon of the second day after surgery, the PCA pump will be removed and you will take pain medication in a pill form (morphine, hydromorphone or oxycodone). These medications usually relieve pain for 3-4 hours. To keep your pain low, you will need to take medications regularly. It is a good idea to take pain medicine 30 minutes before physiotherapy so the medicine has a chance to work. If you take pain medicine regularly and your pain is still not below 4 with movement or if the pain comes back before the next dose, let your nurse or doctor know right away.

Remember, pain is always easier to treat when it is mild to moderate.

Do not wait until your pain is severe to ask for pain relief.

What are patient's concerns about asking for pain relief?

I am not a "good" patient if I tell someone about my pain.

"GOOD" patients DO tell when they hurt.

You are a very important member of your pain management tea, and your help is needed. Please tell the nurse when you hurt and whether the pain treatment is working.

Nurses expect you to tell them when you hurt. They do not want you to "handle it" by yourself. You are helping by telling nurses when you hurt and if your medication is not working. They want you to have as little pain as possible. Tell them anything that has helped you with pain in the past.

Pain does not mean you are healing. Bad pain may slow healing and cause complications. People who have low levels of pain after surgery recover faster.

How and when do I ask for help with nausea?

Please let the nurses know right away when you first start to feel any nausea. Nausea is easier to manage when it is mild.

Medicine for nausea can be given to you through your intravenous line. Usually, these medicines last for 4 hours. If you have nausea before your next dose is due, please let the nurses know.

What else can I do, aside from take medications, to prevent pain and nausea after surgery?

Treatments other than medicines can help to prevent and relieve pain and nausea after surgery. Patients have found the following helpful in addition to medications:

- Listening to music, reading or watching television;
- Use of ice packs over the knee incision;
- Taking relaxing breaths;
- Careful and slow movements when moving from the bed to a chair or from lying to sitting or standing.

Drinking fluids before surgery

Making sure you are well hydrated may help you recover after surgery. Most people need at least 1800 mL (about 8 cups) of fluid over the whole day. A list of the amount of fluid in some common store-bought drinks is in this booklet. Try to avoid drinks that contain caffeine as your main source of fluids (i.e. cola, coffee, regular tea).

I don't have pain, I have "discomfort" or "soreness".

Pain can be called other names. Use the pain scale to rate your pain. If your rating is 4 or more when you move, tell your nurse. Not every person uses the word "pain".

I am afraid to take pain medication because of addiction and/or side effects.

Addiction is a rare problem (less than 0.01%) for people taking medications for pain unless they already have a drug dependency problem.

Nausea and constipation are treatable. Do not refuse to take pain medications because of nausea. Please read the section on nausea prevention. Pain can also cause nausea.

I don't want to have a needle.

Strong pain medication does not have to be given by a needle. Needles often hurt and are often not used anymore. Your pain medication will be given in pill form when the PCA pump is stopped.

What is nausea?

Nausea is an unpleasant experience that may be accompanied by the urge to vomit or dizziness. People may have nausea after surgery because they are dehydrated, have unrelieved pain or are taking certain medications. Tell your nurse about your nausea and do not stop taking your pain medication. Nausea is treatable.

Why is treating nausea so important?

Nausea can make you feel like you don't want to move. Sometimes moving will increase your nausea. Again, movement is important to prevent complications after surgery. If you have nausea, you may also have difficulty eating and drinking. Good nutrition is important for healing and keeping your energy levels up.

When should I stop drinking fluids before my surgery?

Although you need to stop eating at midnight the night before your surgery, you can continue to drink clear fluids (water, apple juice, clear tea etc.) up to four hours before your surgery.
For example, if your surgery is at 11 o'clock, you can drink water up until 7 o'clock that morning.

You may find it helpful to keep track of the fluids you drink in the week just before your surgery. Use the chart at the end of this booklet to keep track.

Please write down any question you have in the space at the end of the booklet. An Advanced Practice Nurse will call you to answer questions before your surgery.

It does not prevent nausea to stop eating and drinking days before surgery.

Remember…..

Pain relief is important to your recovery

Every person's pain is different

Nausea relief is important as well

We are expecting you to tell us about your pain and nausea

YOU ARE A VERY IMPORTANT MEMBER OF OUR TEAM

DRINKING ENOUGH FLUIDS
BEFORE SURGERY

Volumes of some common commercially prepared fluids

Pop (small bottle)	591 mL
Pop (can)	355 mL
Milk carton (small)	250 mL
Milk carton (large)	500 mL
Coffee shop coffee/tea	
Small	225 mL
Medium	280 mL
Large	395 mL
X-Large	565 mL
Bottle water/juice	500 mL

Daily fluid intake checklist

Pre-surgery Day	Check off the number of 8oz (250 mL) servings of fluid you drink each day							
	1	2	3	4	5	6	7	8
Seven								
Six								
Five								
Four								
Three								
Two								
One								

Write your questions down here!

The Advanced Practice Nurse will call you in the week before your surgery and will answer questions about the information in this booklet.

Appendix K

Individualized Education Content Tool

Pre-Knee Study

Participant number ☐☐☐☐

Participant's Date of Birth ☐☐☐☐ ☐☐ ☐☐
year month day

Individualized Education Content Tool – Page 1

Experimental group only

Fill in circle corresponding to known concern if identified by participant and record strategies provided in right-hand column. If new concern identified, record in space provided.

Educational Topic	**Concern**	**Strategies Provided**
Communicating Pain and Nausea to Nursing Staff □ use of pain rating scales □ when and how to report pain	O _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____
Using Analgesics		
Use of Patient Controlled Analgesia device □ pump use and settings □ pre-emptive use □ medications used, onset and duration of effect	O fear of addiction O fear of nausea O remembering to use before activity O _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____
Use of oral analgesics □ types and method of administration □ medications used, onset and duration of effect □ asking for analgesics	O fear of addiction O fear of nausea O asking nurses O _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____ _____

Pre-Knee Study

Participant number ☐☐☐☐

Participant's Date of Birth ☐☐☐☐ ☐☐ ☐☐
year month day

Individualized Education Content Tool – Page 2

Experimental group only
Fill in circle corresponding to known barrier if identified by participant and record strategies provided in right-hand column. If new concern identified, record in space provided.

Educational Topic	**Concern**	**Strategies Provided**
Use of non-pharmacologic approaches ☐ approaches and techniques ☐ when they are helpful	O _____ _____ _____ _____ _____	_____ _____ _____ _____ _____
Using Anti-emetics ☐ types and methods of administration ☐ medications used, onset and duration of effect	O sedation O asking nursing staff O _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____
Recommended Daily Intake of Fluid ☐ Importance of adequate fluid intake ☐ Calculation of RDI O 30 mL/kg body weight O 100 mL/kg for first 10 kg 50 mL/kg for next 10 kg 15 mL/kg for the remainder RDI fluid = _____ mL/day ☐ Common volumes of commercially prepared drinks	O dislike of water O remembering to drink fluids O _____ _____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

End of individualized teaching session. Attach completed tool to Baseline Demographics Questionnaire and put in envelope. Record booked surgery date and participant number on front of envelope. Do provide envelope to research assistant (blinded to group assignment).

Appendix L

Surgical and Postoperative Information Questionnaire

Pre-Knee Study

ENTRY FORM

Participant number ☐☐☐☐

Participant's Date of Birth ☐☐☐☐ ☐☐ ☐☐
year month day

Complete between 1100 and 1300 post-operative day 3 only

7. **Surgical and Postoperative Information Questionnaire**

Surgical Information (Complete using information only from the inside two pages of the Anesthetic Record)

Surgery start time: year ☐☐☐☐ month ☐☐ day ☐☐ 24 hour clock ☐☐☐☐

Surgery end time: year ☐☐☐☐ month ☐☐ day ☐☐ 24 hour clock ☐☐☐☐

Intraoperative blood loss: ☐☐☐☐ Milliliters

Intraoperative fluids administered: ☐☐☐☐ Milliliters

9. **Postoperative Information** (Complete using Medication Administration Record and Transfusion Record: Use time of Post Anesthetic Care Unit discharge as anchor for 24 hour time period.)

Opioid Analgesics - Postoperative day one

Opioid	**Route**	**Dosage**	**Frequency**	**Total Dose**
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg

Continue to page 7

☐☐☐☐
Participant number

Pre-Knee Study

Participant's Date of Birth ☐☐☐☐ ☐☐ ☐☐

ENTRY FORM

Complete between 1100 & 1300 on post-operative day 3 only

Opioid Analgesics - Postoperative Day Two

Opioid	Route	Dosage	Frequency	Total Dose
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg

Opioid Analgesics – Postoperative Day Three

Opioid	Route	Dosage	Frequency	Total Dose
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg
O Morphine O Hydromorphone O Fentanyl O Codeine O Oxycodone	O PCA-IV O IV O SC O PO	☐☐☐ O mg O mcg	Every ☐☐ O minutes O hours	☐☐☐☐ O mg O mcg

Continue to Page 8

Pre-Knee Study

ENTRY FORM

Participant Number ☐☐☐☐

Participant's Date of Birth ☐☐☐☐ year ☐☐ month ☐☐ day

Complete between 1100 and 1300 post-operative day 3 only

Anti-emetic Administration – Postoperative Day One

Anti-emetic	Route	Dosage	Frequency	Number of Doses
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐

Anti-emetic Administration – Postoperative Day Two

Anti-emetic	Route	Dosage	Frequency	Number of Doses
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐

Continue to Page 9

Pre-Knee Study

Participant Number ☐☐☐☐

Participant's Date of Birth ☐☐☐☐ ☐☐ ☐☐
year month day

ENTRY FORM

Complete between 1100 and 1300 post-operative day 3 only

Anti-emetic Administration – Postoperative Day Three

Anti-emetic	Route	Dosage	Frequency	Number of Doses
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐
O Prochlorperazine O Ondansetron O Dimenhydrinate O Metoclopramide	O IV O PO	☐☐☐ O mg O mcg	Every ☐☐ O hours	☐☐

Transfusion Requirements: ☐☐ units

Discharge from hospital: Year ☐☐☐☐ Month ☐☐ Day ☐☐

Questionnaires Completed. Staple all Entry Forms together and place in Completed Forms box.

Appendix M

Activity Questionnaire

Pre-Knee Study

Participant number ☐☐☐☐

ENTRY FORM

Participant's Date of Birth ☐☐☐☐ year ☐☐ month ☐☐ day

Complete between 1100 and 1300 post-operative day 3 only

8. Total Knee Arthroplasty Postoperative Activity Questionnaire

Research Assistant Script: "I am going to read out some activities that you may have done on each day after your surgery. Please tell me if you were able to complete each activity."

Day One		
Up in the chair	O yes	O no
Physiotherapy once	O yes	O no
Walk with walker 5-10 feet	O yes	O no
Up to bathroom	O yes	O no
Day Two		
Up in chair	O yes	O no
Up in chair	O yes	O no
Physiotherapy - morning	O yes	O no
Physiotherapy - afternoon	O yes	O no
Walk with walker 10-15 feet	O yes	O no
Up to bathroom	O yes	O no
Day Three		
Sit at side of bed or chair for breakfast	O yes	O no
Sit at side of bed or chair for lunch	O yes	O no
Up in chair – morning	O yes	O no
Physiotherapy – morning	O yes	O no
Walk with walker 20-40 feet	O yes	O no
Shower with assistance	O yes	O no
Up to bathroom	O yes	O no

Post-operative Day

O 3 Proceed to Page 6 {Surgical and Postoperative Information Questionnaire}

Appendix N

Descriptors, Short Form McGill Pain Questionnaire

Table 1.

Proportion of participants reporting moderate to severe pain by descriptor, MPQ-SF

	Intervention n(%)	Usual Care n(%)
Descriptors MPQ-SF	Participants reporting scores of moderate to severe	
Postoperative day one	n=67	n=62
Throbbing	9(14)	8(14)
Shooting	5(8)	4(7)
Stabbing	6(9)	8(14)
Sharp	12(18)	11(19)
Cramping	11(17)	11(19)
Gnawing	20(30)	17(29)
Hot-Burning	15(23)	11(19)
Aching	26(44)	27(41)
Heavy	22(33)	23(39)
Tender	25(38)	25(42)
Splitting	10(15)	8(14)
Tiring-exhausting	9(14)	8(14)
Sickening	14(21)	8(14)
Fearful	6(9)	4(7)
Punishing-cruel	7(12)	6(9)

	Intervention n(%)	Usual Care n(%)
Descriptors MPQ-SF	Participants reporting scores of moderate to severe	
Postoperative day two	n=66	n=63
Throbbing	10(15)	12(20)
Shooting	5(8)	6(10)
Stabbing	6(9)	2(3)
Sharp	12(18)	5(8)
Cramping	4(6)	5(8)
Gnawing	12(18)	10(17)
Hot-Burning	9(13)	6(10)
Aching	21(31)	19(32)
Heavy	17(25)	13(22)
Tender	23(34)	17(28)
Splitting	6(9)	2(3)
Tiring-exhausting	6(9)	6(10)
Sickening	14(21)	5(8)
Fearful	6(9)	4(7)
Punishing-cruel	10(15)	3(5)
Postoperative day three	n=65	n=60
Throbbing	11(17)	11(18)
Shooting	6(9)	7(12)
Stabbing	3(5)	10(17)

	Intervention n(%)	Usual Care n(%)
Descriptors MPQ-SF	Participants reporting scores of moderate to severe	
Sharp	8(13)	11(18)
Cramping	9(14)	7(12)
Gnawing	11(17)	8(13)
Hot-Burning	10(16)	12(20)
Aching	19(30)	19(32)
Heavy	13(20)	16(27)
Tender	16(25)	15(25)
Splitting	2(3)	6(10)
Tiring-exhausting	6(9)	8(13)
Sickening	8(13)	7(12)
Fearful	3(5)	7(12)
Punishing-cruel	5(8)	6(10)

Appendix O

Table 1.

Opioid equianalgesia conversion

	Intravenous	Oral
Morphine	5mg	10mg
Hydromorphone	1mg	2mg
Oxycodone	--	5mg
Codeine	--	60mg

Eipe, N. & Penning, J. (2010); Patanwala, Duby, Waters & Erstad (2007)