The Effect of an Individualized Education Intervention versus Usual Care on Pain Following Ambulatory Inguinal Hernia Repair

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy

Graduate Department of Nursing Science
University of Toronto

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Abstract

Inguinal hernia repair (IHR) is a common ambulatory surgery procedure performed in Canada, after which many patients experience moderate to severe pain. Limited research has been found that examines interventions to reduce pain following ambulatory surgery, and none specifically for patients undergoing IHR.

This trial evaluated the effectiveness of an individualized Hernia Repair Education Intervention (HREI) for patients following this ambulatory surgery. Participants (N= 82) were randomized to either the intervention or usual care group pre-operatively in the pre-admission clinic. The HREI included a booklet about managing pain and face-to-face session to discuss its content, and two telephone support calls (before surgery and 24 hours after surgery). The primary outcome was WORST 24 hour pain intensity on movement on post-operative day 2. Secondary outcomes included pain intensity at rest and movement, pain-related interference with activities, pain quality, analgesics taken, and adverse effects at post-operative days 2 and 7.

At day 2, the intervention group reported significantly lower scores for all pain intensity outcomes, including WORST 24hr pain on movement (t (df) = 4.7 (73), p< 0.001), WORST 24 hr pain at rest (t (df) = 3.8 (73), p < 0.001), pain NOW at rest (t (df) = 3.3 (73), p = 0.001) and on movement (t (df) = 3.4 (73), p = 0.001). Also on day 2, pain-related interference scores for the
intervention group were lower than the usual care group but not significantly different with the bonferroini correction (t (df) = 2.1 (73), p=0.04). The intervention group took significantly fewer opioids on day 2 (t (df) = 3.0 (73), p=0.004). Although there were no differences in any of the pain or interference outcomes on day 7, 36% (n=26) of the total sample reported moderate-severe pain at day 7. Constipation was the adverse effect identified most often, by both groups, on both days 2 and 7. This intervention was effective at post-operative day 2 but revisions need to be made to the intervention to assess for outcomes over a longer period of time.
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Chapter 1

Introduction and Problem Statement

Surgical procedures that previously required hospitalization for 1 to 2 days are now more frequently performed on an ambulatory or outpatient basis. This shift to ambulatory surgery is related to advances in anesthetic and surgical techniques, as well as fiscal restraints. In Canada, the number of patients having ambulatory surgical procedures has increased considerably over the past two decades. The Canadian Institute of Health Information (CIHI) reported that the number of patients having ambulatory surgery has increased by 31% since 1996 (Canadian Institute of Health Information, [CIHI], 2007). In 2005–2006, six provinces and two territories, including Ontario, reported 1,800,000 same-day surgery visits (CIHI, 2007). Sixty to 71% of patients who undergo ambulatory surgery experience unrelieved moderate to severe pain immediately post-operatively (McGrath et al., 2004), and 34% to 55% of patients continue to have pain 7 days after their surgery (Mattila, Toivonen, Janhunen, Rosenberg, & Hynynen, 2005; Watt-Watson, Chung, Chan, & McGillion, 2004).

Inguinal hernia repair (IHR) is a commonly performed ambulatory surgery procedure in Canada (Cunningham, Temple, Mitchell, 1996). Inguinal hernia occurs most frequently in males, and the average age for hernia repair in adults is 55 (SD ±16). For men, the lifetime risk of developing an inguinal hernia ranges from 6% to 27% (Cunningham et al., 1996; Liem, van derGraff, van Steensel, Boelhouwer, et al., 1997). Inguinal hernia is characterized by a protrusion of the intestine through a weak point or tear in the lower abdominal wall in the inguinal canal, near the groin (Cunningham et al., 1996; Liem et al., 1997; Matthews & Neumayer, 2008). The cause of an inguinal hernia is likely multifactorial with both genetics and environmental factors contributing to its development. Possible etiology of an inguinal hernia...
includes weakening of the abdominal muscles with age, smoking, steroid use, previous abdominal injury, participation in sports, heavy lifting, pregnancy, and an increase in abdominal pressure with peritoneal dialysis (Matthews & Neumayer, 2008). The hernia can be especially painful with coughing, bending or heavy lifting. The resulting protrusion can lead to bowel obstruction due to strangulation, with clinical manifestations of vomiting, crampy abdominal pain, and distension (Bliss, Sawchuk, & Hoeflock, 2006). Surgical repair of the hernia is done to prevent bowel obstruction (Liiem et al., 1997). The three basic IHR surgical approaches include (a) open repair or traditional repair; (b) open tension-free repair; and (c) laparoscopic repair (Liem et al., 1997; Meakins & Barkun, 1997).

IHR has been identified as one of the most painful ambulatory surgery procedures, with 98% of patients reporting pain 24 hours following IHR surgery (Sawhney, Paul, & Alvarado, 2008), and 54% of patients experiencing moderate to severe pain in the first 72 hours (Coll & Ameen, 2006; McGrath et al., 2004; McHugh & Thoms, 2002; Pavlin, Chen, Penaloza, & Buckley, 2004; Rawal, Hylander, Nydahl, Olofsson, & Gupta, 1997). Despite experiencing continued pain, patients do not always take their prescribed analgesics. Analgesics are helpful in managing post-operative pain but may have adverse effects, including nausea, vomiting, or constipation. Almost half of all patients who undergo ambulatory surgery experience these adverse effects, with 45% experiencing constipation and 46% experiencing nausea and/or vomiting in the first 48 hours after surgery (Beauregard, Pomp, & Choiniere, 1998). However, patients receive little or no instruction on how to manage these adverse effects, particularly after discharge from hospital (McGrath et al., 2004; Watt-Watson, Chung et al., 2004). As well, patients may have concerns about addiction, or asking for help to manage their pain and may believe that moderate to severe pain is to be expected, contributes to healing, and therefore is to be tolerated following surgery (Beauregard et al., 1998; Mattila et al., 2005; McGrath et al., 2004; Pavlin et al., 2004;
Watt-Watson, Chung, et al., 2004). Patients are expected to manage this pain and adverse effects of analgesics at home.

Acute post-operative pain after common surgical interventions, including IHR, can lead to persistent pain in 10% to 50% of patients (Kehlet, Jensen, & Woolf, 2006). The reported incidence of persistent pain more than a year post IHR ranges from 6 to 30% (Bozuk, 2003; Bueno, Serralta, Planells, & Rodero, 2004; Kehlet et al., 2006; Königer, Redecke, & Butters, 2004; Kumar, Wilson, Nixon, & Macintyre, 2002; Picchio et al., 2004). The intensity of acute post-operative pain has been found to be a contributing factor to the development of persistent pain at least a year later (Katz, Jackson, Kavanagh, & Sandler, 1996; Callesen, Bech, Kehlet 1999; Katz, Poleshuck, & Andrus, 2005). This persistent post-surgical pain can lead to peripheral and central sensitization as a result of the plasticity of the nervous system that changes with intense stimuli and repeated firing of peripheral nociceptors (Julius & Basbaum, 2001; Kehlet et al., 2006). Therefore, interventions aimed at reducing pain following ambulatory IHR surgery are critical.

Minimal research was found regarding interventions to manage pain following ambulatory surgery, and none were found that included only patients undergoing IHR (Dewar, Craig, Muir, & Cole, 2003; Laurion & Fetzer, 2003). Of the two trials found, one randomized controlled trial included a heterogeneous ambulatory surgery sample that included patients who underwent IHR. This trial assessed the effect of a pre-operative education intervention, with post-operative telephone follow-up and support, on patients’ pain management following discharge from ambulatory surgery (Dewar et al., 2003). This trial demonstrated a positive effect of structured pain education and telephone support on pain intensity at post-operative day 5, and on pain related interference on mood, walking ability, and concentration on post-operative day 3. The second trial was a pilot trial that compared the effects of pre-operative guided imagery or music
versus standard of care on pain, post-operative nausea and vomiting, and length of stay for patients undergoing ambulatory laparoscopic gynecological procedures (Laurion & Fetzer, 2003). The two intervention groups reported less pain, but all groups reported pain scores in the mild (≤ 3) at the time of discharge home. However, this trial had methodological issues in they were unable to control how many times participants listened to their respective audio tapes, and they did not follow participants at home after discharge from hospital.

The purpose of this trial was to examine the effectiveness of an individualized pre-operative pain education intervention, that included verbal and written information regarding managing post-operative pain, and telephone support pre-operatively and after discharge to home, for men having IHR surgery. The pain education intervention booklet provided participants with evidence-informed information, and the content was delivered in conjunction with an individualized discussion regarding the patient’s pain management concerns. Secondary outcomes examined included pain-related interference with usual activities, the use of analgesics, adverse effects, patient concerns regarding pain, and the adequacy of post-operative discharge information.

The conceptual framework used to provide direction to this trial was an adaptation of Dodd’s (2001) Symptom Management Model. This model proposes that symptoms are a unique experience and can only be understood from the perspective of the individual. The model also suggests that individuals at risk for adverse symptom development may benefit from intervention strategies initiated prior to the development of a symptom. The Symptom Management Model was adapted for this study to understand the context of the symptom of pain that is experienced following IHR surgery.
**Problem Statement**

The number of ambulatory surgical procedures performed in Canada is increasing, with IHR being a common surgery (Cunningham et al., 1996). Following IHR many patients experience unrelieved moderate to severe post-operative pain, with up to 54% of patients experiencing pain for as long as 3 days post-operatively (Coll & Ameen, 2006; McGrath et al., 2004; McHugh & Thoms, 2002; Pavlin et al., 2004; Rawal et al., 1997). This unrelieved acute pain can lead to persistent pain for 40% of patients who undergo IHR (Bozuk et al., 2003; Bueno et al., 2004; Kehlet et al., 2006; Königer, et al., 2004; Kumar et al., 2002; Picchio et al., 2004). Analgesics are effective to manage post-operative pain, but some patients stop taking analgesics due to experiencing adverse effects. Forty-five percent of ambulatory surgery patients experience adverse effects of analgesics such as constipation, nausea, or vomiting (Beauregard et al., 1998). Patients may receive no or little instruction on how to manage pain or analgesic related adverse effects, particularly at home (McGrath et al., 2004; Watt-Watson, Chung et al., 2004). There has been limited research examining interventions to reduce post-operative pain for patients undergoing ambulatory surgery and none that specifically focused on patients who have undergone IHR surgery. This randomized controlled trial was conducted to evaluate the effect of an individualized education intervention on pain following ambulatory IHR.
Chapter 2

Review of the Literature

This chapter provides an overview of the literature related to pain and adverse effects experienced by patients who have undergone ambulatory IHR surgery. The discussion will focus on: (a) surgical approaches for IHR; (b) pain following ambulatory surgery; (c) pain following IHR; (d) pain-related interference with usual activities; (e) analgesic use, adverse effects, and concerns regarding pain management; (f) pain theory as the theoretical rationale for an intervention to reduce pain following IHR; (g) persistent pain following IHR; (h) the effectiveness of interventions to manage ambulatory surgery pain; and (i) the conceptual framework that guided this trial.

Surgical Approaches for Inguinal Hernia Repair

Surgical repair of the defect in the abdominal wall is the main treatment for inguinal hernia (Cunningham et al., 1996). The three basic approaches to the surgical repair include (a) open repair utilizing the patient’s own tissue; (b) open tension-free repair, where mesh is used to bridge or cover the defect; and (c) laparoscopic repair, a tension-free repair also utilizing mesh (Liem et al., 1997; Meakins & Barkun, 1997).

The open surgical repair involves suturing ligaments of the internal oblique and transverse muscles, with the incised fascia transversalis to the inguinal ligament. Prosthetic material such as a mesh or a plug is used to reinforce the posterior wall of the inguinal canal, or a patch is used to fill in the defect in the inguinal floor (Liem et al., 1997; Meakins & Barkun, 1997). The laparoscopic IHR approach involves entering the pre-peritoneal sac to reduce the hernia and putting a mesh into place to repair the defect.
The open technique continues to be the most common approach to IHR, possibly because laparoscopic surgery requires special equipment and education for the surgeon (Matthews & Neumayer, 2008). Modifications to the surgical technique have been made over time with varying success to try to improve patient outcomes related to inguinal hernia recurrence rates, and post-operative pain (Meakins & Barkun, 1997). However, studies examining pain after IHR surgery have been minimal and include descriptive studies with mixed surgical samples (that include IHR) to examine pain following ambulatory surgery. The open IHR was the most common approach used with participants in this trial.

**Surgical Pain**

*Pain following ambulatory surgery*

Since 1994, 10 studies have examined the prevalence of acute post-operative pain for patients undergoing ambulatory surgery (Appendix A). These studies included heterogeneous ambulatory patient samples in regard to surgical type, and the time frame for evaluation of adverse effects (Beauregard et al., 1998; Coley, Williams, DaPos, Chen, & Smith, 2002; Coll & Ameen, 2006; Mattila et al., 2005; McGrath et al., 2004; McHugh & Thoms, 2002; Oberle, Allen, & Lynkowski, 1994; Pavlin et al., 2004; Rawal et al., 1997; Watt-Watson, Chung, et al., 2004). These studies included patients who underwent orthopaedic surgeries (e.g., arthroscopy, shoulder repair, bunionectomy), cataract extraction, laparoscopy, mammoplasty, submucosal resection, tubal ligation, hand surgery (e.g., carpal tunnel), otoplasty, adenoidectomy, laparoscopic cholecystectomy, microdiscetomy, hernia repair, and dental extractions. Four studies evaluated patient outcomes using a postal survey, and six studies used telephone surveys. One study examined outcome variables at 1 day, two studies examined outcomes for 2 days, three examined outcomes for 3 days, and three of these studies examined outcomes for 7 days after surgery (Beauregard et al., 1998; Mattila et al., 2005; Watt-Watson, Chung, et al., 2004).
In all studies, pain was the most frequently reported symptom, and reason for subsequent admission to hospital. Moderate to severe pain has been reported by 21% to 62% of ambulatory surgery patients post-operatively on the day of surgery, and 18% to 44% at 24 hours following surgery (Beauregard et al., 1998; Mattila et al., 2005; McGrath et al., 2004; Oberle et al., 1994; Pavlin et al., 2004; Rawal et al., 1997; Watt-Watson, Chung, et al., 2004). Thirteen to 55% of ambulatory surgery patients continued to report moderate to severe pain 7 days after surgery (Beauregard et al., 1998; Watt-Watson, Chung, et al., 2004).

**Pain following IHR**

Inguinal hernia repair is reported to be one of the most painful ambulatory surgeries, with 62% of patients reporting moderate to severe pain at post-operative day 2 (McGrath et al., 2004, Rawal et al., 1997). This acute pain can lead to persistent pain for 6-30% of these patients (Bozuk et al., 2003; Bueno et al., 2004; Haapaniemi & Nilsson, 2002; Könberger, et al., 2004; Kumar et al., 2002; Massaron et al., 2007; Picchio et al., 2004).

Since 1997, eight studies have examined pain that included patients who underwent IHR. One study was a prospective study (Callesen, Bech, Nielsen et al, 1998), and two were retrospective descriptive studies that examined pain in only patients who underwent IHR (Massaron et al., 2007; Sawhney et al., 2008). Five of the studies were prospective, descriptive, and examined pain in ambulatory surgical samples which included patients who underwent IHR (Coll & Ameen, 2006; McHugh & Thoms, 2002; McGrath et al., 2004; Pavlin et al., 2004; Rawal et al., 1997) (Appendix B).

Callesen, Bech, Nielsen et al. (1998) prospectively examined pain following 501 ambulatory IHR or femoral hernia repair in a sample of 466 patients. Four hundred and forty-eight hernia repairs were performed on men and the median age of participants was 60 (range 18-90). Pain
was assessed during rest, cough and mobilization using a 4 point verbal rank scale (none, light, moderate, severe) daily for 1 week and at 4 weeks. Participants mailed completed questionnaires using a pre-addressed stamped envelope. Moderate to severe pain at post-operative day 1, day 6, and 4 weeks was reported by 25% (n = 117), 11% (n = 51), 5% (n = 23) of participants at rest respectively, and by 66% (n = 307), 33% (n = 153), 11% (n = 51) with cough or mobilization respectively. Forty-two percent of participants (n = 196) used analgesics to manage pain for the first week post-operatively.

Massaron et al. (2007) retrospectively examined pain 10 months following IHR surgery (N = 1,440), in a sample of men (n = 1,289) and women (n = 111) whose age ranged between 18–97 years. Data collection was completed using a postal questionnaire. Patients were asked to recall if they experienced pain after their IHR surgery, and if the pain lasted less than 6 months or longer than 6 months. If patients reported they experienced pain for less than 6 months, they completed the McGill Pain Questionnaire –Short Form (MPQ-SF) by telephone. Patients who reported experiencing pain that continued for more than 6 months underwent a physical exam as well as completing the MPQ-SF. Thirty-eight percent of all patients reported experiencing post-operative pain, and of those patients, 19% reported having pain lasting more than 6 months post-operatively. Most patients (81%, n = ) reported having pain in their groin area. The mean MPQ-SF scores for the total PRI was 19.5 (±14.5), PRI-S was 13.3 (± 7.4), and the PRI-A was 6.2 (± 9.4). Pain descriptors reported by 20% or more of patients included aching, stabbing, sharp, tender, and punishing. Although this study provided some information regarding the location of the patients’ pain and the pain descriptors identified, a limitation of this study was that patients were asked to recall their pain experience 10 months after their surgery. Therefore, recall bias is a potential problem in this study as patients may not have remembered the acute post-operative pain they experienced.
Sawhney et al. (2008) retrospectively examined pain and adverse effects following IHR surgery ($N = 98$) for a sample of men whose mean age was 55 ($\pm 17$) years. Data collection were completed by chart audit and information from the ‘Post-operative Telephone Call Checklist.’ The ‘Post-operative Telephone Call Checklist’ was used by nurses to obtain information regarding pain and adverse symptoms at 24 hours following ambulatory surgery. Ninety-eight percent of patients reported experiencing pain 24 hours following IHR surgery (Sawhney et al., 2008). However, the post-operative checklist did not record the intensity of pain nor did it indicate if pain was adequately managed.

From the five prospective, descriptive studies examining pain with heterogeneous ambulatory surgical samples, the method of data collection varied. Three studies used telephone surveys (McGrath et al., 2004; McHugh & Thoms, 2002; Pavlin et al., 2004) and two used postal surveys (Coll & Ameen, 2006; Rawal et al., 1997). Sample sizes ranged from 99 to 5,703 patients, and included from 25 to 244 IHR patients. The response rate varied from 57% to 94%, and the mean age reported in three of the five studies ranged from 34 to 42 years (Coll & Ameen, 2006; McGrath et al., 2004; McHugh & Thoms, 2002; Pavlin et al., 2004; Rawal et al., 1997). Time periods for data collection also varied, ranging from 1 to 4 days post-operatively.

Three studies used either a visual analogue scale (VAS) or numeric rating scale (NRS) to assess pain intensity (Coll & Ameen, 2006; McGrath et al., 2004; Pavlin et al., 2004). Two studies did not use a validated tool to assess pain intensity (McHugh & Thoms, 2002; Rawal et al., 1997). The majority of patients across these five studies reported moderate to severe post-operative pain $\geq 4/10$ (with 0 being no pain and 10 being the worst pain). Specifically, 45% to 66% of patients reporting $\geq 4/10$ pain at post-operative day 1, 62% of patients reporting $\geq 4/10$ pain at post-operative day 2, and 45% of patients reporting $\geq 4/10$ pain at post-operative day 3 (Callesen, Bech, Nielsen et al, 1998; Coll & Ameen, 2006; McGrath et al., 2004, Rawal et al.,
60% of patients reported pain $\geq 4/10$ on the day of surgery, and first and second days after surgery (Coll & Ameen, 2006; McGrath et al., 2004; McHugh & Thoms, 2002; Pavlin et al., 2004; Rawal et al., 1997). Pavlin et al. (2004) found that patients who underwent IHR reported their worst pain as 6.6 the first 24 hours after surgery, and as 5.6 at 48 hours after surgery. Coll and Ameen (2006) reported that 54% of patients continued to report moderate to severe pain at 3 days after surgery. Collectively, these studies indicate that more than 50% of patients report moderate to severe pain following ambulatory IHR surgery for the first 72 hours post-operatively.

*Pain-related interference with usual activities*

Following surgery, unrelieved pain can interfere with a patient’s return to everyday activities. Therefore, an important indicator of post-operative recovery is the ability of individuals to resume their usual activities. No studies have been found that examined the impact of pain on return to usual activities specifically for patients who have undergone ambulatory IHR surgery. Pavlin et al. (2004) examined pain-related interference with usual activities in a heterogeneous ambulatory surgery sample that included IHR (Pavlin et al., 2004). Three other studies of heterogeneous ambulatory surgical samples, that did not include IHR, have examined pain related interference with usual activities (Beauregard et al., 1998; Oberle et al., 1994; Watt-Watson, Chung, et al., 2004). Since there are limited data regarding how pain interferes with usual activities following IHR, findings from all available studies of ambulatory surgery patients will be examined.

Pavlin et al. (2004) reported that pain interfered with activity levels for 73% of ambulatory surgical patients on post-operative day 1, and for 53% on post-operative day 2. This included patients undergoing IHR, knee arthroscopy, pelvic laparoscopy, breast surgery, trans-vaginal
uterine surgery, and plastic surgery. Oberle et al. (1994) reported that pain interfered with the ability to independently get dressed in 36% (n = 105) of patients 3 days following ambulatory surgery procedures which included arthroscopy, bunionectomy, cataract extraction, laparoscopy, mammoplasty, submucosal resection, tubal ligation, hernia repair, shoulder repair, carpal tunnel repair, otoplasty, and adenoidectomy.

Beauregard et al. (1998) assessed pain related interference using the BPI and reported that the BPI score was ≥4 out of 10 for 3 or more daily functions among 63% (n = 53) at post-operative day 2, and 44% (n = 37) at post-operative day 7 for ambulatory surgery patients who underwent gynaecological laparoscopy, knee or shoulder arthroscopy, and carpal tunnel decompression. These daily functions included general activity, working, walking, sleeping, mood, and relations with others. Watt-Watson, Chung, et al.’s (2004) sample of ambulatory shoulder and laparoscopic cholecystectomy surgery patients reported a mean total Brief Pain Inventory-Interference Subscale (BPI-I) score of 30 at post-operative day 2. At post-operative day 7 the mean BPI-I score was 13 for laparoscopic cholecystectomy surgery patients, and 23 for shoulder surgery patients. Pain interference with work remained moderate for patients who underwent ambulatory shoulder (6.1 ± 3.3) and hand (4.2 ± 4) surgery at 7 days post-operatively. In addition, interference with sleep remained moderate for patients who underwent shoulder surgery (5.4 ± 2.8).

The measures used to assess pain-related interference varied between the studies. Two studies used the Brief Pain Inventory-Interference Subscale (BPI-I) (Beauregard et al., 1998; Watt-Watson, Chung, et al., 2004), one study used a 5 point NRS (1-5) to assess interference with sleep and movement (Oberle et al., 1994), and one study used a 101 point NRS (0 to 100) to assess whether pain inhibited activity (Pavlin et al., 2004). Overall, these four studies provide evidence that pain interfered with usual activities following ambulatory surgery, including the
ability to dress, work, and sleep. However, only two studies used a valid and reliable tool to assess interference in specific activities; of these, only one study included patients who underwent hernia repair.

Analygesics, adverse effects, and concerns

A key strategy to manage acute post-operative pain is the administration of analgesics. In the study conducted by Pavlin et al. (2004) 77% (n = 135) of ambulatory surgery patients reported that their pain was relieved with analgesics. Although analgesics are effective, they may cause adverse effects including nausea, vomiting, or constipation. Experiencing adverse effects is one of the main reasons why patients discontinue their use (McGrath et al., 2004; Watt-Watson, Chung, et al., 2004). Almost half of all patients who undergo ambulatory surgery experience adverse effects of analgesics in the first 48 hours following surgery, including constipation in 45%, and nausea and vomiting in 46% of patients (Beauregard et al., 1998; Mattila et al., 2005; McGrath et al., 2004; Pavlin et al., 2004; Watt-Watson, Chung, et al., 2004). Patients who have ambulatory surgery often have to manage these adverse effects home without the advice of a health care professional (McGrath et al., 2004; Watt-Watson, Cheung et al., 2004).

Those patients trying to manage at home may not receive enough or the right information to manage their pain or the adverse effects of analgesics following ambulatory surgery. Three studies examined the adequacy of discharge information following ambulatory surgery (Beauregard et al., 1998; Oberle et al., 1994; Watt-Watson, Chung, et al., 2004). Both Oberle et al. (1994) and Beauregard et al. (1998) found that most patients were dissatisfied with their discharge information. Discharge instructions were not clear or non-existent regarding managing their pain at home, and no information was given on how to use non-pharmacological methods. Watt-Watson, Chung, et al. (2004) reported that only 55% of patients felt they received clear
instructions regarding their medications, and 56% of patients stated they did not know how to change their medication schedule if adverse effects became problematic.

Kastanias, Denny, Robinson, Sabo, and Snaith (2009) examined the informational needs regarding pain management of adult ambulatory surgery patients \((n = 150)\), including a small number of patients who underwent hernia repair \((n = 4, 2.7\%)\). They reported that patients wanted an explanation of the following: (a) what to expect from the pain experience (average pain intensity and types of pain); (b) their analgesics (what to do if the analgesics did not work and how to adjust their analgesics); (c) adverse effects of analgesics (the likelihood of experiencing adverse effects, and how to manage adverse effects); and (d) non-pharmacological methods to manage pain. Patients stated that they preferred to receive information regarding managing pain pre-operatively, they also stated they wanted both written and verbal discharge information about what to do to manage pain, as well as what they would experience and feel (Kastanias et al., 2009; Oberle et al., 1994).

Patients’ concerns regarding pain and analgesics may prevent them from reporting their pain to health care professionals and from taking analgesics to manage their pain. The American Pain Society Outcome Questionnaire was developed to assess pain and satisfaction with pain management among acute pain and cancer pain patients (American Pain Society Quality of Care Committee, 1995). This questionnaire includes the Barriers Questionnaire Short Form (BQ-SF) that asks about common concerns regarding pain management, including the ability of analgesics to control pain, addiction to analgesics, characteristics of good patients, adverse effects of analgesics, saving analgesics until pain is severe, and that pain indicates that an illness is becoming worse. Beauregard et al. (1998) used the BQ-SF in their study of pain following ambulatory surgery and found that 62% of study participants strongly believed that they could easily become addicted to analgesics and that 49% strongly believed that it was easier to tolerate
pain than the adverse effects of analgesics. McGrath et al. (2004) reported that 13% of ambulatory surgery patients felt unprepared to manage pain at home. This was due to the fact that their prescription was not explained, they waited too long before taking analgesia, or they did not fill their prescription because they were concerned about becoming addicted to their pain medication. These data provide critical information about patients’ concerns and why they may not take analgesics post-operatively despite experiencing considerable pain following ambulatory surgery.

This literature points to gaps in the education and support that ambulatory IHR patients’ receive. An education intervention to manage pain for ambulatory IHR patients would ideally include information regarding types of analgesics, when to use analgesics, adverse effects of analgesics and strategies to minimize adverse effects, and common concerns regarding managing pain. This information would be provided in both a written and verbal format and presented to the patient in a standardized way that can be individualized to address specific patient needs.

**Pain Theory**

Pain is more than the result of a noxious stimulus; it is a subjective experience with multifactorial influences. It also includes sensory, cognitive, and affective dimensions. The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk, 1994, p.209 ). This definition reflects Melzack and Wall’s Gate Control Theory (GCT) of pain, which provides the basis for understanding the pain experience. Since the development of GCT, further research has led to a more advanced understanding of pain mechanisms and the potential consequences of unrelieved, acute post-operative pain.
GCT proposed that sensory inputs, both noxious and innocuous, are conducted by primary afferent fibres to the dorsal horn (Melzack & Wall, 1965, 1970). Noxious stimuli are transmitted by C-fibre nociceptors, with slow conducting unmyelinated axons, and A-delta nociceptors with thinly myelinated axons. The wide dynamic range (WDR) neurons or “T-cells” in the substantia gelatinosa (SG) in the dorsal horn function as a gate control mechanism and modulate afferent input prior to central transmission to the thalamus and cerebral cortex. An increase in activity in large, myelinated, non-nociceptive primary afferents (i.e., A-beta afferents) can block the noxious activity transmitted by small, nociceptive afferents through the WDR cells in the SG and inhibit pain transmission. However, pain transmission to second order neurons in the SG can occur if impulses from small nociceptive fibres reach a critical threshold without being blocked. Nociceptive pathways ascend from the T-cells in the SG to the thalamus and cerebral cortex and transmit sensory-discriminative information regarding pain that contributes to the motivational-affective processing of pain, which, in turn can activate descending inhibitory systems.

Melzack and Wall’s (1965, 1970) GCT integrated earlier thinking from Specificity Theory and Pattern Theory to propose an alternative theoretical view of the pain experience. Specificity Theory suggests that specific pain receptors in body tissues carried nociceptive impulses through a straight line transmission to a pain centre in the brain. Therefore, pain intensity was thought to be directly proportional to the degree of tissue damage. However, Melzack and Wall (1970) determined that this theory was too simplistic and expanded on the thinking that specialized nerve fibres exist. They proposed that sensory input was modulated in the central nervous system, which influenced pain perception and response. The modulation of sensory input in the central nervous system, specifically in the dorsal horn and the cerebrum, continues to be a central component of current explanations of nociception, pain perception, and response.
Another important tenet of GCT was developed from ideas related to Pattern Theory. Goldscheider, who focused on abnormal firing patterns, proposed that the intensity of the non-noxious stimuli and central summation were both critical determinants of pain. Noordenbas’s concept that faster, larger, and myelinated fibre input could block painful slower, smaller, unmyelinated fibre input was the basis for the gating mechanism concept (Melzack & Wall, 1965). Noxious stimuli enter an active nervous system that is a product of past experiences, culture, emotions, and expectations. Therefore, the intensity and quality of pain are determined by factors unique to individuals, including past experiences and cultural beliefs (Melzack & Wall, 1970). Melzack and Wall (1970) postulated that these central influences are mediated through a gate control system. For example, anxiety or excitement may open or close the gate through a central control trigger that activates selective brain processes that control sensory input.

More recently, research has identified neuronal modifiability or “plasticity” of the nervous system to change with intense stimuli as an important mediator of both acute and persistent pain that results in peripheral and central sensitization (Julius & Basbaum, 2001; Woolf & Salter, 2000). Pain mechanisms in the peripheral and central nervous systems can change in response to continued noxious stimulation, a process known as sensitization (Basbaum & Julius, 2006). Sensitization of peripheral nociceptors can occur, after trauma such as surgery, with the release of biochemical mediators related to the inflammatory process. Repeated noxious stimuli with severe and persistent injury may cause dorsal horn spinal cord neurons to become increasingly responsive to all input, resulting in central sensitization (Julius & Basbaum, 2001).

In acute post-operative pain, nociceptors in the periphery are stimulated by the neurochemical mediators of the inflammatory response, including prostaglandins, substance P, and glutamate (Julius & Basbaum, 2001; Kehlet et al., 2006). This acute inflammatory response is a normal
physiological response that is a self-limiting process and typically lasts for 10 days (Rote, 2002). This multifactoral, non-specific defense mechanism takes place following cellular injury to defend against infection and facilitate tissue repair. The inflammatory response is activated by the immune system and maintained by three plasma protein systems: the complement system, the clotting system, and the kinin system. It is mediated and facilitated by the local release of biochemicals, including bradykinin, prostaglandins, leukotrienes, serotonin, histamine, substance P, thromboxanes, platelet activating factor, adenosine and ATP, protons, and free radicals (Meyer et al., 2006). Mast cells synthesize biochemical mediators, including leukotrienes, tumour necrosis factor, and neurotrophins (including nerve growth factor). These mediators work synergistically to induce inflammatory pain and hyperalgesia. Therefore, analgesics, such as non-steroidal anti-inflammatory drugs and opioids, are used to prevent the release of these mediators (Craig, Sorkin, 2001; Meyer, Ringkamp, Campbell, & Raja, 2006).

Post-operatively, if neuronal modifications occur in the dorsal horn of the spinal cord, an individual may experience persistent pain even after the usual tissue healing time has passed (Julius & Basbaum, 2001; Kehlet et al., 2006). Kehlet et al. (2006) report that 10% to 50% of patients experience persistent pain after common surgeries, including IHR. Unrelieved moderate to severe pain in the acute post-operative period leads to repeated firing of peripheral nociceptors that can result in an ongoing persistent pain problem. The basis for persistent pain is in place within hours after an injury (Carr & Goudas, 1999). Therefore, acute pain should be considered the commencement of “an extensive, persistent nociceptive and behavioural cascade triggered by tissue injury” (Carr & Goudas, 1999, p. 2051).

In summary, pain theory highlights that pain is a subjective and individual experience. The perception of pain is influenced by the physiological response as well as past experience, culture and emotions. Pain theories point to the use of strategies such as pharmacological and non-
pharmacological interventions that can increase the inhibitory mechanism related to the pain experience. Strategies to manage IHR pain would include both pharmacological and non-pharmacological interventions that reflect the multidimensionality of the pain experience.

**Persistent Pain following IHR**

Risk factors for the development of persistent pain after inguinal hernia surgery include age less than 65 years, the use of mesh, the presence of pre-operative pain, moderate to severe post-operative pain, recurrence of hernia, and ambulatory surgery (Cunningham et al., 1996; Callesen, et al., 1999; Dennis & O’Riordan, 2007; Kehlet et al., 2006; Königer, et al., 2004; Massaron et al., 2007). The incidence of persistent pain more than 1 year post IHR ranges from 6 to 30% (Bozuk et al., 2003; Bueno et al., 2004; Callesen, Bech, Kehlet, 1999; Haapaniemi & Nilsson, 2002; Königer, et al., 2004; Kumar et al., 2002; Picchio et al., 2004). Callsen et al. (1999) reported that patients were seven times more likely to report moderate to severe pain 1 year after surgery if they had moderate to severe pain at 4 weeks after surgery.

Studies examining the impact of modifying the surgical technique on the risk of developing persistent post-surgical pain have reported mixed results. Although variation in surgical technique did not impact patient outcomes in two studies (Cunningham et al., 1996; Picchio et al., 2004), the laparoscopic surgical approach to IHR did facilitate a decrease in persistent pain in three others (Bozuk et al., 2003; Königer, et al., 2004; Kumar et al., 2002). Of the five studies that examined the development of persistent pain following IHR surgery, three were randomized trials and two were descriptive, postal surveys (Appendix C). Variation in surgical technique did not reduce the incidence of persistent pain in the trial that examined the impact of nerve preservation, or in the trial that examined the impact of different approaches to the open IHR (Cunningham et al., 1996; Picchio et al., 2004). A trial examining laparoscopic versus open surgical approach reported that moderate to severe pain was experienced less frequently with the
Cunningham et al.’s (1996) randomized controlled trial, that was conducted in Canada, evaluated the impact of open surgical techniques on the long-term development of pain and numbness at 6 months, 1 year, and 2 years after IHR. Patients (N = 276) were randomized to one of three standard open surgical approaches: Bassini, McVay, or Shouldice. They found no difference in the incidence of persistent pain based on surgical technique. Moderate to severe pain was reported by 11.9% (n = 33) of patients at 1 year, and 10.6% (n = 29) at 2 years of patients in all 3 groups. Picchio et al.’s (2004) randomized controlled trial examined the effect of preservation or elective division of the ilioinguinal nerve on pain and post-operative symptoms after open inguinal repair. Patients (N = 813) were randomized to either ilioinguinal nerve preservation (n = 408) or ilioinguinal nerve resection (n = 405). At 6 months they found no statistically significant differences (p = 0.55) between the two groups, with 12% (n = 49) of the nerve preservation group versus 8% (n = 32) of the nerve resection group reporting moderate to severe pain. At 1 year post-operatively, there were no statistically significant differences between the two groups with 6% (n = 24) of the nerve preservation group and 6% (n = 24) of the nerve resection group reporting moderate to severe pain (Picchio et al., 2004).

However, Köninger, et al. (2004) reported different results in their study comparing IHR surgical approaches and the development of persistent post-surgical pain. Patients (N = 280) were randomly assigned to either an open approach, including Shouldice (n = 93), Litchenstein (n = 93), or a laparoscopic transabdominal pre-peritoneal (TAPP, n = 94) approach. A statistically significant difference in pain was found with lower scores for the TAPP approach versus the open approach (p = 0.01). At a median of 52 months after surgery, moderate to
severe pain was reported by 16% (n = 12) of patients with a Shouldice repair, 9% (n = 7) with a Lichtenstein repair, and 1.2% (n = 1) with a TAPP repair.

Three postal surveys examined the incidence of groin pain 6 months or longer following either laparoscopic or open IHR surgery (Callesen, Bech, Kehlet, 1999; Bozuk et al., 2003; Kumar et al., 2002). At 1 year following surgery, Callesen et al (1999) found that pain was reported by 19% (n = 80) of respondents (N = 419), this pain was moderate to severe for 6% (n = 24), and pain interfered with daily function for 6% (n = 24). Only 9 respondents who had moderate to severe pain were using analgesics to manage their pain. At 21 months following surgery, Kumar et al. (2002) found that pain or discomfort was reported by 30% (n = 136) of respondents (N = 454), and groin pain was reported more often (p = 0.01) in patients who underwent open surgery (38%, n = 82), than laparoscopic surgery (23%, n = 54). From a sample of (N = 139) patients who underwent IHR, Bozuk et al. (2003) found that pain was reported more often (p = 0.035) in the open repair group (27%, n = 37) than in the laparoscopic repair group (14%, n = 20). Analgesics were used to manage persistent post-surgical pain in 1% of patients who underwent laparoscopic surgery, and 4% (p = 0.5) of patients who underwent open surgery (Bozuk et al., 2003).

The results of these studies indicate that varying the surgical technique for IHR does not eliminate persistent pain; however, the laparoscopic technique may decrease the incidence of persistent pain. Moderate to severe post-operative pain has been identified as a risk factor for the development of persistent pain, and since varying the surgical technique has not eliminated moderate to severe pain, finding an intervention to reduce pain in the immediate post-operative phase is important. Implementing pharmacological and non-pharmacological strategies to manage pain prior to IHR surgery and continuing them post-operatively may help address pain during the acute phase.
Summary of Research

IHR is reported to be one of the most painful ambulatory surgeries, with 62% of patients experiencing moderate to severe post-operative pain at post-operative day 2 (Rawal et al., 1997). This unrelieved, acute post-operative pain can lead to neuronal plasticity resulting in peripheral and central sensitization. This sensitization may result in pain long after the usual time for tissue healing. A persistent pain problem has been documented in 10% to 50% of patients undergoing common surgical procedures (Kehlet et al., 2006). Current evidence indicates that 6% to 30% of patients undergoing IHR live with some degree of pain 1 year after surgery (Bozuk et al., 2003; Bueno et al., 2004; Kehlet et al., 2006; Königinger, et al., 2004; Kumar et al., 2002, Picchio et al., 2004). As well, unrelieved post-operative pain can interfere with the patients’ ability to perform usual daily activities. Although no data were found describing pain-related interference for IHR patients, patients undergoing other ambulatory surgeries have reported that pain interferes with their sleep, ability to work, and ability to dress. It is reasonable to expect that pain will interfere with these activities for patients undergoing IHR.

Analgesics are effective in managing post-operative pain, but patients may avoid taking analgesics because they experience adverse effects or have concerns regarding analgesic use. The most commonly reported adverse effects of analgesics use include constipation, nausea, and vomiting (Beauregard, et al., 1998). The latter may result in patients avoiding or discontinuing analgesics early. Patients’ concerns regarding pain management, such as the fear of becoming addicted to opioids, also impact the use of analgesics post-operatively. Following ambulatory IHR, patients are required to manage their pain and any adverse effects of analgesics at home independently. However, patients report that they do not receive adequate information to manage pain at home (McGrath, et al., 2004; Watt-Watson, Chung, et al., 2004).
The available data provide information regarding the pain experienced by patients following IHR. It also identifies gaps in pre-operative education and patients’ knowledge regarding strategies for the effective management of post-operative pain. It is imperative to close this gap by providing pre-operative education regarding pain management strategies, adverse effects of analgesics, and common concerns regarding pain management, as well as providing post-operative support. This trial evaluated the effectiveness of an intervention that included these components.

**Interventions to Manage Pain Following Ambulatory Surgery**

Although acute pain is a problem for patients undergoing ambulatory surgery, there is limited research regarding the effectiveness of non-surgical interventions for the management of post-operative pain in this population. Of the two trials found (Dewar et al., 2003; Laurion & Fetzer, 2003), only Dewar et al. included patients who had IHR in their sample (Appendix D).

Dewar et al. (2003) conducted a randomized controlled trial to assess the effect of a pre-operative education intervention, with post-operative telephone follow-up and support, on patients’ pain following discharge to home after ambulatory surgery. Two hundred and thirty-eight patients who underwent anal surgery (n = 85), arthroscopic surgery (n = 69), hernia repair (n = 32), mammary reduction or enhancement (n = 36) were randomized to receive either usual care or structured pre-operative teaching with post-operative telephone advice on post-operative days 1, 2, and 3. The intervention included verbal and written pre-operative teaching regarding pain management, and post-operative telephone advice regarding pain, nausea, vomiting, constipation, dizziness, and grogginess. Advice was provided regarding pain management, including adverse effects of analgesics. Both the control group and intervention group were given a diary to record daily pain intensity scores, analgesics used to manage pain, adverse effects, interference of pain with usual activities, and the helpfulness of pre-operative education.
Pain intensity was documented by patients using an 11 point NRS (0 to 10). The usual care group received one telephone call on post-operative day 2 to remind them to complete their diary. Outcome data were collected using the diary on post-operative days 1, 2, 3, and 4 and by telephone on post-operative day 5. Two hundred and twenty-two (93%) patients returned their diary. They reported no differences between the groups for pain at post-operative days 1, 2, 3, or 4. There was a significant difference ($p = 0.04$) in pain intensity at post-operative day 5 with the intervention group reporting lower pain intensity scores ($2.8 \pm 2.3$ vs $3.6 \pm 2.6$). There was also a significant difference in pain related interference with mood ($p = 0.04$), walking ($p = 0.05$) relations with others ($p = 0.04$) and concentration ($p = 0.01$) at post-operative day 3, with the intervention group reporting lower interference scores. The majority of participants in the intervention group reported that both the written information (60%) and the telephone follow-up (80%) they received were helpful.

This trial provides information regarding the effectiveness of a structured approach to education intervention for patients undergoing ambulatory surgery. However, the intervention was provided to a heterogeneous ambulatory surgery sample, which does not allow for the generalization of the findings to one specific surgical group. Although a large number of patients were included in the trial ($N = 238$), a sample size calculation was not reported, and it is unclear if the trial was sufficiently powered to detect a statistical difference between the intervention and control groups. Moreover, the authors relied on a pain diary that was completed by the patients to assess the outcome variables. This diary included a valid tool to assess pain intensity (0 to 10 NRS) but did not use a valid tool to assess the impact of pain on usual activities. A Bonferroni correction was not applied to outcomes measured on post-operative days 2, 3, 4 and 5, therefore a more stringent level of significance for these outcomes was not considered for multiple measures.
Laurion and Fetzer (2003) conducted a pilot randomized controlled trial to assess the effectiveness of guided imagery or music listened to twice a day pre-operatively versus standard of care on pain, post-operative nausea and vomiting, and length of stay for patients undergoing ambulatory laparoscopic gynecological procedures (Laurion & Fetzer, 2003). Women ($N = 84$) were randomly assigned to one of three groups: a guided imagery audiotape, a music therapy audiotape, or usual peri-operative nursing care group. Pain was assessed using an 11 point NRS (0 to 10) at three time points post-operatively: (a) on admission to the post-anesthetic care unit (PACU), (b) 1 hour after admission, and (c) on discharge home. There were no differences between the three groups regarding the incidence of post-operative nausea and vomiting, with 27 patients (32%) reporting nausea, and 10 patients (12%) reporting both nausea and vomiting. Length of stay was shorter for the group of patients who received usual peri-operative nursing care (210 minutes), as compared to the guided imagery group (244 minutes) and the music therapy group (252 minutes); however, this difference was not statistically or clinically significant. There was no difference in the intensity of pain experienced post-operatively on admission to the PACU, and 1 hour after admission. Pain at time of discharge home was statistically lower for the two intervention groups: the pre-operative guided imagery group reported a mean pain score of 1.5 ($\pm 1.5$), the music therapy group reported a mean score of 1.1 ($\pm 1.1$), and the usual peri-operative care group reported a mean score of 2.4 ($\pm 1.6$, Laurion & Fetzer, 2003). However, the reported pain intensity for all groups was low, and in the mild range ($\leq 3$ out of 10), and differences between the groups were not clinically significant. A clinically significant difference in pain scores would reflect a 2-point difference between the usual care and intervention groups (Farrar, Portenoy, Berlin, Kinman, & Strom, 2000; Farrar, Young, LaMoreaux, Werth, & Poole, 2001). This pilot trial was not sufficiently powered to detect a significant difference in pain between the intervention groups and usual care group. Also, a methodological issue related to the inability to be sure that participants in the intervention
groups listened to their respective audio tapes twice a day pre-operatively. Since patients were not assessed after discharge, it is not known if the intervention groups used these pain management techniques at home as a strategy to manage pain.

In summary, limited research was found that examined post-operative interventions for the management of pain for patients undergoing ambulatory surgery, and none specifically for patients undergoing IHR surgery. Dewar et al.’s trial (2003) of structured pre-operative education and post-operative telephone advice provides baseline information regarding the acceptance of telephone support and advice in a heterogeneous group of patients who have undergone ambulatory surgery. Although music and relaxation therapy may be an effective adjunct to oral analgesics for the management of post-operative pain, Laurion and Fetzer’s trial (2003) did not provide information regarding the use of these interventions following discharge from the hospital post-operatively. The interventions in these trials did not provide a clear strategy on managing pain after ambulatory surgery. A trial examining an intervention to effectively manage pain following ambulatory surgery is needed.

**Conceptual Framework**

The conceptual framework that was used to guide this trial was adapted from the Symptom Management Model developed by Dodd et al. (2001) (see Figure 1). This section will present an overview of the Symptom Management Model and discuss the adaptation of the model for this trial.

*The Symptom Management Model*

The Symptom Management Model provides direction for selecting clinical interventions associated with a variety of symptoms, and views symptom management as a dynamic process that is modified based on individual outcomes. The model includes three interrelated
components: the symptom experience, symptom management strategies, and symptom status outcomes, and provides the framework for understanding the relationship between these components (Dodd, et al, 2001) (See Figure 1). The model also includes propositions regarding the nature of symptoms and contextual influencing variables of the person, health and illness.


and environment. Research utilizing this model has been reported in studies of cancer patients and hospitalized medical surgical patients (Kris & Dodd, 2004; Miakowski and Dodd 2004).
Symptoms are defined as the subjective experiences of the individual and reflect changes in the biopsychosocial functioning, sensations, or cognition. An examination of symptoms is based on an individuals’ perceptions of them and their related self-report (Dodd et al., 2001). Contextual factors influence an individual’s symptom experience, the management of symptoms, and symptom status outcomes. Contextual factors include personal, health and illness, and environmental variables. Strategies for symptom management aim to prevent the symptom experience or alleviate the symptom. Since this experience is subjective, symptoms are best managed using an individualized approach. Therefore, implementation of any individualized intervention needs to ensure that the essential elements comprising interventions that are responsible for producing the intended outcomes are delivered (Kreuter, Stretcher, & Glassman, 1999). Individualizing interventions enhances their relevance to individual patients, which promotes the intervention’s utility in addressing the their unique needs and hopefully the achievement of favourable outcomes.

*Adaptation of the Symptom Management Model*

Dodd et al.’s (2001) Symptom Management Model is broad and allows for individualization of symptom management strategies. The adapted model for this trial was based on the premise that effective management of symptoms needs to consider three components: symptom experience, symptom management strategies, and symptom status outcomes. These three components are influenced by three contextual variables: personal variables, contextual variables, and environmental variables (see Figure 2). The adapted model provided direction to examine the impact of an individualized pain management intervention on patients’ symptom experience and outcomes related to pain, pain-related interference with usual activities, analgesic use, adverse effects, and concerns regarding managing pain. This intervention, the Hernia Repair Education Intervention (HREI), had two components: 1) a booklet that was discussed with each participant.
in the pre-admission clinic and 2) telephone support calls prior to and after surgery to discuss any issues or concerns related to the information given in the clinic.

Figure 2: Adaptation of the Symptom Management Model

The contextual variables related to person, health and illness, and environment need to be understood for effective symptom management. The adapted model provided information that was collected within the domain of the following contextual influencing factors.

**Personal Variables.** These variables relate to demographic, psychological, sociological, physiological, and developmental factors. Data were collected regarding the participant’s personal variables including age, and sex.
Health and Illness Variables. These variables have both a direct and indirect effect on symptom experience, management, and outcomes. They include risk factors, health status, and disease or injury. Health status can take into account any chronic diseases the individual may have prior to undergoing surgery. Data collected included previous surgeries, and the type of IHR surgery (laparoscopic, open, mesh).

Environmental Variables. These variables are the context within which a symptom is perceived and managed. They include physical, social, and cultural variables such as employment status, living conditions, and partner status. Data were collected regarding the environmental variables of employment status, home life (partner status, dwelling type, number of people living within the home), and concerns regarding pain and management strategies.

Although these contextual variables have not been addressed in the literature for patients undergoing IHR surgery, clinically they are problematic. In studies of patients undergoing ambulatory surgery, concerns regarding symptoms and management strategies have influenced the use of analgesics to manage post-operative pain. Beauregard et al. (1998) reported that 62% of patients undergoing ambulatory surgery believed they could easily become addicted to analgesics, and 49% strongly believed that it was easier to tolerate pain than the adverse effects of analgesics. McGrath et al. (2004) reported that 13% of ambulatory surgical patients waited “too long” before taking analgesia, or they did not fill their prescription because they were concerned about becoming addicted to their pain medication.

Symptom Experience

Symptom experience involves an individual’s subjective perception, evaluation, and response to a symptom. The perception of a symptom is defined as an individual becoming aware of a change in the way they feel or behave as compared to their usual or baseline sensation or
behaviour. Symptom *evaluation* is based on the intensity, location, temporal nature, frequency, and affective impact of the symptom on the individual. An individual’s *response* to symptoms includes physiological, psychological, sociocultural, and behavioural reactions. Symptom perception, evaluation, and response are all interrelated and can occur simultaneously.

Following IHR surgery, pain is the most commonly reported symptom and it can interfere with everyday activities (McGrath et al., 2004; Sawhney et al., 2008). The majority of patients use prescribed analgesics to manage post-operative pain (Sawhney et al., 2008). Analgesics may have adverse effects including nausea, vomiting, and constipation (Beauregard et al., 1998; McGrath et al., 2004; Watt-Watson, Chung, et al., 2004). Patients have received inadequate discharge instructions regarding pain and adverse effects management, with only 55% of patients reporting they received clear instruction regarding their analgesics (Watt-Watson, Chung et al., 2004). As patients experience adverse symptoms, they make subjective evaluations regarding the severity, cause, treatability, and the interference of symptoms with usual daily activities. These evaluations are based on past experience, current knowledge, and concerns regarding the symptom. Therefore, the HREI was designed address these issues and provide participants with information on options to manage pain and adverse effects of analgesics, and how to report unrelieved pain.

*Symptom Management Strategies*

The aim of symptom management strategies is to prevent or alleviate symptoms through biomedical, professional, and self-care interventions. Symptom management begins with an individual’s subjective assessment of the symptom. Following assessment, intervention strategies may be targeted at one or more components of the symptom experience to achieve the intended symptom management outcomes. The model includes specifications of what, when,
where, why, how much, to whom, and how the symptom intervention will be delivered. Symptom management is a dynamic process requiring changes in management strategies based on response to and acceptance of interventions.

The HREI provided evidence-based information regarding pain management strategies and strategies to prevent or reduce adverse effects of analgesics. It also provided information regarding common patient concerns regarding pain management. The delivery of the HREI was based on a standardized protocol during the face-to-face education session and the pre-operative and post-operative telephone support calls. Although a standardized protocol was used to guide the intervention, information was individualized to address each participant’s pain management concerns. The participants’ concerns were given priority during the delivery of the education intervention.

**Symptom Status Outcomes**

Symptom status outcomes are based on symptom management strategies as well as symptom experience. Outcomes were based on the individual’s symptom experience following IHR surgery. The HREI was designed to achieve the outcomes of reducing: (a) pain, (b) pain-related interference with usual activities, (c) adverse effects associated with analgesic use, and (d) concerns regarding pain. Specifically, the HREI booklet content addressed the consequences of unrelieved acute pain, how to communicate pain using a NRS, strategies for managing pain using pharmacological and non-pharmacological methods, how to manage adverse effects, and common concerns regarding pain management.
Research Questions

Primary research question

At post-operative day 2, what is the impact of the HREI versus usual care on WORST 24-hour pain intensity on movement following ambulatory IHR surgery?

Secondary research questions

1. At post-operative days 2 and 7, what is the impact of the HREI versus usual care on: (a) pain intensity NOW at rest and with movement and WORST pain intensity in the past 24 hours at rest, (b) pain related interference with activities, (c) pain quality, (d) pain descriptors, (e) analgesics taken, and (f) the frequency and severity of adverse effects of analgesics?

2. At post-operative day 7 following ambulatory IHR surgery, what is the impact of an individualized pain education intervention versus usual care on WORST pain intensity in the past 24 hours on movement?

Additional exploratory questions

At post-operative day 7, what do the usual care group and intervention group report regarding (a) patient concerns regarding pain management, (b) use of non-pharmacological pain interventions, (c) the adequacy of post-discharge information, and (d) the unplanned use of health care resources?

Definitions

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (Merskey&Bogduk, 1994). Pain will be measured by the MPQ-SF (Melzack, 1987).

Pain-related interference with usual activities is defined as pain that interferes with an individual’s ability to participate in activities such as walking, work, relations with others, and
sleep as measured by the Brief Pain Inventory Short Form Interference Subscale (BPI-I) (Cleeland& Ryan, 1994).

*Analgesic taken* is defined as the use of pharmacological methods to manage pain and can include the use of opioid and non-opioid analgesics and is measured using the Analgesic and Adverse Effects Questionnaire (AAEQ, Watt-Watson, Stevens, et al, 2004).

*Appropriate analgesic use* refers to the amount of analgesic taken to keep pain ratings ≤ 4/10 (Myles & Power, 2007).

*Adverse effects of analgesics* is defined as physiological outcomes of analgesic use on the gastric and central nervous systems, such as nausea and constipation, and will be measured with the AAEQ (Watt-Watson, Stevens, et al., 2004).

*Patient concerns regarding pain management* is defined as concerns about reporting pain and the use of analgesics that contribute to poor pain management as measured by the BQ-SF (American Pain Society Quality of Care Committee, 1995; Ward, Goldber, Miller-McCauley, et al., 1993).

*Patient contextual variables* are related to person, health and illness, and environmental variables and include demographic information, surgical experience, employment status, and partner status. Patient contextual variables will be measured using the Peri-operative Inguinal Hernia Questionnaire (PIHQ, Dodd et al., 2001).

*Non-pharmacological pain interventions* is defined as such non-drug methods used to manage pain as rest, distraction, massage, or exercise, as measured by the Non-Pharmacological Interventions Inventory (NPI).
Chapter 3

Research Design and Method

The Hernia Repair Education Intervention (HREI) was a randomized controlled trial evaluating the effectiveness of an individualized pre-operative pain education intervention and telephone support versus usual care on pain intensity for patients discharged after ambulatory IHR surgery. Secondary outcomes examined included pain-related interference with usual activities, pain quality, the use of analgesics, the prevalence of adverse effects, and patient concerns about pain management. Patient concerns, the use of non-pharmacological pain management strategies, and adequacy of post-operative discharge information were also explored.

Setting

The trial was conducted at 2 hospitals in southern Ontario, 1 University affiliated tertiary care hospital, and 1 community hospital. Institutional Research Ethics Board approval from each hospital and University Research Ethics Board approval was obtained prior to recruiting patients to this trial. Patient recruitment took place in the pre-admission clinic in each respective hospital. All elective ambulatory surgery patients attended the pre-admission clinic prior to surgery for a nursing assessment, pre and post-operative education, diagnostic testing, and, if necessary, an anaesthesia consult.

Inclusion criteria

The target sample of patients included those scheduled for elective IHR as an ambulatory surgery procedure. Patients were eligible for inclusion in the trial if they were male, able to speak, read, and understand English, were willing to participate in the study, and had telephone access.
Exclusion criteria

Patients were excluded from recruitment if they were scheduled for a repeat IHR on the same surgical site, or having emergency surgery.

Recruitment

Potential participants were informed about the trial through posters in the hospital’s pre-admission clinic. The pre-admission clinic nurse also spoke to patients scheduled for IHR surgery to identify interested patients. The names of interested patients were released to the investigator or research assistant. The research assistant met with all interested patients in a private office during their pre-admission visit to confirm eligibility, explain the trial and obtain informed consent (Appendix E). All eligible patients received a verbal and written explanation of the trial, including risks and benefits of participating in the study, their right to withdraw from the trial at any time, that information collected would remain anonymous, and information would be stored securely to maintain confidentiality. Patients were encouraged to ask questions prior to consenting to participate in the trial. All participants received a copy of the signed consent form. Baseline demographic data were collected using the Peri-operative Inguinal Hernia Questionnaire (PIHQ) after consent was obtained.

To minimize contamination between the intervention group and the usual care group, participants were recruited and randomized in a private office. All trial participants received a trial package that included a thank-you letter, description of the study, a copy of their signed consent, and copies of the outcome measures in an opaque envelope. Only participants in the intervention group received the HREI booklet. The booklet was included in the opaque envelope. The booklet is based on earlier work from Watt-Watson, Stevens et al. (2004) and is 2.5 cm in thickness and did not add to the bulk of the envelope provided to participants in the
intervention group. Therefore, hospital staff, nurses in the pre-admission clinic, and study participants were not able to identify group allocation by looking at the trial package.

**Trial manoeuvre**

Randomization occurred after baseline data were collected. Randomization was centrally controlled using a password protected, web-based randomization service (www.randomize.net). Eligible and consenting participants were randomly allocated to one of two groups: the usual care group or the intervention group. The intervention was initiated immediately in a private office in the preadmission clinic for participants randomized to the intervention group. Outcomes were measured at post-operative days 2 and 7.

**Description of usual care**

Participants in both groups received the usual pre-operative preparation for patients undergoing elective IHR surgery that occurred no later than one week prior to surgery. During this visit, they received one-on-one pre-operative education from a registered nurse in a private office over a time frame of approximately 30 minutes. The information included both verbal and written information about the admission process, the surgical procedure, and post-operative care in the post-anaesthetic care unit (PACU) and day surgery unit. Post-discharge pain management information was minimal and consisted of patients being told not to wait until the pain became severe before taking prescribed analgesics. Patients were given a booklet that also provided post-discharge instructions including not drive a car for 24 hours after the anaesthetic, doing light activity but no heavy lifting, eating light meals, avoiding alcoholic beverages, and to take only their regular medications and those prescribed by the surgeon. They were advised to have adult supervision overnight at home, and to contact the surgeon or the emergency department if there were any problems after surgery. Specific written information regarding pain management
stated it was normal to feel soreness, a prescription for pain medications would be given to the patient post-operatively, and that constipation was an adverse effect of analgesics.

On the day of surgery, participants arrived at the hospital for their procedure 2 hours pre-operatively and were discharged home once they had recovered from the anaesthetic. Post-operative management of recovery from anaesthesia occurred in the PACU followed by the day surgery unit until the patient was discharged from the hospital, usually within 6 hours. A brief, unstructured, follow-up telephone call is made to all patients (except patients who have surgery on Friday) at 24 hours after surgery by a Registered Nurse.

The hernia repair education intervention (HREI)

Participants randomized to the intervention group received the Hernia Repair Education Intervention (HREI) in addition to usual care. The HREI consisted of written information in the form of a booklet, an individualized face to face education session and two telephone support calls. The face to face education session focused on the content outlined in the booklet, took 20 minutes, and occurred in a private office in the pre-admission clinic a maximum of 7 days prior to surgery. The first telephone support call occurred 1 to 2 days prior to surgery, and the second telephone support call occurred 24 hours after surgery. The HREI education intervention was provided by an Nurse Practitioner with a specialty practice in acute pain management.

The HREI booklet (see Appendix F) was adapted from earlier research by Watt-Watson, Stevens et al. (2004). Content of the booklet was evidence-based and included: the definition of pain, the importance of managing pain after surgery, how to communicate a pain intensity, commonly used analgesics, when to use analgesics, how to manage common adverse effects of analgesics such as nausea and constipation, non-pharmacological methods to manage pain, and clarification of common patient concerns regarding pain management such as fear of addiction.
or being able to ‘handle the pain.’ Input and consensus was obtained by 4 experts in pain management from the disciplines in nursing and medicine regarding the key content domains. The booklet was pilot tested for readability at the grade 6 level, feasibility and usefulness in a sample of 9 men between the ages of 22 and 65. Lay reviewers reported that the content was easy to understand and useful.

The booklet was reviewed with each participant in the intervention group and was used to guide the discussion regarding post-operative pain management. To individually tailor the intervention, the Nurse Practitioner asked participants to identify their specific concerns regarding post-operative pain management as they discussed each section of the booklet. When the participant indicated that a specific topic was a concern, the Nurse Practitioner spent additional time discussing the concern during the individualized education session. The individualized concern check list was used to document patient concerns and was referred to during the telephone support calls (Appendix G). For example, if addiction to analgesics was a concern, the Nurse Practitioner explored why it was a concern and then provided evidenced-based information regarding addiction and acute post-operative pain. This approach allowed for the customization, or tailoring, of the intervention (Gerrish, 2000; Lauver et al., 2002).

Participants in the intervention group also received two telephone support calls. The purpose of these calls was to review the information that participants received in the booklet, and to address any remaining concerns regarding post-operative pain management. The first telephone support call occurred 1 to 2 days prior to surgery, and reviewed the information provided pre-operatively. The second telephone support call occurred 24 hours after surgery, and reviewed any concerns at home related to the booklet and pain management. This 24 hour telephone support call replaced the usual call provided by the day surgery nurses 24 hours after surgery.
Outcome measures

A research assistant collected data on post-operative days 2 and 7. Data collection occurred over the telephone, and participants received a copy of the outcome measures so they could refer to the measures during data collection. Outcome variables and measures are outlined in Table 1.

Baseline information

The Peri-operative Inguinal Hernia Questionnaire (PIHQ) was developed for this study to collect demographic and surgical information (Appendix H). Part 1 of the PIHQ was completed in the pre-admission clinic; it included socio-demographic and medical history such as: patient’s age, previous surgery, previous IHR, living arrangements (eg: alone, with family, with friends etc), partner status, employment status, plan to return to work or school. Part 2 of the PIHQ was completed post-operatively to collect data about the type of IHR surgery (open or laparoscopic); type of anesthetic received; analgesics received; and discharge prescriptions.

Primary outcome

Pain intensity

Pain intensity, including the primary outcome of WORST 24-hour pain intensity was measured using the 11 point NRS from the McGill Pain Questionnaire- Short Form (MPQ-SF) (0 representing no pain and 10 representing “worst pain ever”) (Jensen & Karoly, 2001; Melzack, 1987). This NRS was used in place of the VAS included in the MPQ-SF. The NRS is a well-established standard measure that correlates highly with VAS scores, has demonstrated sensitivity to changes in pain intensity, does not require any special equipment to administer, and can be used easily for data collection over the telephone (Jensen & Karoly, 2001). NRS involves asking patients to rate their pain from 0 to 10, with 0 representing no pain and 10 representing “worst pain ever” (Jensen & Karoly, 2001). Using the NRS, mild pain is
represented as a score between 1 and 3, moderate pain between 4 and 6, and severe pain between 7 and 10 (Palos, Mendoza, Mobley, Cantor, Cleeland, 2006). Four NRS scores were obtained including pain NOW at rest and on movement, and WORST pain in the past 24 hours at rest and on movement.

Table 1. Study Instruments and Timing of Administration

<table>
<thead>
<tr>
<th>Time</th>
<th>Outcome Measure</th>
<th>Data/Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (pre-admission</td>
<td>Demographic and peri-operative</td>
<td>PIHQ</td>
</tr>
<tr>
<td>surgery unit &amp; day surgery</td>
<td>surgical information</td>
<td></td>
</tr>
<tr>
<td>48 hours post-operatively</td>
<td>Pain Intensity</td>
<td>MPQ-SF (NRS)</td>
</tr>
<tr>
<td>Primary Outcome:</td>
<td>Pain Related-Interference</td>
<td>BPI-I</td>
</tr>
<tr>
<td>Secondary Outcomes:</td>
<td>Pain Quality</td>
<td>MPQ-SF (PRI, PPI)</td>
</tr>
<tr>
<td></td>
<td>Analgesia and adverse effects</td>
<td>AAEQ</td>
</tr>
<tr>
<td>7 days post-operatively</td>
<td>Pain Intensity</td>
<td>MPQ-SF (NRS)</td>
</tr>
<tr>
<td>Secondary Outcomes:</td>
<td>Pain Related-Interference</td>
<td>BPI-I</td>
</tr>
<tr>
<td></td>
<td>Pain Quality</td>
<td>MPQ-SF (PRI, PPI)</td>
</tr>
<tr>
<td></td>
<td>Analgesia and adverse effects</td>
<td>AAEQ</td>
</tr>
</tbody>
</table>

Note: PIHQ Peri-operative Inguinal Hernia Questionnaire; MPQ-SF (NRS) = McGill Pain Questionnaire-Short Form, Numeric Rating Scale; MPQ-SF (PRI, PPI) = McGill Pain Questionnaire-Short Form, Pain Rating Index, Present Pain Intensity; BPI= Brief Pain Inventory- Interference Subscale; AAEQ = Analgesic use and adverse effects questionnaire; BQ-SF = Barriers Questionnaire Short Form
Secondary outcomes

*Pain-related inference with usual activities*

The Brief Pain Inventory-Inference Subscale (BPI- I) was used to measure pain related-interference with usual activities related to general activity, mood, walking ability, normal work, relations with other people, sleep and enjoyment of life (Cleeland & Ryan, 1994). The Brief Pain Inventory (BPI) is a valid and reliable instrument that was developed in 1989 to provide information on pain intensity and the degree to which pain interferes with activities in patients with cancer (Cleeland & Ryan, 1994). The BPI-SF measures pain intensity, pain related interference, and effectiveness of pain relief measures, and can be self-administered (Cleeland & Ryan, 1994). The BPI-SF consists of nine items including 2 items assessing pain prevalence, 4 items assessing pain intensity, 2 items assessing pain treatment and effectiveness, and 1 item assessing pain related interference (BPI-I) (Keller et al., 2004).

The BPI-SF has well established reliability and the psychometric properties have been documented in validation studies of cancer and non-cancer pain, including surgical pain (Keller et al, 2004; Mendoza, Chen, Brugger, Hubbard et al., 2004; Mendoza, Mayne, Rublee, Cleeland, 2006). The BPI-SF has been used to evaluate post-operative pain after both ambulatory and cardiovascular surgery (Beauregard et al., 1998; Dewar et al.2003; Mendoza et al., 2004; Watt-Watson, Cheung et al., 2004; Watt-Watson, Stevens et al., 2004).

The BPI- I measures interference with 8 activities using an 11 point numerical rating scales (0 = no interference and 10 = complete interference). It provides an individual score for each activity and a total score by adding the ratings of all activities (Cleeland & Ryan, 1994). A high score indicated a greater degree of pain related interference with the specific activity. A high internal consistency ($\alpha = 0.71$ to 0.92) has been reported for the interference subscale when using the
BPI-SF with cardiac surgery patients (Mendoza et al., 2004; Watt-Watson, Stevens, et al. 2004).

In this trial, the BPI-I was administered to patients on the post-operative days 2 and 7, by telephone.

**Pain quality**

Pain quality was assessed using the McGill Pain Questionnaire-Short Form (MPQ-SF) Pain Rating Index (PRI) and Present Pain Intensity (PPI) (Melzack, 1987). The MPQ-SF correlates highly with the long form McGill Pain Questionnaire and is sensitive to clinical change brought about by pain management techniques (Melzack & Katz, 2001). The MPQ-SF can be self-administered. It was developed to be used under circumstances where time to obtain information from patients is limited and in pain research where pain intensity alone does not provide enough information (Melzack, 1987).

The MPQ-SF consists of the Pain Rating Index (PRI), Present Pain Intensity (PPI) and visual analogue scale (Melzack, 1987, 2005). The PRI consists of 15 descriptive items, 11 sensory and 4 affective, which are rated on a four point intensity scale, with 0 = none, 1 = mild, 2 = moderate, and 3 = severe. The Present Pain Intensity is a global rating of pain and includes 6 verbal descriptors each with a numerical rating from 0 to 5 (0 = no pain, 1 = mild, 2 = discomforting, 3 = distressing, 4 = horrible, and 5 = excruciating). The MPQ-SF can be administered in five minutes, which was important for this trial as the questionnaire was be completed over the telephone.

The psychometric properties of the MPQ-SF have been well established in validation studies of cancer and non-cancer pain, including: surgical pain, labour pain, postherpatic neuralgia, and diabetic neuropathy (Melzack, 1987; Zalon, 1999; McDonald & Weiskopf, 2001, Watt-Watson, Stevens, et al., 2004, Wilkie, Savedra, Holzemer, Tesler, Paul, 1990). Studies that have used the
MPQ-SF with surgical samples report a high internal consistency for this measure ($\alpha = 0.81$; Watt-Watson, Stevens, et al., 2004). Test-retest reliability has been established in patients with persistent back pain, however it is difficult to establish in patients with acute pain due to the variable nature of the pain (Zalon, 1999).

**Analgesics and adverse effects**

Analgesics taken and the presence of adverse effects of analgesics was assessed using the Analgesic and Adverse Effects Questionnaire (AAEQ) (Appendix I). The AAEQ is a tool that was developed by Watt-Watson, Stevens, et al. (2004) and was modified to include analgesic use for this trial. The AAEQ collects data regarding the type and dose of analgesics used to manage pain. Participants were asked to recall which type and how much analgesia they have used in the previous 24 hours. Analgesic doses were converted to standardized parenteral morphine equivalents (Hardman & Limbird, 2001). Adverse effects of analgesics, including constipation, nausea, vomiting, and sedation, were rated on an 11 point NRS ($0 =$ not present and $10 =$ adverse effect present and very bothersome).

**Additional exploratory questions**

**Concerns regarding managing pain**

The Barriers Questionnaire (BQ) was developed by Ward and colleagues in 1993 to identify cancer patients’ concerns regarding pain management that may prevent patients from reporting pain and using analgesics. The BQ is a 27 item, self- report measure designed to identify beliefs regarding pain management in the following eight subscales: fear of addiction; concern about tolerance; concern about side effects; fatalism; desire to be a ‘good’ patient; fear of distracting one’s physician from treating the disease; concern that pain means disease progression; and fear of injections (Ward, Goldberg, Miller-McCauley, Mueller, Nolan, Pawlik-Plank, Robbins,
Stormoen, Weissman, 1993). Each of the items on the BQ is rated using a six point numeric scale where 0 = do not agree at all and 5 = agree very much (Ward et al., 1993; Ward, Donovan, Owen, Grosen, Serlin, 2000). The BQ has well established reliability and internal consistency ($\alpha = 0.87$ to $0.90$) (Ward et al., 2000).

The Barriers Questionnaire - short form (BQ-SF) is an eight item measure that includes one item from each of the eight subscales from the BQ. This subset of items, excluding the fear of injection category has been included in the American Pain Society’s Patient Outcome Questionnaire to identify patient barriers to effective pain management in the treatment of acute pain and cancer pain (American Pain Society Quality of Care Committee, 1995). The BQ-SF has an internal consistency ($\alpha = 0.72$ and a test-retest reliability of 0.85 (American Pain Society Quality of Care Committee, 1995). In a study of patients undergoing coronary artery bypass surgery, Watt-Watson, Stevens et al. (2004) reported a high internal consistency ($\alpha = 0.85$) when using the BQ-SF to identify concerns about seeking help and taking analgesics. The BQ-SF takes approximately 5 minutes to administer.

**Adequacy of discharge information**

The adequacy of discharge information and the unplanned use of health care resources were assessed using questions from the American Pain Society Patient outcomes questionnaire (POQ-DI) (American Pain Society Quality of Care Committee, 1995). These questions were designed to identify gaps in communication and the clarity of instructions regarding medication use. The unplanned use of health care resources was also assessed, including unplanned communication or visits to a physician or nurse after surgery.
Non-pharmacological methods to manage pain

The use of non-pharmacological interventions for the management of pain was assessed using the Non-Pharmacological Intervention Inventory (NPI) (Appendix J). This inventory was developed for this trial and includes a list of commonly used non-pharmacological interventions.

Sample Size

Sample size estimation for this study was based on the WORST 24-hour pain on movement on post-operative day 2. The literature reports that following IHR 62% of patients experience moderate to severe pain for the first two days following surgery (Rawal et al., 1997). Farrar et al. (2000, 2001) report a clinically significant reduction in acute pain as a mean difference of two points (20%). Therefore a mean two point reduction in the NRS for WORST 24-hour pain on movement was anticipated between the intervention and usual care groups for this trial. A standard deviation of three was used for this trial and is based on data on post-operative day 2 from a post-operative ambulatory surgery sample (Watt-Watson, Chung, et al., 2004). For this trial, it was expected there would be similar variability in acute pain on post-operative day 2 as reported by Watt-Watson, Chung, et al. (2004).

Allowing for an alpha of 0.05, and power set at 80%, the required sample for each group was 37 (Kirby, Gebskey, Keech, 2002; Statistics tool box: http://department.obg.cuhk.edu.hk/researchsupport/Sample_size_CompMeanIndependent.asp). However, based on a study by Dewar and colleagues (2003), it was assumed that about 10% of participants might be lost to follow up; therefore 82 participants were recruited for this trial. To minimize loss to follow-up, contact information was re-confirmed with participants prior to discharge home. Loss to follow-up occurred due to cancellation of surgery after randomization, unexpected hospital admission, or an inability to contact the study participant by telephone post-operatively.
Data analysis

An intention to treat analysis was used, in which all participants randomized were included in the analysis. SAS 9.2 software was used for analysis (Cary NC, USA, copyright 2008). Demographic and baseline variables were analyzed using descriptive statistics reporting means, standard deviations, and percentages. A significance level of $p < 0.05$ was considered statistically significant for the primary outcome of WORST-24 hour pain on movement. Using the Bonferroni correction, a more stringent level of significance of $0.01$ was used for the secondary outcomes of pain NOW at rest and on movement, WORST-24 hour pain at rest, pain-related interference, pain quality, analgesic use, adverse effects of analgesics, and concerns regarding pain management. To evaluate the primary outcome of WORST-24 hour pain on movement, the scores for the intervention group and the control group were compared using Students’ unpaired t-tests under the Satterthwaite assumption of unequal variances. Differences between the groups for the secondary outcomes were also compared using the Students’ unpaired t-tests.

Data management

All data were entered by the research assistant 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 research assistant for accuracy monitoring purposes. The duplicate databases were compared for accuracy and adjusted as required. The trial database was backed-up onto a second password protected hospital based network server, as well as a portable storage device (i.e. USB Mass Storage Device) locked in an private office in the hospital. 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 were kept in a locked file cabinet accessible only by the trial investigator.

**Ethical consideration**

Ethics approval for this study was obtained from the Research Ethics Board of the University of Toronto and participating hospital sites. Participants were given a full explanation of the trial and their rights as participants. Participants were informed that their decision to participate in the study would not affect their usual care in anyway. Participants signed a written consent prior to entering the trial. Each participant received a copy of the signed consent form. Strategies to ensure participants’ privacy and confidentiality included: using study code numbers, and storing contact information in a data base separate from other data. All consent forms, questionnaires, databases, and coding information were stored in a locked cabinet in the in the locked private office. All identifying documents will be destroyed in accordance with the University of Toronto and the Toronto Academic Health Sciences Council guidelines. These guidelines recommend that written consent forms be kept for 5 years.
Chapter 4

Results

The results of this trial are presented in this chapter and include a description of the sample, and an analysis of the primary, secondary, and additional research questions.

Derivation of sample and attrition

Participant flow through the trial is presented in Figure 3. One hundred and fourteen patients were screened for eligibility. Thirty-two patients were excluded from participation. Of these, 30 patients did not meet the inclusion criteria due to language barrier, and 2 patients declined to participate. At total of 82 participants were randomized following baseline demographic data collection in the pre-admission clinic.

The attrition rate for this trial was low. At post-operative day 2, the attrition rate was 8% \((n = 7)\), with 75 participants completing data collection for the primary outcome (38 participants in the usual care group, and 37 participants in the intervention group). The attrition rate at post-operative day 7 was 4% \((n = 3)\), with 72 participants completing data collection for the secondary outcomes (36 participants in the usual care group, and 36 participants in the intervention group; see Figure 3). Of the 7 participants who did not complete data collection at post-operative day 2, 2 participants (one from each group) had their surgery cancelled after baseline data collection and randomization were completed; 2 participants from the usual care group withdrew from the trial following surgery (both stated they were not feeling well, were having pain, and did not want to complete data collection); 3 participants, 1 from the usual care group and 2 from the intervention group, were admitted to hospital post-operatively and were
Figure 3. Flow of participants through the Hernia Repair Education Intervention.

*Primary outcome.*
lost to follow-up. At post-operative day 7, an additional 3 participants were lost to follow-up due
to an inability to contact participants by telephone.

**Baseline characteristics**

Demographic data were collected using the Peri-operative Inguinal Hernia Questionnaire
(PIHQ) and are reported in Table 2. All participants were male; the majority lived with a partner
or family member. The mean age of the usual care and intervention groups was 59 (±14) and 61
(±16) years respectively. Forty-six percent (n = 38) of all participants were retired. All
participants who were working or in school anticipated they would be back to work or school in
approximately 3 weeks. Seventy-eight percent (n = 64) of all participants had experienced a
previous surgery, and 12% (n = 10) of participants had a previous inguinal hernia repair on the
contralateral side.

Table 2

**Baseline Demographics of Participants (PIHQ–Part 1)**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Usual care (n = 42)</th>
<th>Intervention group (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married/partner</td>
<td>28 (67)</td>
<td>26 (65)</td>
</tr>
<tr>
<td>Residence with stairs</td>
<td>19 (45)</td>
<td>30 (75)</td>
</tr>
<tr>
<td>Adult support at home</td>
<td>31 (74)</td>
<td>31 (78)</td>
</tr>
<tr>
<td>Employed/ student</td>
<td>23 (55)</td>
<td>21 (53)</td>
</tr>
<tr>
<td>Previous IHR on the contralateral side</td>
<td>4 (10)</td>
<td>6 (15)</td>
</tr>
</tbody>
</table>

1IHR = inguinal hernia repair
Seventy-five \((n = 30)\) of the participants in the intervention group lived in a multiple story home, requiring them to use stairs after surgery, while this was true for only 45\% \((n = 19)\) of participants in the usual care group.

**Surgical data**

Table 3 reports the type of inguinal hernia repair and type of surgical anaesthetic participants received. The mean length of hospital stay was 9.2 \((\pm 13.1, \text{median} = 6.5, \text{IQR} = 4)\) hours for participants in the usual care group and 8.5 \((\pm 8.8, \text{median} = 6, \text{IQR} = 3.5)\) hours for those in the intervention group. Fifty-one percent \((n = 41)\) of the total group had an open right inguinal hernia repair. In addition to a general anaesthetic, 56\% \((n = 45)\) had local anaesthetic infiltrated into the surgical site by the surgeon at the end of the surgery to help reduce immediate post-operative pain while in the PACU.

Of the total participants, 72 were discharged home on their surgical day (ambulatory surgery) as planned, and 8 were admitted to hospital post-operatively. Two participants (2.5\%) were admitted to hospital overnight because they did not have adult support at home. Other reasons for admission to hospital included a delayed surgical start time \((n = 1)\), sleep apnea \((n = 1)\), pain \((n = 2)\), unable to urinate \((n = 1)\), and cardiac changes requiring monitoring \((n = 1)\).

**Intervention**

All participants in the intervention group received the HREI booklet and individualized education session during the pre-admission visit. Telephone support was conducted with 36 of the 39 participants in the week prior to surgery and with 37 of the 39 participants 24 hours post-operatively. During the telephone support prior to surgery, the most common questions asked by participants were related to: (a) when to use analgesics, (b) the adverse effects of analgesics, (c) the importance of managing pain, and (d) how to communicate with health care providers when
Table 3

*Type of Inguinal Hernia Repair and Anaesthetic Received*

<table>
<thead>
<tr>
<th>Surgical Information</th>
<th>Usual care group</th>
<th>Intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$(n = 41)$</td>
<td>$(n = 39)$</td>
</tr>
<tr>
<td></td>
<td>$n$ (%)</td>
<td>$n$ (%)</td>
</tr>
<tr>
<td>Type of IHR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R open</td>
<td>19 (46)</td>
<td>22 (56)</td>
</tr>
<tr>
<td>L open</td>
<td>22 (54)</td>
<td>17 (44)</td>
</tr>
<tr>
<td>Type of anesthetic received</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinal/epidural</td>
<td>1 (2)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>General</td>
<td>32 (78)</td>
<td>25 (64)</td>
</tr>
<tr>
<td>Sedation with local anesthetic</td>
<td>8 (20)</td>
<td>13 (33)</td>
</tr>
</tbody>
</table>

Note: IHR= inguinal hernia repair; R= right; L = left

they were having pain. This telephone call ranged from 5 to 10 minutes in duration. During the telephone support 24 hours after surgery, the most common questions asked by participants related to: (a) the adverse effects of analgesics (i.e., constipation and nausea); (b) when to use analgesics; and (c) non-pharmacological methods to manage pain (i.e., splinting the incision when changing positions). This telephone call ranged from 10 to 15 minutes in duration.

At post-operative day seven, participants in the intervention group $(n = 36)$ were asked to provide feedback regarding the HREI booklet. Thirty (83%) of the participants in the intervention group reported that they read the HREI booklet. One participant read half of the
booklet, and 5 participants did not read the booklet. Participants stated they did not read the HREI booklet because the information was reviewed during the pre-admission visit, or that it was too much information. When asked if anyone else besides themselves had read the HREI booklet, 11 (31%) reported that their partner had read it. Three participants who did not read the HREI booklet reported that their partners read the booklet. When asked how helpful the HREI booklet was on a scale from 0 to 10 (with 0 = not helpful and 10 = extremely helpful), 70% \((n = 25)\) of participants rated it as 7 or higher.

**Primary research question**

*At post-operative day 2, what is the impact of the HREI versus usual care on WORST 24-hour pain intensity on movement following ambulatory IHR surgery?*

Four pain intensity ratings including pain NOW at rest and with movement, and WORST 24 hour pain at rest and with movement are reported in Table 4. The intervention group reported a statistically lower pain intensity score for WORST 24 hour pain on movement \((p=0.0001)\) with a mean pain score for the intervention group of 4.7 \((±2.2)\) and a mean score for the usual care group of 7.2 \((±2.8)\) . Moderate to severe \((≥ 4/10)\) WORST 24h hour pain on movement was reported by 95% \((n = 36)\) of participants in the usual care group versus 68% \((n = 25)\) in the intervention group.

**Secondary research questions**

1. *At post-operative days 2 and 7, what is the impact of the HREI versus usual care on pain intensity NOW at rest and with movement and WORST pain intensity in the past 24 hours at rest; and at post-operative day 7 what is the impact of an individualized pain education intervention versus usual care on WORST pain intensity in the past 24 hours on movement?*
Table 4

*Pain Intensity at Post-operative Day 2*

<table>
<thead>
<tr>
<th>NRS (0–10)</th>
<th>Usual care (n = 38)</th>
<th>Intervention group (n = 37)</th>
<th>(t(df))</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain NOW at rest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>(M (SD))</td>
<td>(M (SD))</td>
<td>(t(df))</td>
<td>(p)</td>
</tr>
<tr>
<td>(n (%))</td>
<td>(n (%))</td>
<td>(n (%))</td>
<td>(n (%))</td>
<td>(n (%))</td>
</tr>
<tr>
<td>0</td>
<td>6 (16)</td>
<td>11 (30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3</td>
<td>19 (50)</td>
<td>23 (62)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–6</td>
<td>9 (24)</td>
<td>3 (8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–10</td>
<td>4 (11)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain NOW on movement</td>
<td>(M (SD))</td>
<td>(M (SD))</td>
<td>(3.4 (73))</td>
<td>0.001</td>
</tr>
<tr>
<td>Total score</td>
<td>5.5 (2.5)</td>
<td>3.7 (1.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n (%))</td>
<td>(n (%))</td>
<td>(n (%))</td>
<td>(n (%))</td>
<td>(n (%))</td>
</tr>
<tr>
<td>0</td>
<td>1 (3)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3</td>
<td>7 (18)</td>
<td>16 (43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–6</td>
<td>19 (50)</td>
<td>17 (46)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–10</td>
<td>11 (29)</td>
<td>3 (8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The total pain intensity scores for the intervention group were significantly lower than those for the usual care group for all ratings at post-operative day 2. At rest, moderate to severe WORST 24 hour pain was reported by 66% (n = 25) of participants in the usual care group versus 24% (n = 9) in the intervention group. Moderate to severe pain NOW on movement was reported by
79% \((n = 30)\) of participants in the usual care group versus 54% \((n = 20)\) in the intervention group, and moderate to severe pain NOW at rest was reported by 34% \((n = 13)\) of participants in the usual care group versus 8% \((n = 3)\) in the intervention group.

The results for the four intensity ratings at post-operative day 7 are reported in Table 5. No statistically significant differences in pain intensity scores were obtained for any of the four ratings. The majority of the total participants reported experiencing no pain \((n = 35)\) or mild pain \((n = 31)\) NOW with rest and no pain \((n = 10)\) or mild pain \((n = 44)\) NOW with movement. Moderate to severe WORST pain in the past 24 hours with movement was reported by 36% \((n = 26)\) of the total participants \((n = 16\) from the usual care group, and \(n = 10\) from the intervention group).

2. At post-operative days 2 and 7, what is the impact of the HREI versus usual care on pain-related interference with usual activities, and pain quality?

Pain related interference was measured using the BPI–I at post-operative days 2 and 7. The total interference scores are reported in Tables 6 and 7, respectively. Interference scores for both groups, on days 2 and 7, were low and no statistically significant differences were found. The difference between the groups for the total pain interference scores, at post-operative day 2, were lower for the participants in the intervention group, but not significant with the bonferroini correction \((p = 0.04)\). For exploratory purposes, individual interference subscale item scores were compared between the 2 groups. At post-operative day 2, participants in the intervention group had lower interference scores that were statistically significant for general activity \((p = 0.006)\) and for walking ability \((p = 0.008)\). At post-operative day 7, there were no significant differences for any of the individual interference subscale items.
Table 5

**Pain Intensity at Post-operative day 7**

<table>
<thead>
<tr>
<th>NRS (0–10)</th>
<th>Usual care (n = 38)</th>
<th>Intervention group (n = 37)</th>
<th>t(df)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>M (SD)</strong></td>
<td><strong>M (SD)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain NOW at rest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>1.1 (1.6)</td>
<td>1.0 (1.4)</td>
<td>0.31 (70)</td>
<td>0.76</td>
</tr>
<tr>
<td>n (%)</td>
<td>18 (50)</td>
<td>17 (47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3</td>
<td>14 (39)</td>
<td>17 (47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–6</td>
<td>4 (11)</td>
<td>2 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–10</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain NOW on movement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>2.6 (1.8)</td>
<td>2.2 (1.6)</td>
<td>0.96 (70)</td>
<td>0.34</td>
</tr>
<tr>
<td>n (%)</td>
<td>5 (14)</td>
<td>5 (14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3</td>
<td>20 (56)</td>
<td>24 (67)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–6</td>
<td>10 (28)</td>
<td>6 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–10</td>
<td>1 (3)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS (0–10)</td>
<td>Usual care $(n = 38)$</td>
<td>Intervention group $(n = 37)$</td>
<td>$t(df)$</td>
<td>$p$</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------</td>
<td>-------------------------------</td>
<td>---------</td>
<td>-----</td>
</tr>
<tr>
<td><strong>WORST 24-hr pain at rest</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>$M (SD)$</td>
<td>$M (SD)$</td>
<td>0.40 (70)</td>
<td>0.69</td>
</tr>
<tr>
<td>$n (%)$</td>
<td>$n (%)$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>16 (44)</td>
<td>10 (28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3</td>
<td>13 (26)</td>
<td>22 (61)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–6</td>
<td>6 (17)</td>
<td>4 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–10</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>WORST 24-hr pain on movement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>$M (SD)$</td>
<td>$M (SD)$</td>
<td>0.95 (70)</td>
<td>0.35</td>
</tr>
<tr>
<td>$n (%)$</td>
<td>$n (%)$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>3 (8)</td>
<td>2 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3</td>
<td>17 (47)</td>
<td>24 (67)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–6</td>
<td>12 (33)</td>
<td>7 (19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–10</td>
<td>4 (11)</td>
<td>3 (8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: NRS = Numeric Rating Scale; 0 = no; 1-3 = mild pain; 4-6 = moderate pain; 7-10 = severe pain
### Table 6

**Pain Related Interference at day 2 Post-operatively**

<table>
<thead>
<tr>
<th>Interference scores</th>
<th>Usual care (n = 38)</th>
<th>Intervention group (n = 37)</th>
<th>t(df)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPI-I</td>
<td>M (SD)</td>
<td>M (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (0–70)</td>
<td>28.5 (15.7)</td>
<td>21.2 (15)</td>
<td>2.1 (73)</td>
<td>0.04</td>
</tr>
<tr>
<td>Subscales (0–10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General activity</td>
<td>5.7 (2.9)</td>
<td>3.9 (2.6)</td>
<td>2.8 (73)</td>
<td>0.006</td>
</tr>
<tr>
<td>Mood</td>
<td>2.7 (3.1)</td>
<td>2.3 (2.4)</td>
<td>0.64 (73)</td>
<td>0.52</td>
</tr>
<tr>
<td>Walking ability</td>
<td>5.4 (3.0)</td>
<td>3.7 (2.4)</td>
<td>2.7 (73)</td>
<td>0.008</td>
</tr>
<tr>
<td>Normal work</td>
<td>5.3 (3.1)</td>
<td>4.2 (3.2)</td>
<td>1.6 (73)</td>
<td>0.11</td>
</tr>
<tr>
<td>Relationships with others</td>
<td>2.0 (2.5)</td>
<td>1.5 (2.2)</td>
<td>0.88 (73)</td>
<td>0.38</td>
</tr>
<tr>
<td>Sleep</td>
<td>3.2 (3.4)</td>
<td>2.5 (3)</td>
<td>0.98 (73)</td>
<td>0.33</td>
</tr>
<tr>
<td>Enjoyment of life</td>
<td>4.1 (3.2)</td>
<td>3.2 (3)</td>
<td>0.2 (73)</td>
<td>0.18</td>
</tr>
</tbody>
</table>

Note: BPI-I = Brief Pain Inventory - Interference

Pain quality was measured using the Pain Rating Index (PRI) and the Present Pain Intensity (PPI) from the MPQ-SF. The PRI scores were divided into sensory (PRI-S), affective (PRI-A) and total dimensions (PRI-T). Mean total sensory, total affective, and total scores are reported in Table 8. There were no statistically significant differences in total sensory, total affective, and total scores between the usual care and intervention groups at post-operative days 2 and 7. Results for the Present Pain Intensity (PPI) are reported in Table 9. There was no statistically significant difference between the usual care and intervention groups at post-operative days 2 and 7.
Table 7

*Pain Related Interference at day 7 Post-operatively*

<table>
<thead>
<tr>
<th>Interference scores BPI-I</th>
<th>(n = 36) M (SD)</th>
<th>(n = 36) M (SD)</th>
<th>t(df)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total (0–70)</td>
<td>11.8 (11.9)</td>
<td>10.6 (11)</td>
<td>0.46 (70)</td>
<td>0.64</td>
</tr>
<tr>
<td>Subscales (0–10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General activity</td>
<td>2.0 (2.0)</td>
<td>1.8 (1.8)</td>
<td>0.62 (70)</td>
<td>0.53</td>
</tr>
<tr>
<td>Mood</td>
<td>0.83 (1.8)</td>
<td>0.94 (1.7)</td>
<td>0.27 (70)</td>
<td>0.78</td>
</tr>
<tr>
<td>Walking ability</td>
<td>2.3 (2.1)</td>
<td>1.8 (1.5)</td>
<td>1.2 (70)</td>
<td>0.22</td>
</tr>
<tr>
<td>Normal work</td>
<td>2.7 (2.6)</td>
<td>2.5 (2.8)</td>
<td>0.56 (70)</td>
<td>0.57</td>
</tr>
<tr>
<td>Relationships with others</td>
<td>0.97 (1.8)</td>
<td>0.92 (1.8)</td>
<td>0.13 (70)</td>
<td>0.90</td>
</tr>
<tr>
<td>Sleep</td>
<td>1.0 (2.2)</td>
<td>1.3 (2.0)</td>
<td>0.74 (70)</td>
<td>0.46</td>
</tr>
<tr>
<td>Enjoyment of life</td>
<td>1.8 (2.5)</td>
<td>1.3 (1.9)</td>
<td>0.97 (70)</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Note: BPI-I = Brief Pain Inventory- Interference

Table 10 includes the pain descriptors from the MPQ-SF reported by 20% or more of the total participants. The most frequent descriptors rated as moderate to severe by the total participants at post-operative day 2 were sharp (n = 32), tender (n = 31), stabbing (n = 25), aching (n = 23), and tiring/exhausting (n = 15). A small number of participants described their pain as sickening (n = 6), fearful (n = 6), punishing or cruel (n = 7) in the moderate to severe range at post-operative day 2. At post-operative day 7 the most frequent descriptors rated as moderate to severe by participants were tender (n = 15), and tiring/exhausting (n = 7).
Table 8

Pain Rating Index (PRI): Sensory (PRI–S), Affective (PRI–A), and Total (PRI–T)

<table>
<thead>
<tr>
<th>MPQ-SF PRI</th>
<th>Usual care ($n = 38$ at day 2; $n = 36$ at day 7) M (SD)</th>
<th>Intervention group ($n = 37$ at day 2; $n = 36$ at day 7) M (SD)</th>
<th>t(df)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total sensory (0–33)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>8.5 (5.6)</td>
<td>6.8 (6.1)</td>
<td>1.3 (73)</td>
<td>0.2</td>
</tr>
<tr>
<td>Day 7</td>
<td>3.9 (4.7)</td>
<td>3.0 (3.4)</td>
<td>1.0 (70)</td>
<td>0.3</td>
</tr>
<tr>
<td>Total affective (0–12)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>1.6 (2.7)</td>
<td>1.5 (2.3)</td>
<td>0.2 (73)</td>
<td>0.9</td>
</tr>
<tr>
<td>Day 7</td>
<td>0.5 (1.0)</td>
<td>0.6 (1.2)</td>
<td>0.4 (70)</td>
<td>0.7</td>
</tr>
<tr>
<td>Total score (0–45)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>10.1 (7.5)</td>
<td>8.2 (8.1)</td>
<td>1.9 (73)</td>
<td>0.3</td>
</tr>
<tr>
<td>Day 7</td>
<td>4.6 (5.5)</td>
<td>3.5 (4.3)</td>
<td>0.9 (70)</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Note: MPQ-SF = McGill Pain Questionnaire-Short Form

3. At post-operative days 2 and 7, what is the impact of the HREI versus usual care on analgesics taken, and adverse effects of analgesics?

Data regarding the analgesia taken while in hospital are reported in Table 11 and discharge prescriptions are reported in Table 12. While in hospital, there was no significant difference in the mean amount of opioid taken, in morphine equivalents; participants in the usual care group
Table 9

_Present Pain Intensity (PPI) Ratings_

<table>
<thead>
<tr>
<th>MPQ-SF PPI (0–6)</th>
<th>Usual care ((n = 38 \text{ at Day 2; } n = 36 \text{ at Day 7}))</th>
<th>Intervention group ((n = 37 \text{ at Day 2; } n = 36 \text{ at Day 7}))</th>
<th>(t(df))</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 2</td>
<td>1.68 (1.13)</td>
<td>1.16 (0.69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 7</td>
<td>1.00 (0.76)</td>
<td>0.78 (0.59)</td>
<td>1.39 (70)</td>
<td>0.17</td>
</tr>
</tbody>
</table>

Note: MPQ-SF = McGill Pain Questionnaire-Short Form

Table 10

_Moderate to Severe (≥ 2) Pain Descriptors Reported by 20% or More of Participants at days 2 and 7_

<table>
<thead>
<tr>
<th>MPQ-SF Items (0–3)</th>
<th>Usual care ((n = 38))</th>
<th>Intervention ((n = 37))</th>
<th>Usual care ((n = 36))</th>
<th>Intervention ((n = 36))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stabbing</td>
<td>17 (44.7)</td>
<td>8 (21.6)</td>
<td>3 (8.3)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Sharp</td>
<td>20 (52.6)</td>
<td>12 (32.4)</td>
<td>2 (5.6)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Aching</td>
<td>12 (31.5)</td>
<td>11 (29.7)</td>
<td>4 (11.1)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Tender</td>
<td>20 (52.6)</td>
<td>11 (29.7)</td>
<td>7 (19.4)</td>
<td>8 (22.2)</td>
</tr>
<tr>
<td>Tiring/exhausting</td>
<td>7 (18.5)</td>
<td>8 (21.6)</td>
<td>4 (11.1)</td>
<td>3 (8.3)</td>
</tr>
</tbody>
</table>

Note: MPQ-SF = McGill Pain Questionnaire-Short Form
and intervention group received 25.2 (±13.2) mg and 23.1 (±14.4) mg respectively. There was a large range in the amount of opioid taken for both groups. Forty-eight percent (n = 38) of the total participants received a non-steroidal anti-inflammatory drug (NSAID) and 58% (n = 46) received acetaminophen to manage pain while in hospital. The most common discharge prescription for pain management was acetaminophen (300mg) with codeine (30mg) and caffeine (15mg), with 56% (n = 45) of all participants (usual care n = 18, and intervention groups n = 27) receiving this prescription.

Table 11.

*Analgesia Taken While in Hospital*

<table>
<thead>
<tr>
<th>Analgesia taken</th>
<th>Usual care group (n = 41)</th>
<th>Intervention group (n = 39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total opioid taken in hospital (mg in morphine equivalents)</td>
<td><em>M (SD)</em></td>
<td><em>M (SD)</em></td>
</tr>
<tr>
<td></td>
<td>25.2 (±13.2)</td>
<td>23.1 (±14.4)</td>
</tr>
<tr>
<td>Non-opioid analgesics administered in hospital</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>NSAID (yes)</td>
<td>22 (54)</td>
<td>16 (41)</td>
</tr>
<tr>
<td>Acetaminophen (yes)</td>
<td>21 (51)</td>
<td>25 (64)</td>
</tr>
</tbody>
</table>

Note: NSAID = non-steroidal anti-inflammatory drug

The amount of oral opioids taken at post-operative days 2 and 7 is reported in Table 13. At post-operative day 2, there was a statistically significant difference (*p* = 0.004) between the intervention group and usual care group regarding amount of opioid taken. Participants in the intervention group took less opioid than those in the usual care group. Two participants in the usual care group took more than 100 mg of morphine equivalents in the first 24 hours after surgery, and this increased the mean opioid taken (this is also reflected in the large standard
deviation). As a form of sensitivity analysis, two outliers were removed from analysis, and there was still a statistically significant difference ($p = 0.007$) in amount of opioid taken between the intervention and usual care groups. At post-operative day 7, there was no statistically significant difference ($p = 0.5$) in amount of opioid taken between the intervention and usual care groups. A small number of participants in both groups reported taking an NSAID to manage their post-operative pain at home. Five percent ($n = 2$) of the usual care group and 20% ($n = 8$) of the intervention group took an NSAID to manage pain at post-operative day 2, and 2.4% ($n = 1$) of the usual care group and 17.5% ($n = 7$) of the intervention group took an NSAID to manage pain at post-operative day 7.

Table 12.

Discharge prescriptions

<table>
<thead>
<tr>
<th>Discharge prescription</th>
<th>Usual care (n = 41)</th>
<th>Intervention group (n = 41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 300mg + codeine 30mg + caffeine 15mg</td>
<td>18 (43.9)</td>
<td>27 (69.2)</td>
</tr>
<tr>
<td>Acetaminophen 300mg + codeine 15 mg + caffeine 15mg</td>
<td>1 (2.4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Acetaminophen 300mg + codeine 7.5mg + caffeine 15mg</td>
<td>1 (2.4)</td>
<td>2 (5.1)</td>
</tr>
<tr>
<td>Acetaminophen 325mg + oxycodone 5mg</td>
<td>15 (36.6)</td>
<td>6 (15.4)</td>
</tr>
<tr>
<td>Acetaminophen 325mg + tramadol 37.5mg</td>
<td>6 (14.6)</td>
<td>4 (10.3)</td>
</tr>
</tbody>
</table>
3. Frequency and severity of adverse effects of analgesics for patients undergoing ambulatory IHR at post-operative days 2 and 7.

Adverse effects of analgesics were reported by 83% \((n = 62)\) of all participants \((n = 33\) usual care, and \(n = 29\) intervention group) at post-operative day 2, and by 22% \((n = 16)\) of participants \((n = 10\) usual care, and \(n = 6\) intervention group) at post-operative day 7 (see Table 14). Twenty five percent \((n = 19)\) of participants reported experiencing two or more adverse effects, that were rated as moderate to severe \((> 4/10)\) at post-operative day 2 \((n = 10\) usual care, and \(n = 9\) intervention group). Constipation was the most common adverse effect identified by all participants, with moderate to severe constipation reported by 56% \((n = 42)\) at 2 days, and 13% \((n = 9)\) at 7 days post-operatively. Other reported moderate to severe adverse effects included sedation and nausea.

<table>
<thead>
<tr>
<th></th>
<th>Usual care</th>
<th>Intervention group</th>
<th>(t(df))</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total opioid use (mg in morphine equivalents)</td>
<td>((n = 38) at day 2; (n = 36) at day 7)</td>
<td>((n = 37) at day 2; (n = 36) at day 7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(M(SD))</td>
<td>(M(SD))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>23.1 (26.5)</td>
<td>9.2 (11.2)</td>
<td>3.0 (73)</td>
<td>0.004</td>
</tr>
<tr>
<td>Day 7</td>
<td>1.47 (3.0)</td>
<td>2.02 (3.9)</td>
<td>0.7 (70)</td>
<td>0.50</td>
</tr>
</tbody>
</table>
Table 14.

*Adverse Effects of Analgesics*

<table>
<thead>
<tr>
<th></th>
<th>Usual care (n = 38) at day 2; (n = 36) at day 7</th>
<th>Intervention group (n = 37) at day 2; (n = 36) at day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reported any adverse effect</strong></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Day 2</td>
<td>33 (87)</td>
<td>29 (78)</td>
</tr>
<tr>
<td>Day 7</td>
<td>10 (28)</td>
<td>6 (17)</td>
</tr>
<tr>
<td><strong>Reported 2 or more moderate to severe adverse effects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>10 (26)</td>
<td>9 (24)</td>
</tr>
<tr>
<td>Day 7</td>
<td>0 (0)</td>
<td>3 (8)</td>
</tr>
<tr>
<td><strong>Moderate to severe constipation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>25 (66)</td>
<td>17 (46)</td>
</tr>
<tr>
<td>Day 7</td>
<td>3 (8)</td>
<td>6 (17)</td>
</tr>
<tr>
<td><strong>Moderate to severe nausea</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>4 (11)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Day 7</td>
<td>0 (0)</td>
<td>2 (6)</td>
</tr>
<tr>
<td><strong>Moderate to severe sedation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>12 (32)</td>
<td>8 (22)</td>
</tr>
<tr>
<td>Day 7</td>
<td>0 (0)</td>
<td>3 (8)</td>
</tr>
</tbody>
</table>

**Additional exploratory questions**

*At post-operative day 7, what do the usual care group and intervention group report regarding*

(a) *patient concerns regarding pain management*, (b) *use of non-pharmacological pain*
interventions, (c) the adequacy of post-discharge information, and (d) the unplanned use of health care resources?

Scores for patient concerns regarding pain management are reported in Table 15. Scores for all items were low (see Appendix K). There was no difference in the total score for patient concerns regarding pain management for participants in the usual care and intervention groups.

Participants in both the intervention and usual care groups used non-pharmacological measures to manage their pain (see Table 16). Thirty-five percent of the total sample used more than one non-pharmacological intervention to manage pain. Distraction was the most commonly reported non-pharmacological measure used to manage pain. This included activities such as watching television, listening to music, and reading.

Table 15

Patient Concerns Regarding Pain Management at Post-operative day 7

<table>
<thead>
<tr>
<th>BQ-SF</th>
<th>Usual care group</th>
<th>Intervention group</th>
<th>t(df)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 36 M (SD)</td>
<td>n = 36 M (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score (0–70)</td>
<td>11.56 (6.5)</td>
<td>11.17 (6.8)</td>
<td>0.25 (70)</td>
<td>0.81</td>
</tr>
</tbody>
</table>

Note: BPQ-SF = Barriers Questionnaire – Short Form
Table 16.

**Use of Non-pharmacological Interventions to Manage Pain**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Usual care (n = 36)</th>
<th>Intervention group (n = 36)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Exercise</td>
<td>9 (25.0)</td>
<td>9 (25.0)</td>
</tr>
<tr>
<td>Massage</td>
<td>3 (8.3)</td>
<td>5 (13.8)</td>
</tr>
<tr>
<td>Positioning / splinting incision</td>
<td>10 (27.8)</td>
<td>14 (38.9)</td>
</tr>
<tr>
<td>Relaxation/meditation/ deep breathing</td>
<td>2 (5.6)</td>
<td>6 (17.0)</td>
</tr>
<tr>
<td>Distracting activities</td>
<td>19 (52.8)</td>
<td>26 (72.2)</td>
</tr>
</tbody>
</table>

Table 17 reports the adequacy of discharge information and the unplanned use of health care resources. The majority of participants from both groups (92%, n = 66) reported they were prepared to manage their pain at home. Participants from both groups (n = 8) reported that they utilized health care resources that they had not planned for post-operatively. Six participants from the usual care group contacted a physician post-operatively for the following reasons: (a) unmanaged pain and to change their prescription (n = 4); (b) constipation and sedation with analgesics (n = 1), and (c) emergency department admission due to abdominal pain caused by constipation (n = 1). Two participants from the intervention group contacted a physician for the following reasons: (a) clarification regarding drug interactions between warfarin and their prescribed analgesic (n = 1); and (b) emergency department admission due to chest pain (n = 1). Four (11%) participants in the usual care group were dissatisfied with their pain treatment overall. Thirty-six percent (n = 13) of participants in the intervention group were very satisfied with their pain treatment as compared to 25% (n = 9) of participants in the usual care group.
On exploration, 75% (n = 27) participants in the intervention group reported the information they received during their pre-admission visit was very helpful. All participants (100%) in the intervention group reported that instructions regarding their schedule for taking medications were clear, and 72% (n = 26) reported that instructions about how to change their medications were clear.

Table 17

*Discharge Information and Unplanned use of Health care Resources*

<table>
<thead>
<tr>
<th>APS-POQ</th>
<th>Usual care (n = 36)</th>
<th>Intervention group (n = 36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepared to manage pain at home (yes)</td>
<td>31 (66)</td>
<td>35 (97)</td>
</tr>
<tr>
<td>Unplanned use of health care resources (yes)</td>
<td>6 (17)</td>
<td>2 (6)</td>
</tr>
</tbody>
</table>

How satisfied are you with your pain treatment overall?

| Satisfied | 1 (3) | 0 (0) |
| Dissatisfied | 3 (8) | 0 (0) |
| Slightly dissatisfied | 1 (3) | 0 (0) |
| Slightly satisfied | 4 (11) | 1 (3) |
| Satisfied | 18 (50) | 22 (61) |
| Very satisfied | 9 (25) | 13 (36) |

Note: APS-POQ = American Pain Society Patient Outcomes Questionnaire
Chapter 5

Discussion

This chapter focuses on a description of the strengths and limitations of the trial, and a review of the results in the context of the available evidence.

Strengths

This randomized controlled trial was the first to examine the outcomes of an education intervention on post-operative pain for patients undergoing ambulatory IHR. The adapted Symptom Management Model was the conceptual framework that guided the design of the intervention and the selection of outcomes.

A strength of this trial was the use of a standardized education intervention (the HREI) that was individualized to the participant. The HREI was provided in addition to the usual post-operative care for the ambulatory IHR population, and was provided in both a verbal and written format. The booklet, which was utilized as part of the education intervention, was adapted from a previous trial (Watt-Watson, Stevens et al., 2004) and was reviewed for content validity by both experts and lay people. Providing pre-operative education in both a verbal and written format was recommended by earlier research as well as practice guidelines for pain management (Beauregard et al, 1998; Dewar et al, 2003; Dewar, Scott & Muir, 2004; Kastanias et al., 2009; McGrath et al, 2004; Oberle et al, 1994; RNAO, 2007; Watt-Watson, Cheung et al, 2004; Watt-Watson, Stevens et al., 2004). Providing written and verbal education also facilitated the individualization of the intervention during the pre-admission clinic visit and during the telephone support. During the educational session, the investigator individualized educational material according to questions asked and comments made by participants. This way of individualizing the intervention aimed to increase its relevance to individual participants, which
in turn addressed the participants’ unique needs and increased their ability to utilize the intervention, ultimately leading to the achievement of favourable outcomes (Richards et al., 2007). The booklet also served as a resource to participants when participants they were at home, with the majority of the participants and/or participants’ partners (n = 33) reporting they read the booklet. During the telephone support calls, prior to and after surgery, the information provided in the booklet was reviewed with participants again. Participants were engaged with the intervention and had a positive response to the intervention. There were no anticipated risks to participants and no adverse events occurred that were related to the intervention.

This trial utilized a rigorous randomized controlled design. Selection bias was not a concern as randomization was centrally controlled and randomization sequence was concealed using a password protected web based tool, www.randomize.net. Only participants randomized to the intervention group received the intervention, and to minimize the likelihood of contamination, the intervention was delivered by the investigator. Although it was not possible to blind participants to their group allocation, all documents related to the study were placed in an opaque envelope so that other study participants and health care personnel were not aware of which group the participant was allocated to. Attrition bias was not a concern for this trial as only 7 participants were lost to follow-up at post-operative day 2.

Reliable and valid measures that were appropriate for telephone data collection and for ambulatory IHR patients were used to collect data on the trial outcomes. The post-operative data were collected by telephone by the same research assistant for all participants. To reduce the possibility of ascertainment bias by trial personnel during data collection, the research assistant who collected the data were blinded to group allocation. Two hospital sites were used to recruit participants to this trial, one University affiliated teaching hospital and one community hospital. The patient population and standardized procedures for usual care were similar between the two
sites. The HREI was designed so it could be easily integrated into the current usual care provided to patients undergoing ambulatory IHR. Data analysis was guided by the intention to treat approach and all participants were analyzed in the groups to which they were randomized.

**Limitations**

One limitation of this trial was related to recruitment. Only men who were able to speak and read English were recruited. Consequently, 30 patients did not meet the eligibility criteria because they did not speak and read English. The intervention for this trial was directed only at participants, with no component of clinician education. Including a component of education for clinicians might be helpful in supporting appropriate analgesic prescribing practices. The intervention was delivered by the trial investigator, a Nurse Practitioner with a strong commitment to pain management. Although a standard protocol was used to deliver the intervention, the use of nurses whose primary role is pre and post-operative care of ambulatory surgery patients to deliver the intervention would strengthen the external validity and clinical applicability during subsequent evaluation of the HREI. Also, this trial was not adequately powered to detect differences between the intervention and usual care groups at post-operative day 7 or longer.

**Discussion of Trial Findings**

**Sample characteristics**

Baseline characteristics of the trial sample were similar between groups with a mean age of 59 (±14) in the intervention group and 61 (±16) in the usual care group. This mean age is slightly higher than the reported mean age of 55 (±16) in other studies (Cunningham et al, 1996, Liem et al, 1997, Sawhney et al., 2010).
Pain

The HREI was effective in decreasing WORST 24-hour pain movement at post-operative day 2. There was a statistically significant difference in pain intensity scores for pain NOW at rest and on movement, and WORST 24 hour pain at rest at post-operative day 2. Findings from this trial were both statistically and clinically significant in decreasing immediate post-operative pain. Farrar et al. (2001) report that a clinically significant reduction in acute pain as a mean difference of 2 points or 20% on an 11 point NRS. In this trial, there was a 20% difference in pain intensity rating scores between the two groups for all pain intensity scores measured at post-operative day 2, including the primary outcome of WORST 24 hour pain at rest and on movement (Farrar et al, 2001). Similar to other studies which found that 60% of IHR patients reported moderate to severe pain at 24 hours post-operatively (Coll & Ameen, 2006; McHugh & Thoms, 2002; McGrath et al, 2004; Pavlin et al, 2004) 58% (n = 36) of participants in the usual care group (versus 22%, n = 25 of the intervention group) reported severe (>6/10) WORST 24-hour pain on movement.

In comparison, the findings from this trial are different than results of other trials examining education interventions for pain management following surgery. Dewar et al. (2004), in their trial with a heterogeneous sample of ambulatory surgery patients (N = 238), did not find a significant difference in pain intensity between the intervention and usual care groups at post-operative days 1, 2, 3 and 4. They did report a significant difference in pain intensity between groups at post-operative day 5 (p = 0.04) with the intervention group reporting lower pain scores. Watt-Watson, Stevens et al (2004), in their trial with cardiac surgery patients (N= 406), did not find a significant difference in pain intensity between the intervention and usual care groups at post-operative days 2 to 5, and pain intensity scores remained in the moderate range. Similar to the HREI, the trial by Dewar et al (2003) and Watt-Watson, Stevens et al 92004)
found that between post-operative days 2 to 5 mean pain intensity scores decreased. Results from the HREI trial may be different than these trials as the HREI included a homogenous surgical population, data were prospectively collected by a blinded research assistant, and the intervention was provided by a single Nurse Practitioner who offered consistent, standardized education.

The HREI was completed in the early post-operative period and it did not show a sustained effect at post-operative day 7. There was no statistically significant difference in pain intensity at post-operative day 7, the mean pain intensity scores for pain NOW at rest and on movement and WORST pain in the past 24-hours at rest and on movement were in the mild range (<3/10) for both groups and there was no statistically significant difference between them. However, this trial was not powered to test a difference at this time point.

Although mean pain intensity scores were mild at post-operative day 7, 36% (n = 26) of the total participants reported moderate to severe WORST pain in the past 24 hours on movement. This is similar to Callesen, et al. (1998) who found that 33% of patients reported moderate to severe pain 6 days after ambulatory IHR or femoral hernia repair. In their follow-up study, 1 year after surgery, Callesen et al. (1999) found that patients who had moderate to severe pain at 4 weeks after surgery had a 7 fold higher risk of developing persistent pain. The 2011, international guidelines for the prevention and management of persistent pain following IHR defined persistent neuropathic pain following IHR as “a pain arising as a direct consequence of a nerve lesion or a disease affecting the somatosensory system, in patients who did not have groin pain before their original hernia operation, or, if they did, the post-operative pain differs from the pre-operative pain” (Alfieri, Amid, Campanelli, et al, 2011, pg 241). Risk factors for the development of persistent pain include: having ambulatory surgery, age less than 65 years, and immediate severe post-operative pain (Aasvang et al., 2010; Alfieri, Amid, Campanelli et al.,
2011; Kehlet, Jensen & Woolf, 2006; Linderoth, et al, 2011; Massaron, et al, 2007). Moderate to severe pain at 1 week after surgery could lead to a persistent problem for some participants in this trial as 81% (n = 61) of the total participants had one or more of the risk factors for the development of persistent pain at one year post-operatively. Further examination of patients with moderate to severe pain at 7 days post-operatively is needed to determine specific education needs for this group. Extending the HREI by providing an additional telephone support call at post-operative day 5, might be helpful in reducing pain intensity at post-operative day 7. An adequately powered trial with a longer evaluation period is needed to examine the effect of this intervention on the development of persistent pain.

Pain-related interference with usual activities

There was no difference between the intervention and usual care groups in total scores for pain related interference with activity, as measured by the BPI-I at post-operative days 2 and 7. Examination of individual scores found a difference for general activity and walking ability at post-operative day 2, with the intervention group reporting less interference. These results are different than Dewar et al’s (2003) trial who reported significant differences in pain-related interference with relations with others (p = 0.05) at post-operative day 2, and mood (p = 0.04) and walking (p = 0.05) on post-operative day 3, with the intervention group reporting less interference than the usual care group.

Although no trials were found that used the BPI-I as an outcome measurement with patients undergoing ambulatory IHR, the study by Watt-Watson, Chung et al (2004) reported similar mean BPI-I scores for patients who underwent ambulatory laparoscopic cholecystectomy as were found in this trial. Further examination of how these two patient populations are similar
and which interventions would be helpful in decreasing pain related interference with activities is needed.

The written and verbal information provided as part of the HREI emphasized the importance of using analgesics before pain became severe and prior to doing activities that would induce pain. The effective use and appropriate timing of analgesics may have contributed to this reduction in pain related interference. However, the relationship between the timing of analgesics and performing activities that may induce pain was not specifically explored in this trial.

The scores for the MPQ-SF PRI, including the PRI-S, PRI-A, PRI-T, and the PPI all decreased over time, but this intervention failed to find differences in the quality of pain between the intervention and usual care groups. The pain reported in this trial was primarily sensory-discriminative in quality, with the highest scores being reported for the PRI-S at both 2 and 7 days post-operatively. Similarly, the sample of IHR patients in the study by Massaroon et al (2007) reported pain that was primarily sensory-discriminative in quality.

Pain descriptions provided by patients communicate more precise information about the quality of the pain they are experiencing. Although this trial did not find a difference between the groups for the MPQ-SF, the pain descriptors rated as moderate to severe by 20% or more of the total participants (stabbing, sharp, aching, tender, and tiring or exhausting) were similar to the descriptors (aching, sharp, tender, and heavy) reported by 20% or more of participants in the study by Massaron et al (2007). A small number of participants in this trial and in the study by Massaroon described their pain as punishing or cruel. Combining the descriptors reported in this trial and the study by Massaroon, provides a baseline of pain descriptors used by patients who have undergone IHR. These descriptors depict both nociceptive and neuropathic pain qualities.

Understanding the common pain descriptors that post-operative IHR patients use can assist
clinicians in tailoring pain treatments for this population. Modifying the HREI to include the information regarding how the pain may feel (the quality of the pain that patients may potentially experience) may better prepare patients to choose options to manage their pain. This modification is supported by earlier studies that report that ambulatory surgery patients would like to receive information regarding the type and severity of pain they will experience post-operatively (Kastanias et al., 2009; McGrath et al., 2004; Oberle et al., 1994). In addition, future trials with ambulatory IHR patients should test interventions which provide patients with strategies to manage these common pain descriptors. This would include prescribing and encouraging the use of analgesics that manage both nociceptive and neuropathic pain, in conjunction with non-pharmacological interventions.

*Analgesics and adverse effects*

At post-operative day 2 there was a significant difference between the intervention and usual care groups in the amount of opioids taken, with the usual care group taking a larger amount of opioid. Differences in opioid taken by the usual care group did not translate into lower pain scores. This may have been related to the timing of taking the opioid. Studies have reported that ambulatory surgery patients wait until their pain is severe before taking opioids, taking them as a last resort (McGrath et al., 2004; Older, Carr, Layzell, 2010). Participants in the usual care group may have waited until they experienced severe pain before taking an opioid which would have led to the need for a larger dose for effective pain relief.

Multimodal analgesic regimens for ambulatory surgery patients include the use of acetaminophen, NSAIDs, and opioids (Kamming et al, 2004; Fengling & Cheung, 2001; Rawal, 2007). Following surgery, non-steroidal anti-inflammatory drugs (NSAID’s) were taken by a small number of trial participants, with a greater number of participants in the intervention
group using NSAID’s as compared to the usual care group. Information regarding the use of
NSAID’s in conjunction with opioids was included as part of the HREI, and this may have
contributed to the higher NSAID use in the intervention group. Older et al (2010) in their study
which explored patients’ use of analgesics following ambulatory surgery, found that the
relationship between the patient and the health care provider was an important factor that
encouraged patients to use their analgesics. Patients wanted clear instructions on how and when
to use analgesics (Kastanias et al, 2009; Older et al, 2010; McGrath et al, 2004; Watt-Watson,
Chung et al, 2004). Participants in this trial were given specific instructions on when to use their
analgesics and were supported in the effective use of analgesics throughout the intervention.

Despite its variable efficacy and concerns regarding drug safety, acetaminophen 300 mg with
codeine 30mg and caffeine 15mg was reported to be the most common discharge prescription
for this sample, and continues to be prescribed for patients undergoing ambulatory surgery
(Alam, Gomes, Zheng et al., 2012; Beauregard et al, 1998; Kircheiner et al, 2007; Mattila et al,
2005; Watt-Watson, Chung et al, 2004). The HREI was focused on providing individualized
education and support to trial participants, and did not address the pain management practices of
clinicians. A lack of understanding of opioid analgesia among health professionals was identified in
Watt-Watson, Stevens et al’s (2004) trial of 406 cardiac surgery patients, and they recommended
that future trials include focus groups with staff to discuss issues affecting pain management in the
postoperative setting. Adding an education component for clinicians to the HREI would be
beneficial to encourage appropriate analgesic prescribing practices. Such education would
include information regarding the metabolism of codeine, as well as the effectiveness of
multimodal analgesia in the management of pain. Also clinicians would be encouraged to
individualize their instructions to ambulatory surgery patients regarding when, how often, and
for how long to use analgesics.
The adverse effects of analgesics, including constipation, nausea and sedation, were reported by participants in both groups and there was no difference in the frequency of adverse effects between the groups. Dewar et al (2003) also reported no difference in the frequency of adverse effects between the usual care and intervention groups following ambulatory surgery. In this trial, at post-operative day 7, the severity of adverse effects decreased as analgesic use decreased. Constipation was the most commonly reported adverse effect, with a total of 56% of the total sample reporting moderate to severe constipation at post-operative day 2. The reported frequency of constipation in this trial was higher than the frequencies reported by Beauregard et al (1998), and Watt-Watson, Chung et al (2004) of 45% and 17% respectively. Patients needed specific information regarding the appropriate management of constipation. Revising the HREI to include a step by step outline describing interventions to manage opioid related constipation might reduce the frequency of moderate to severe constipation found in this trial. Most patients whose pain is being managed with opioids experience constipation. It was recommended that prophylactic laxatives be initiated whenever opioid therapy is initiated (Panchal, Muller-Schwefe, Wurzelmann, 2007). The HREI booklet included information regarding non-pharmacological measures to facilitate bowel movements such as having a bowel movement at the same time every day, mobility and physical activity, increased dietary fibre, and increased fluid intake. More emphasis on pharmacological and non-pharmacological methods to prevent and treat constipation would be necessary in any future intervention.

**Concerns, non-pharmacological interventions, and discharge information**

At post-operative day 7 the BQ-SF was administered to assess participant concerns regarding managing pain. Scores for all items were low for both groups. The fear of addiction has been reported to be the most common concern by patients undergoing ambulatory surgery and discussing the risk of addiction with patients to reduce this fear has been recommended
(Beauregard et al, 1998; McGrath et al, 2004; Older, Carr & Layzell, 2010; Watt-Watson, Chung et al, 2004). Beauregard et al (1998) found that 62% of participants strongly believed (a score of >3/5) that they could become addicted to opioid analgesics. These results differ from those of this trial with a low mean score for the concern ‘people get addicted to pain medicine easily’ (2 [±1.6] intervention group, 2 [±1.5] usual care). Beauregard et al (1998) also reported that 49% of participants strongly believed it was ‘easier to put up with pain than with the side effects that come from pain medicine’, 44% strongly believed that ‘pain medicine should be saved in case the pain gets worse’, and 31% strongly believed that ‘pain medicine cannot really control pain’. The mean scores reported in this trial were lower. Although the BQ-SF was a valid and reliable tool to assess patients’ concerns regarding pain management it may have been difficult for participants to understand as it was administered over the telephone. Completing the BQ-SF with all participants as an interview schedule prior to randomization would have provided an opportunity to explain the measure. This approach would have also provided some baseline information regarding participants’ concerns that could have been used to guide the intervention.

The HREI included information on the use of non-pharmacological therapies to manage pain, as recommended by earlier studies (Beauregard et al, 1998; McGrath et al, 2004; Oberle et al, 1994; Watt-Watson et al, 2004). Although the intervention group received specific information, the types of non-pharmacological therapies reported were similar between the two groups. The questions asked to elicit information may not have been specific enough to capture non-pharmacological strategies to manage pain. A more focused questionnaire, asking about specific non-pharmacological techniques, may have garnered a different result. Also, adapting the HREI to give participants specific information about when and how often to use non-pharmacological interventions may have helped with their implementation.
Adequacy of discharge information was assessed on post-operative day 7 using the APS-POQ. More participants in the intervention group reported they were prepared to manage their pain at home as compared to participants in the usual care group. This included having adequate information on when to use and how to change their analgesics. Only participants from the usual care group reported they were dissatisfied with their pain treatment overall, even though participants from both groups reported moderate to severe post-operative pain. However, only 30% of the total participants were very satisfied with their pain treatment overall. Further exploration is needed to determine why participants were not very satisfied with their pain care, and what improvements could be implemented. Patients in the intervention group reported that both the HREI booklet and telephone support were helpful in managing their post-operative pain. The HREI appeared to be effective in preparing patients to manage their analgesics and pain at home.

Six (17%) participants from the usual care group and 2 (6%) participants in the intervention group contacted a health care provider to get help with post-operative pain. The number of participants in the usual care group that contacted a health care provider was similar to the findings by McGrath et al (2004) who reported that 12% of ambulatory surgery patients contacted a health care provider. In several studies, patients identified the need for information about pain management to help with the recovery period after discharge and found that pain was one reason for emergency department visits associated with shortened hospital stays after ambulatory surgery (Beauregard et al, 1998; McHugh & Thoms, 2002; Oberle, et al, 1994; Mattilla, et al. 2005; Watt-Watson, Cheung et al, 2004). The HREI may have been helpful in reducing contact with health care providers post-operatively.
Chapter 6

Summary, Implications for Practice and Research, Conclusions

Inguinal hernia repair (IHR) is a common surgery performed in Canada (Cunningham et al., 1997). IHR is also reported to be one of the most painful ambulatory surgeries, with 54% of patients reporting moderate to severe post-operative pain 72 hours following surgery (Coll & Ameen, 2006; McHugh & Thoms, 2002; McGrath et al., 2004; Pavlin et al., 2004; Rawal et al., 1997). Also, persistent post-surgical pain is a problem for this patient population. Cumulative evidence suggests that as many as 30% of patients may experience persistent pain following IHR (Bozuk, et al, 2003; Bueno, et al, 2004; Kehlet et al, 2006; Koniger et al, 2004; Picchio et al, 2004). To date, there have been no randomized controlled trials that have examined the effectiveness of individualized education interventions to manage pain following ambulatory IHR.

The Hernia Repair Education Intervention (HREI) trial is the first to prospectively examine the outcomes of an individualized education intervention on pain for patients undergoing ambulatory IHR. This randomized controlled trial was conducted at two hospitals, a University affiliated teaching hospital and a community hospital. An adapted version of Dodd’s (2001) Symptom Management Model was the framework used to guide the development and delivery of the intervention as well as outcome selection. The HREI included the delivery of a booklet with information regarding managing pain and adverse effects of analgesics, an individualized education session administered during the participants’ pre-admission visit to the hospital, and two telephone support calls. The primary outcome of interest was the impact of the HREI versus usual care on WORST 24-hour pain intensity on movement following ambulatory IHR at post-operative day 2. Trial outcomes were examined on 2 and 7 days post-operatively.
Eighty-two patients scheduled for an elective IHR were randomized to receive either usual care \((n = 42)\) or the intervention \((n = 40)\). Baseline characteristics between the intervention and usual care groups were similar. All participants were male, and the mean age of participants in the usual care group was 59 (±14) years and in the intervention group was 61 (±16) years. Data for the primary outcome were available from 75 participants.

There was a statistically significant difference \((p < 0.001)\) for the primary outcome of WORST 24-hour pain on movement, with mean pain scores at post-operative day 2 for the intervention and usual care groups of 4.7 (±2.2) and 7.2 (±2.8) respectively. There was also a statistically significant difference between the intervention group and usual care group for pain NOW at rest and on movement and WORST 24-hour pain at rest \((p \leq 0.001)\) at post-operative day 2. Although the total BPI-I scores were not statistically different between groups with the Bonferroini correction, the intervention group reported lower pain-related interference scores at post-operative day 2. There was a statistically significant difference in the individual subscales for the BPI-I for general activity \((p = 0.006)\) and walking \((p = 0.008)\) at post-operative day 2, with the intervention group reporting lower pain-related interference scores. As well, opioid use was significantly lower \((p = 0.004)\) in the intervention group as compared to the usual care group at post-operative day 2. However, no statistically significant differences were found between the groups for pain quality at post-operative days 2 or 7, and there were no statistically significant differences found for pain intensity, pain related interference, and concerns regarding analgesics at post-operative day 7.

**Implications for research**

This trial provides direction for future research on pain following IHR. Future research needs to: examine components of the intervention; include clearer information regarding the management of adverse effects of opioids, include pain education for health care professionals; evaluate the
impact of extending the length of the intervention; examine the measurement tools used; and evaluate the effectiveness when nurses, whose role is to care for ambulatory surgery patients, provide the intervention.

Although there was a difference in pain intensity and pain-related interference with general activities and walking at post-operative day 2, revisions to the HREI are necessary to address the pain at post-operative day 7 and the adverse effects of opioids reported by participants in this trial. Moderate to severe constipation at day 2 was a reported by 56% of the total sample. Revising the intervention to include clearer and specific information regarding the prevention and management of constipation may reduce the frequency of this adverse effect.

Concurrently educating both clinicians and patients about evidenced based strategies to manage pain and adverse effects of opioids may improve outcomes for patients. Including pain education for health care professionals might be helpful in supporting appropriate analgesic prescribing practices and the management of adverse effects of opioids. This education would include information regarding the metabolism of codeine, the effectiveness of multimodal analgesia in the management of pain following surgery, and the prevention and management of opioid induced constipation. Including education for both patients and health care professionals about the assessment and management of nociceptive and neuropathic pain may improve the patients’ pain experience.

Findings for the total sample indicated that the 36% reported moderate to severe worst pain in the past 24 hours on movement at post-operative day 7. Unrelieved acute pain and stress response as a result of surgery can have psychological and physiological consequences for patients (Andersen & Kehlet, 2011; Carr & Thomas, 1997; Kehlet, 1997). The phenomenon of peripheral and central sensitization associated with prolonged and repetitive nociceptive input can create the physiology for
a persistent pain problem (Bausbaum & Jessell, 2000, Julius & Basbaum, 2001). Risk factors for the development of persistent post-surgical pain following IHR include undergoing ambulatory surgery, age less than 65 years, and experiencing severe post-operative pain (Aasvang, et al, 2010; Kehlet et al, 2006; Jensen & Woolf, 2006; Linderroth et al, 2001; Massaroon et al, 2007). Sixty-one of the total participants in this trial have one or more risk factors for the development of post-surgical persistent pain. Extending the length/timing of the intervention to potentially influence long term outcomes is also required. Since no differences were found regarding the outcome measures at post-operative day 7, the HREI could be extended with a larger sample and including a telephone support call at post-operative day 5 for those with moderate to severe pain. An adequately powered trial to examine the effect this intervention on the development of persistent pain is necessary.

Implications for future research with respect to measurement tools are related to the use of the BQ-SF to examine patient concerns, as well as the tool used to assess the use of non-pharmacological interventions used to manage pain. The BQ-SF uses a NRS to determine a patient’s agreement with different concerns regarding pain management. It may have been difficult for patients to complete the NRS over the telephone. Using the BQ-SF during the pre-admission visit to collect baseline data regarding pain management concerns would provide an opportunity to review this measure with patients. This trial used an open ended question to determine if participants used any non-pharmacological interventions to manage pain. Asking participants about the use of specific non-pharmacological interventions, and how and when they were used, would determine if participants in the intervention group implemented the information they received as part of the intervention.

The HREI was delivered by one Nurse Practitioner, which helped to minimize individual variation, and helped to ensure a standardized approach. A replication of this trial including...
nurses whose primary role is the pre and post-operative care of ambulatory surgery patients to deliver the intervention is necessary to strengthen the external validity and clinical applicability. Having more than one health care provider deliver the intervention could introduce a limitation related to the individualizing the intervention while providing the standardized information. Providing education to nurses regarding the standardized protocol used in this trial, and education on how to individualize the information to meet the patients’ pain management may help to reduce this limitation.

**Implications for practice**

Evidence from this trial indicates that the HREI was effective in decreasing pain intensity, pain-related interference with general activity and walking at post-operative day 2. The findings suggest that the HREI may have the potential for improving patient outcomes related to pain following ambulatory IHR.

The HREI was designed so it can be integrated into the current standard of care provided to ambulatory IHR patients. Prior to implementing the HREI, revisions to the intervention should be implemented and tested. Practice changes should encompass recommendations from current research and evidenced based guidelines on pain assessment and management. A consistent approach in the delivery of care for patients undergoing ambulatory surgery, including IHR, needs to encompass the pre-operative and post-operative phases. For ambulatory surgery patients, this includes putting a system in place to provide support at home.

Nurses caring for ambulatory surgery patients would need to be involved in the future delivery of the intervention. Presentation of the findings to the nurses in the pre-admission clinic and administrators at the respective trial sites is an important starting point for discussion of practice changes. In implementing the HREI, nurses would require the appropriate education to deliver
this type of individualized intervention. This would include education regarding the use of valid and reliable tools to assess and manage pain and adverse effects of analgesics. Conducting a focus group to determine the nurses’ needs to deliver this intervention would provide valuable information. Additionally, providing both physicians and nurses with evidenced based pain education is important. This includes providing education regarding the metabolism of codeine and the benefits of multimodal analgesia to manage post-operative pain.

**Conclusion**

The purpose of this trial was to evaluate the impact of the Hernia Repair Education Intervention (HREI) on pain following inguinal hernia repair (IHR). The HREI was found to be effective in decreasing pain intensity, and pain related interference with general activity and walking at post-operative day 2. There was also a difference in analgesic use between the usual care and intervention groups. There were no differences between the groups on any of the outcomes measured at post-operative day 7, and 36% of participants reported moderate to severe pain on movement on day 7. Also, constipation was the adverse effect reported most frequently by participants in both groups.

Modifying and re-testing the HREI is required prior to implementing this intervention into clinical practice. This includes revising the intervention to include clearer information regarding the prevention and management of constipation, and concurrently providing patients and health care providers with education regarding effective post-operative pain management. Extending the length of the intervention might impact outcomes at post-operative day 7. Also, an adequately powered trial with a longer evaluation period is necessary to determine if this intervention is successful in decreasing the development of persistent post-surgical pain in patients undergoing IHR.
References


*Archives of Surgery, 139,* 755–758.


Richards, C. K., Enderline, C. A., Beck, C., McSweeney, J. C., Jones, T. C., & Roberson, P. K. 


Toronto, Canada: Registered Nurses Association of Ontario.


Statistics tool box: Sample size for comparing means of two independent groups. *(nd).*


Appendices
### Appendix A

Evidence Tables: Acute Pain and Adverse Effects following Ambulatory Surgery

<table>
<thead>
<tr>
<th>Study author /date</th>
<th>N</th>
<th>Study Design / Intervention</th>
<th>Outcomes</th>
<th>Results (P value)</th>
<th>Patient Sample</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oberle, Allen &amp; Lynkowski, (1994)</td>
<td>N= 294 Mean age 39 (range 16-85)</td>
<td>Descriptive, telephone survey on POD #4</td>
<td>POD 0 to 3 pain, nausea, vomiting; interference with dressing; pre-operative teaching evaluation / knowledge Tool: 1-5 NRS for each symptom (1= very little; 5= a great deal)</td>
<td><strong>Severe post-op pain:</strong> POD # 0 = 62.5% POD # 1 = 44%; POD #2 = 19%; POD #3 = 6%. Nausea: POD # 0 = 2.1 (± 2) POD # 1 = 0.7 (± 1.4) POD #2 = 0.4 (±1.1) POD #3 = 0.2 (±0.9) <strong>Vomiting:</strong> POD # 0 = 1.3 (± 2) POD # 1= 0.3 (± 1) POD #2 = 0.2 (±0.8) POD #3 = 0 (±0.4) <strong>Interference:</strong> POD # 3 getting dressed = 36% <strong>Teaching:</strong> 25% given little or no info; most teaching done immediately before or after surgery. Preference: written information (behavioral and sensory)</td>
<td>varied surgical types (arthroscopcy, bunionectomy, cataract extraction, laparoscopy, mammoplasty, submucosal resection, tubal ligation, major procedures – hernia repair/shoulder repair, minor procedures – carpal tunnel/otoplasty/adenoidectomy)</td>
<td>Severe post-op pain can continue for 3 days after surgery Support for pre-op education in both written and verbal format</td>
</tr>
</tbody>
</table>
Beauregard, Pomp, Choiniere (1998)

N = 89 (53 women & 36 men)
Response rate 94% (84/89).
Mean age = 39.6±8.9

Prospective Descriptive Self administered mail questionnaire.

4 measurement times (POD # 0, 1, 2, 7)

Mod – severe pain (on average)
POD # 0 = 42%
POD #1= 40%;
POD # 2= 24%;
POD #7 =13%.

Interference with 3+ on BPI
POD#1 = 77%
POD # 2 = 63%
POD # 7 = 44%.

Most frequent meds: tylenol + codeine or tylenol alone;
Non-pharm: 18% (ice, relaxation, massage)

Barriers:
62% addiction
49% adverse effects
44% save meds for worse pain
31% pain medicine cannot control pain

Discharge information:
62% instructions were not clear or non-existent regarding pain, no non-pharmacological

25% contacted MD/RN/Pharmacist for pain

Mixed ambulatory surgery population: (Gyne laparoscopy, knee & shoulder arthroscopy, carpal tunnel)

Severe post-op pain can continue for 7 days after surgery.

Pain can interfere with usual activities for 7 days after surgery.

Provide information on non-pharmacological interventions to manage pain with instructions.

Include education regarding addiction, management of adverse effects, and when to use pain medicine.

<table>
<thead>
<tr>
<th>N = 180</th>
<th>Prospective descriptive study with repeated measures. Data collected via telephone interviews.</th>
</tr>
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<tbody>
<tr>
<td>Mean age = 42 ±15</td>
<td>4 measurement times (POD # 1, 2, 3, 7) Pain, interference (BPI), analgesic use, analgesic adverse effects, post d/c complications, use of resources, satisfaction, clarity of discharge instructions (Patient Outcome Questionnaire, APS), Barriers Questionnaire</td>
</tr>
<tr>
<td>pain ↓ @ 72 h &amp; 7 days for LC and shoulder severe pain POD # 7: 55% shoulder 20% hand 0 L aposcopic Cholecystectomy (LC) BPI-I: mean @ POD#2 = 30; POD#7 = 13 LC &amp; 23 Shoulder; Moderate Interference work = Shoulder (6.1±3.3) &amp; hand (4.2±4); sleep = Shoulder (5.4±2.8) Analgesics: None POD #3 = 50% Tylenol# 3 most common. Pain relief with analgesics: 61-73% Used Non-pharmacological interventions: 6% Adverse effects: 40% constipation = 12% @ 24 hr, 17% @ 72hr; nausea = 14% @ 24 hr, 8% 72 hr; patients avoid using acetaminophen + codeine due to constipation D/C information: 69% adequate; 73% prepared to manage at home; 55% instructions re</td>
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<tr>
<td>Laparoscopic Cholecystectomy (LC) (54), hand (78) and shoulder surgery (48)</td>
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<tr>
<td>Severe post-op pain can continue for 7 days after surgery. Pain can interfere with usual activities for 7 days after surgery.</td>
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<tr>
<td>Medications clear; 56% unclear how to change medication schedule etc.</td>
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Mattila, Toivonen, Janhunen, Rosenberg, & Hynynen, (2005)  
N= 3910 pts  
n=2732  
(adults n=2144 children n=588)  
Response rate 69%  
2 sites  
Adults mean age 45 (15-86)  
Prospective, observational, cohort study. Self-administered postal questionnaire  
8 measurement times POD 0 to POD 7. incidence and intensity of symptoms: pain, bleeding, drowsiness, dizziness, nausea, vomiting, headache, backache, sore throat, hoarseness, temperature >37C & difficulty voiding.  
Grade all symptoms every evening using a 4 point NRS: nonexistent, mild, moderate or severe  
Overall Incidence:  
Pain= 57%  
Nausea=21%  
Vomiting=6%  
Drowsiness=52%  
Moderate-severe pain:  
POD#0=21%  
POD#1=18%  
POD#2=6%  
POD#3=6%  
POD#7=2%  
5% admitted to hospital due to: pain or PONV (most after GI surgery)  
Analgesics:  
NSAID (73%); Tylenol +codeine (13%); tramadol (5%)  
8% unplanned use of resources most on POD2 due to pain  
adults: ortho, gyne children: ENT
## Appendix B

### Evidence Tables: Acute Pain and Adverse Effects following Ambulatory IHR

<table>
<thead>
<tr>
<th>Study author /date</th>
<th>N</th>
<th>Study Design / Intervention</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Callesen, Bech, Nielsen et al. (1998) prospectively</td>
<td>N = 500 ambulatory IHR or femoral hernia repair in 466 patients. 488 in men and 53 were women. The median age=60 (range 18-90).</td>
<td>Prospective descriptive study Participants mailed completed questionnaires using a pre-addressed stamped envelope.</td>
<td>Pain was assessed during rest, cough and mobilization using a 4 point verbal rank scale (none, light, moderate, severe) daily for 1 week and at 4 weeks.</td>
<td>Moderate to severe pain: At rest: day 1 = 25% (n = 117); day 6 = 11% (n = 51); 4 weeks = 5% (n = 23) With Cough or mobilization: day 1 = 66% (n = 307); day 6 = 33% (153); 4 weeks = 11% (51)</td>
<td>ambulatory IHR or femoral hernia</td>
<td>There is a need for analgesics even 1 week after surgery After 4 weeks a large number of patients continued to have moderate to severe pain.</td>
</tr>
<tr>
<td>Rawal, Hylander, Nydahl, Olofsson, &amp; Gupta (1997)</td>
<td>N=1100 age 5-88 yrs, Response rate: 94% (n=1035)</td>
<td>Descriptive postal questionnaire of postoperative analgesia.</td>
<td>1 measurement time: POD # 2 pain</td>
<td>mild pain = 65% moderate-to-severe pain: inguinal hernia (62%); orthopedic (41%); hand (37%); varicose vein (36 %); satisfied with post-op pain = 95%</td>
<td>Inguinal hernia, orthopaedic, hand, varicose vein surgery</td>
<td>Following IHR patients have moderate to severe pain at 48 hours.</td>
</tr>
<tr>
<td>McHugh &amp; Thoms (2002)</td>
<td>N= 110</td>
<td>Descriptive, prospective telephone</td>
<td>3 measurement times: in hospital</td>
<td>severe pain: in day surgery unit 17%, laparoscopy (31%), dental</td>
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</table>
| Pavlin, Chen, Penaloza, & Buckle (2004) | Prospective, Observational Surveillance | 175 | Various procedures (hernia repair, vasectomy, hernia repair, arthroscopy, cyst removal, other) | 42±1 years | 65% pain assessed in day surgery unit | Extractions (23%), vasectomy (13%), hernia repair (10%), arthroscopy (8%), cyst removal (4%), other (11%) | Inadequate pain by POD#2 was reported by 47 patients |}

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</table>
| Pavlin, Chen, Penaloza, & Buckle (2004) | Prospective | 5703 | Various procedures (inguinal hernia surgery, knee arthroscopy, pelvic laparoscopy, breast surgery, transvaginal uterine surgery, plastic surgery) | 57 years | 56% pain assessed in day surgery unit | Extractions (23%), vasectomy (13%), hernia repair (10%), arthroscopy (8%), cyst removal (4%), other (11%) | Inadequate pain by POD#2 was reported by 47 patients |}

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<tr>
<th>Study</th>
<th>Study Design</th>
<th>N</th>
<th>Procedure</th>
<th>Mean Age</th>
<th>Pain Assessment and Management</th>
<th>Complications</th>
<th>Conclusion</th>
</tr>
</thead>
</table>
| Pavlin, Chen, Penaloza, & Buckle (2004) | Prospective | 5703 | Various procedures (inguinal hernia surgery, knee arthroscopy, pelvic laparoscopy, breast surgery, transvaginal uterine surgery, plastic surgery) | 57 years | 56% pain assessed in day surgery unit | Extractions (23%), vasectomy (13%), hernia repair (10%), arthroscopy (8%), cyst removal (4%), other (11%) | Inadequate pain by POD#2 was reported by 47 patients |}
<table>
<thead>
<tr>
<th>Kamming, Curti, King (2004)</th>
<th>Response Rate 57% (n = 152 IHR)</th>
<th>Descriptive telephone interview</th>
<th>Pain: 0-10 NRS Yes/no questions regarding post-operative instructions, patient satisfaction. Identify the most painful surgical types. 7 procedures with highest incidence of pain: microdiscectomy, Laparoscopic Cholecystectomy, shoulder, elbow, hand, ankle, inguinal hernia and knee</th>
<th>Discharge information: 13% felt unable to manage related to: prescription not explained, waiting too long to take meds, did not fill prescription, afraid of addiction 9% called nurse re: pain, prescription counseling, dressing change 3.4% called MD re: pain, abdominal distention, bleeding, nausea and vomiting</th>
<th>45% of IHR patients have mod-severe pain on POD#1. Patients need clear instructions regarding medications, how to use analgesics and the fear of addiction.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coll &amp; Ameen, (2006)</td>
<td>N = 599</td>
<td>Descriptive, prospective, postal survey</td>
<td>Data for POD # 0, 1, 2, 3 Intensity and duration of pain (VAS)</td>
<td>Moderate to severe pain Hernia Repair: POD#0 = 59% POD#3 = 54% All groups overall: POD#0 = 59% POD#1 = 60%</td>
<td>Hernia repair, varicose vein, lap sterilization Patients undergoing hernia repair continue to have moderate to severe pain at POD#3</td>
</tr>
<tr>
<td>Massaron, Bona, Fumagalli, Battafarano, Elmore, Rosati (2007)</td>
<td>Response rate: 79%</td>
<td>POD#2 = 54% POD#3 = 44%</td>
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</table>
| N = 2752  
Response rate:  
n = 1440 (54%)  
Male = 1329  
Age greater than 65 years = 1128 | postal questionnaire. Patients asked to recall if they experienced pain after their IHR surgery, and if the pain lasted less than 6 months or longer than 6 months. Pain for less than 6 months = MPQ-SF by telephone. Pain more than 6 months = physical exam plus MPQ-SF. | pain | 
| 38% = post-operative pain  
19% = pain lasting more than 6 months  
81% = pain in their groin area.  
MPQ-SF: total PRI 19.5 (±14.5), PRI-S 13.3 (± 7.4), PRI-A 6.2 (± 9.4). Pain descriptors reported by 20% or more included: aching, stabbing, sharp, tender, and punishing. | 

<table>
<thead>
<tr>
<th>Sawhney, Paul, Alvarado (2008)</th>
<th>N= 98</th>
<th>Pain, bleeding, sore throat, nausea vomiting, analgesic use and type</th>
</tr>
</thead>
</table>
| Retrospective chart review of post-operative check –list (check list information was collected on POD#1 by telephone) | Pain: 81%  
Bleeding: 18%  
Difficulty voiding: 9%  
Sore throat: 7.1  
Nausea/Vomiting: 5.8%  
**Analgesic use:** 88% used their prescribed analgesics  
most common prescription prescribed analgesic was acetaminophen + codeine. | IHR | 
| Majority of patients undergoing IHR experience pain on POD#1 |
# Appendix C

Evidence Tables: Persistent Pain after IHR

<table>
<thead>
<tr>
<th>Study author /date</th>
<th>N</th>
<th>Study Design / Intervention</th>
<th>Outcomes</th>
<th>Results (P value)</th>
<th>Patient Sample</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Koninger, Redbeck, Butters (2004)</td>
<td>N = 280</td>
<td>Male patients Mean age = 53</td>
<td>Randomized to 1 of 3 surgical techniques: (Shouldice, Lichtenstein or TAPP)</td>
<td>1 measurement time between 46 - 60 months post-op (median 52)</td>
<td>Shouldice repair n= 93 (age: 53)</td>
<td>Patients who underwent open repair had more persistent pain and limitations in activities than those who had TAPP repair.</td>
</tr>
<tr>
<td></td>
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<td>Pain intensity (0-100 VAS), Character and frequency of discomfort and pain, pain associated with physical strain and limitations to daily life and physical activities.</td>
<td>Moderate to severe pain: Shouldice: 16% Lichtenstein: 9% TAPP: 1.2% (p &lt; 0.01)</td>
<td>Lichtenstein repair n= 93 (age: 56)</td>
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<td>Pain with light physical strain: Shouldice = 5.4% Lichtenstein = 3.9% Unable to work: Lichtenstein: 2.6% Limitation in social activities: Shouldice = 2.7% Limited in sports: Shouldice = 9.5% Lichtenstein = 5.3%</td>
<td></td>
<td>TAPP repair n = 94 (age: 53)</td>
<td></td>
</tr>
<tr>
<td>Bozuk, Schuster, Stewart, Hicks, Greaney, Waxman (2003)</td>
<td>N = 346</td>
<td>Response rate 66% (n = 239 patients)</td>
<td>Mailed Questionnaire Compared open vs laparoscopic techniques.</td>
<td>1 measurement time post-op 1 yr (mean 180 days) Pain (mild, moderate, severe) Opioid use; Non-</td>
<td>open repair n= 139</td>
<td>Moderate to severe persistent pain is a problem for patients undergoing either open or lap IHR.</td>
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<td>Pain: open repair = 24% lap repair = 12% (p = 0.035)</td>
<td>laparoscopic repair n= 90</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Methodology</td>
<td>Findings</td>
<td></td>
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<tr>
<td>Kumar, Wilson, Nixon, Macintyre (2002)</td>
<td>N = 560 men</td>
<td>Mailed questionnaire (n = 454)</td>
<td>Opioid analgesic use severe pain: both groups 2.2</td>
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<td>Non-opioid analgesics: Open repair: 3.6% Laparoscopic: 1.1%</td>
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<tr>
<td>Picchio, Palimento, Attanasio, Matarazzo, Bambini, Caliendo, (2004)</td>
<td>N = 813 patients</td>
<td>Double blind RCT of surgical technique: open hernia repair with preservation of the ilioinguinal nerve or division of the ilioinguinal nerve</td>
<td>Persistent pain is a problem for patients undergoing either open or lap IHR and can interfere with physical activities</td>
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<tr>
<td>Callesen, Bech, Kehlet, 1999</td>
<td>N = 466</td>
<td>Mailed questionnaire (n = 419 returned)</td>
<td>Pain: n = 80 mod-severe: n = 25 analgesic use n = 9</td>
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<tr>
<td>Study</td>
<td>N</td>
<td>Type</td>
<td>Measurement times</td>
<td>Pain</td>
<td>Return to work, presence of numbness, other problems</td>
<td>All surgical types compared are open IHR</td>
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<tr>
<td>N = 276</td>
<td>RCT to surgical type: Bassini, McVay and Shouldice repair.</td>
<td>6 months, 1 &amp; 2 years</td>
<td>Pain: 0-10 @ 6 months. At 1 &amp; 2 years asked to rate pain using none, mild, moderate or severe.</td>
<td>moderate to severe pain: was reported 6 months: 55.5% 1 year: 11.9% 2 years: 10.6%</td>
<td>All surgical types compared are open IHR.</td>
<td>no difference in the incidence of persistent pain following IHR based on variation of open surgical technique</td>
</tr>
<tr>
<td>Cunningham, Temple, Mitchell, Nixon, Preshaw, Hagen (1996)</td>
<td></td>
<td></td>
<td></td>
<td>(all reported mod – severe pain) interfere with activities n = 24 MD visit due to pain n = 10</td>
<td>Compared to earlier study (1998) of pain at 4 weeks post-op: frequency of mod-severe pain was 7x higher at 1 yr if had mod – severe pain at 4 weeks</td>
<td></td>
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<tr>
<td>Pain (4 point verbal rating scale: none, mild, moderate, severe)</td>
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<tr>
<td>Analgesic use</td>
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<td>Interference with activities</td>
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</table>
### Appendix D

Evidence Tables: Interventions to Manage Acute Pain Following Ambulatory Surgery

<table>
<thead>
<tr>
<th>Study author /date</th>
<th>N</th>
<th>Study Design / Intervention</th>
<th>Outcomes</th>
<th>Results (P value)</th>
<th>Patient Sample</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laurion &amp; Fetzer</td>
<td>84</td>
<td>convenience sample N= 84 women</td>
<td>Pilot RCT 3 groups:</td>
<td></td>
<td>Gynecological day surgery</td>
<td>pain for all groups was in the mild range; and differences are not be clinically significant.</td>
</tr>
<tr>
<td>(2003)</td>
<td></td>
<td>Pilot RCT 3 groups: group 1 = guided imagery audiotape, group 2 = a music audiotape, group 3 = standard care.</td>
<td>Pain: 0 to 10 NRS, opioid use, nausea, vomiting</td>
<td>Pain: PACU admission: Group 1 = 1 Group 2 = 0.8 Group 3 = 1.5 1 hr post-arrival Group 1 = 2.9 Group 2 = 2.1 Group 3 = 3.5 At discharge Group 1 = 1.5 Group 2 = 1.1 Group 3 = 2.4</td>
<td>Guided imagery or music audiotape or standard of care</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3 measurement times: on PACU admission, 1h post arrival, discharge home</td>
<td>Length of stay in minutes.</td>
<td>Opioid use: Group 1 = 9.6 Group 2 = 7 Group 3 = 9.8 Nausea = 27 (32%) Nausea + vomiting: 10 (12%)</td>
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<td>LOS: group 1 = 244 min group 2 = 252 min group 3 = 210 min</td>
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<tr>
<td>Dewar, Craig, Muir, &amp; Cole (2003)</td>
<td>N = 238 ambulatory surgery patients; response rate 93% (n=222): hernia repair (n = 32) mean age: intervention group = 42.5 control group = 41.4</td>
<td>RCT: preoperative education intervention, with post-operative telephone follow-up and support vs usual care 5 measurement times (POD # 1, 2, 3, 4, 5) Spielberger State Trait Anxiety Inventory (State), Interference questions, pain diary: pain score, meds, side effects, helpfulness of educations and for control helpfulness of telephone calls</td>
<td>Mean pain: POD#1: Intervention = 5.12 Control = 4.84 POD#2: Intervention = 4.54 Control = 4.39 POD#3 Intervention = 3.4 Control = 3.86 POD #4 Intervention = 2.87 Control = 3.45 POD#5 Intervention = 2.85±2.3 Control = 3.55±2.63 (p=0.04) Adverse effects: No difference between the intervention and control group Interference: POD # 1: no differences POD # 2: Intervention group improved scores on their relations with others (p = 0.05) and concentration (p = 0.01); POD#3 significant difference between the control and intervention groups on: Mood (p = 0.04); walking (p= 0.05); relations with others (p= 0.04) Analgesics: No difference in groups between the amount of meds taken Discharge information: Helpfulness of: written instructions: 60% (intervention) vs 37%(control) telephone advice: 79.6%</td>
<td>breast reduction or enhancement, arthroscopy, anal surgery, inguinal hernia n = 135 male n = 87 female Provides some information regarding the effect of structured education on post-op pain.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix E

Title of Research Project: The Effect of an Individualized Education Intervention versus Usual Care on Pain Following Ambulatory Inguinal Hernia Repair

Investigators:

Lianne Jeffs, RN, MN, PhD(c)
Director of Nursing/Clinical Research
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30 Bond Street, Toronto, Ontario

Mona Sawhney, RN, MN, PhD(c)
PhD Student
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Judy Watt-Watson, RN, PhD
Academic Supervisor
Bloomberg Faculty of Nursing, University of Toronto
155 College Street, Toronto, Ontario

Project Funding: Registered Nurses Association of Ontario Best Practice Guidelines Fellowship

Purpose of the Research:

The purpose of the study is to investigate the impact of an individually delivered pre-operative preparation program for patients undergoing ambulatory inguinal hernia repair on pain after surgery.

Description of the Research:

You are being asked to participate in this study because you are male and have been scheduled for an elective (non-emergency) surgical repair of your inguinal hernia. You cannot participate in this study if you are having a repeat inguinal hernia repair or if you are undergoing emergency surgery.

If you agree to participate in this study you will be randomly assigned to receive the individualized pain education program or to receive the usual pain education. Also, you will be contacted by phone and asked several questions that will help us to understand how much pain you are experiencing and what helps you manage your pain after surgery. The pain education
program consists of the usual pain education plus written information in the form of a booklet, an individualized face to face education session and two telephone support calls (one before your surgery and one 24 hours after your surgery) about pain management once you go home. The individualized face to face session will take about 20 minutes and will occur in a private office in the pre-admission unit. Usual education care consists of written information about your surgery and managing pain plus a telephone call 24 hours after surgery. Regardless of which group you are in, you will receive the usual care related to pain relief after surgery.

Potential Harms, Injuries, Discomforts or Inconvenience:

If you who agree to participate in this study you will receive a phone call to answer a number of questions by phone 48 hours and 7 days after surgery.

Potential Benefits:

You may not directly benefit from this study, you will be given additional information about pain after surgery and how to manage it.

Confidentiality:

If you agree to participate in this study you will not be identified by name but only by a participant ID number. That number will not in any way be identifiable to you without the master ID sheet. The master ID list will be kept in a locked drawer separate from all data so your responses will not be directly identifiable to you. All data will be recorded on computerized files coded with the anonymous ID number as it is collected from you. The data will be encrypted and kept in a password protected file. Only people involved in the study will have access to your data but not to your personal identity. Data will be analyzed in an anonymous fashion, using the participant ID numbers only. All of your personal information will be destroyed once the study is complete.

Publication of Results:

The results of this study will be published as part of a PhD thesis at the University of Toronto, Faculty of Nursing and no information that can identify you will be included in the published results.

Participation and Withdrawal:

You have the right to withdraw from the study at any time. Withdrawal from the study will not affect your care in any way. If you withdraw from the study, any information collected from you to that time will be included anonymously in the study analysis.

Questions:

If you have any questions about the study, please call Mona Sawhney at 416-967-8591 or Dr. Judy Watt-Watson at 416-978-2850. If you have any questions about your rights as a research participant, please call Dr. Julie Spence, Chair of the Research Ethics Board, at 416 360 4000 x 2557.
Consent:

The research study has been explained to me, and my questions have been answered to my satisfaction. I have the right not to participate and the right to withdraw without affecting my care at St. Michael’s Hospital. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me.

I have been told that I have not waived my legal rights nor released the investigators or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

I consent to participate. I have been told I will be given a signed copy of this consent form.

I hereby consent to participate.

____________________________________
Name of Participant (please print)

____________________________________
Signature

____________________________________
Date

I confirm that I have explained the nature of the study to the participant. I have answered all questions.

____________________________________
Name of person who obtained consent

____________________________________
Position

____________________________________
Signature

____________________________________
Date
Consent to Participate in a Research Study

Title of Research Project: The Effect of an Individualized Education Intervention versus Usual Care on Pain Following Ambulatory Inguinal Hernia Repair

Investigators:
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155 College Street, Toronto, Ontario

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The pain education program consists of the usual pain education plus written information in the form of a booklet, an individualized face to face education session and two telephone support calls (one before your surgery and one 24 hours after your surgery) about pain management once you go home. The individualized face to face session will take about 20 minutes and will occur in a private office in the pre-admission unit. Usual education care consists of written information about your surgery and managing pain plus a telephone call 24 hours after surgery. Regardless of which group you are in, you will recieve the usual care releated to pain relief after surgery.

Potential Harms, Injuries, Discomforts or Inconvenience

If you who agree to participate in this study you will receive a phone call to answer a number of questions by phone 48 hours and 7 days after surgery.

Potential Benefits:

You may not directly benefit from this study, you will be given additional information about pain after surgery and how to manage it.

Confidentiality:

If you agree to participate in this study you will not be identified by name but only by a participant ID number. That number will not in any way be identifiable to you without the master ID sheet. The master ID list will be kept in a locked drawer separate from all data so your responses will not be directly identifiable to you. All data will be recorded on computerized files coded with the anonymous ID number as it is collected from you. The data will be encrypted and kept in a password protected file. Only people involved in the study will have access to your data but not to your personal identity. Data will be analyzed in an anonymous fashion, using the participant ID numbers only. All of your personal information will be destroyed once the study is complete.

Publication of Results:

The results of this study will be published as part of a PhD thesis at the University of Toronto, Faculty of Nursing and no information that can identify you will be included in the published results.

Participation and Withdrawal:

You have the right to withdraw from the study at any time. Withdrawal from the study will not affect your care in any way. If you withdraw from the study, any information collected from you to that time will be included anonymously in the study analysis.
Questions:

If you have any questions about the study, please call Mona Sawhney at 416-967-8591 or Dr. Judy Watt-Watson at 416-978-2850.

If you have any questions about your rights as a research participant, please call the Chair of the Research Ethics Board, at 905-845-2571.

Consent

The research study has been explained to me, and my questions have been answered to my satisfaction. I have the right not to participate and the right to withdraw without affecting my care at Halton Health. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me.

I have been told that I have not waived my legal rights nor released the investigators or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

I consent to participate. I have been told I will be given a signed copy of this consent form.

I hereby consent to participate.

I confirm that I have explained the nature of the study to the participant. I have answered all questions.

____________________________________
Name of Participant (please print)

____________________________________
Signature

____________________________________
Date

____________________________________
Name of person who obtained consent

____________________________________
Position

____________________________________
Signature

____________________________________
Date
Appendix F

Hernia Repair Education Intervention\(^1\) for Pain Management

If you have any questions contact
Mona Sawhney at: 416-xxxxxxx
mona.sawahney@utoronto.ca

Adapted with permission from Watt-Watson et al. (2004)\(^1\)

© Mona Sawhney 2009
Introduction:

This booklet discusses how to manage your symptoms after your inguinal hernia repair surgery. It explains ways to manage symptoms such as pain, nausea or constipation, and how to ask for help when you need it.
What is pain?

Pain is an unpleasant sensation that is different for every person.

There are many words people use to describe pain like: ‘soreness’, ‘discomfort’, or ‘aching’.

Pain can tell you when something is wrong with your body and when you need to ask for help.

People feel pain differently. You are the only one who knows about your pain. Inguinal hernia repair surgery can be painful because it involves skin, muscle and nerves being cut or moved. Walking and moving are important to help you recover after surgery but may cause some pain. Good treatments are available to manage your pain.
Why is pain relief so important?

Moderate to severe pain can stop you from being able to move around, breathing properly, and doing your usual activities like getting dressed or sleeping well. It also adds stress to your body and makes it harder to recover after your surgery. It is important for you to have as little pain as possible so that you can get moving sooner and get better faster.

There are many good treatments that can help to relieve pain after your surgery. This includes taking medicine for pain, holding your incision with a pillow when you are moving, and taking deep relaxing breaths. Everyone’s pain experience is different and you need to choose what works best for you. You can use more than one way to manage your pain at the same time.

Some people think they have to be “tough” and put up with the pain they have after surgery. Putting up with the pain can slow down your recovery and for some people it can lead to chronic pain. Good pain relief is possible with your help.
When do I treat my pain?

A pain rating scale can help you decide when to do something to relieve your pain. You can use a scale from 0 to 10 to determine how much pain you are having.

<table>
<thead>
<tr>
<th>0</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Worst Pain</td>
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</table>

You may find that your pain is less when you are resting and more when you are moving.

If your pain is 4 (moderate) or more you should treat your pain.

If the pain is stopping you from moving, you should treat your pain.
What drug treatments are available for pain relief?

You will receive a prescription for pain medicine that you can take at home. **It is important to have this prescription filled, even if you do not feel pain immediately after your surgery.**

You can ask your pharmacist for specific information regarding your prescription pain medicine. If this medicine does not control your pain you need to call your doctor.

Most patients have a prescription for Tylenol #3® or Percocet®. Tylenol #3® contains acetaminophen and codeine. Percocet® contains acetaminophen and oxycodone. You should not take more than 4000 mg of acetaminophen a day.

You may also be prescribed anti-inflammatory drugs (NSAID), such as ibuprofen or celecoxib. You can take these drugs in addition to Percocet® or Tylenol #3® as they work to relieve pain in different ways.
How often should I take pain medicine?

Medicine usually relieves pain for about 4 hours. You may have very little pain when you are resting but it is important to move around and walk. If your pain rating is 4 or more on the pain scale when you are moving you may need to take pain medicine every 4 hours.

Do not wait until your pain is severe to treat your pain.

Remember, pain is always easier to treat when it is mild or moderate. Pain medicine can take 30 to 40 minutes to start to work.

If you are taking your pain medicine regularly and your pain is still 4 or more (moderate or severe), you should contact your doctor to change your pain medicine. You may need to add another treatment for your pain.
What are common side effects of pain medicine?

Pain medicine can cause side effects such as constipation or nausea. Severe pain can also cause these side effects, so it is important to treat your pain. If you are experiencing side effects you may not want to move, eat, drink, or do your regular activities. It is possible to prevent or manage these side effects.

Constipation:

When you have constipation you may not feel like eating and you may experience nausea. You can prevent constipation by eating foods that are high in fibre and drinking plenty of fluids.

You may require a stool softener or laxative to relieve constipation. You can ask your pharmacist or doctor for a laxative that may work best for you.

Most people need at least 1800 mL (about 8 cups) of fluid, such as water, a day. Try to avoid drinks that contain caffeine as your main source of fluid (for example, cola, coffee, or black tea).

Foods that are high in fibre include: bran, whole grain bread, fresh fruits, dried fruit (such as prunes, apricots or figs), vegetables, and legumes (such as chick peas, lima beans and soya beans). Drinking prune juice or apple juice can also help relieve constipation.

You should not hold back the urge to have a bowel movement.
Nausea:

Nausea is an unpleasant experience and you may feel like vomiting. People have nausea after surgery because of severe pain, if they are dehydrated (do not drink enough fluid), or because of the pain medicine they are taking. To help prevent nausea take your pain medicine with food. If you experience nausea treat it right away.

Nausea can be treated with anti-nausea medicine. You can ask your pharmacist or doctor for medicine to treat your nausea.

Some foods and drinks that may help decrease nausea include: dry crackers, plain potato chips, and gingerale.
What non-drug treatments can be used to treat pain?

Non-drug treatments can also help to treat your pain after inguinal hernia repair surgery.

Patients have found the following helpful in addition to pain medicine:
- Use a small pillow to support your incision when moving or getting out of bed
- Do activities such a listening to music, reading, watching TV
- Take slow deep breaths when you have pain to help you relax
- Try meditation
- Walk or move around
What are patients' concerns about managing their pain?

Many patients have concerns that stop them from telling someone about their pain and/or using pain medicine.

**Concern:** I am not a ‘good’ patient if I tell someone about my pain.

**Response:** ‘Good’ patients do tell when they hurt. You are helping the nurses and doctors when you let them know you are having pain. We cannot help manage your pain effectively unless you tell us about your pain.

Unrelieved pain may slow healing and cause complications. People who have good pain control after surgery recover faster.

**Concern:** I don’t have pain; I have “discomfort” or “soreness”.

**Response:** Pain can be called other names. Use the pain scale to rate your pain. If your rating is 4 or more when you move you should treat your pain. If your pain is stopping you from moving, you should treat your pain.

**Concern:** I am afraid to take pain medicine because of addiction.

**Response:** Addiction is a rare problem (less than 0.01%) for people taking pain medicine unless they already have a drug abuse problem.
**Concern:** I am afraid to take pain medicine because it makes me feel sick.

**Response:** Side effects such as constipation and nausea are treatable. Do not refuse to take pain medicine because it makes you feel sick. Remember, severe pain can also cause nausea or constipation.
Remember

Pain relief is important for your recovery

Every person’s pain is different

Good methods are available to treat your pain

If your pain is not controlled, tell your doctor
Appendix G

Individualized Concerns Checklist

<table>
<thead>
<tr>
<th>Participant identified concern</th>
<th>Pre-operative clinic</th>
<th>Pre-operative support call</th>
<th>Post-operative support call</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition of pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Importance of managing pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communicating pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When to use analgesics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse effects of analgesics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-pharmacological methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Addiction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Being able to handle the pain</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix H

Peri- operative Inguinal Hernia Questionnaire (PIHQ)

Part 1: To be completed during the pre-admission visit after consent is obtained.

Date of Birth: D □□/M □□/Y □□□□

Partner Status: Married/ partner ☐

Single/ Widow/ Divorced ☐

Type of residence: single story apartment or home ☐

Multiple story apartment or home ☐

Living arrangements:

alone ☐

With family ☐

With friends/others ☐

Previous surgery: yes ☐ no ☐

If yes: type of surgery:

______________________________

Employment status: working ☐

In school ☐

Retired/currently not working ☐

If you are working or attending school, when do you anticipate you will return to work or school? ________________________________
PIHQ Part 2: To be completed prior to discharge following surgery

Time of OR: __ __ __ __

Time of discharge home: __ __ __ __

Type of IHR: R open □
L open □
R laparoscopic □
L laparoscopic □

Type of anesthetic: spinal □
General □
Sedation with local anesthetic □

Analgesics received while in hospital (please list type and dose):

______________________________________________________
______________________________________________________
______________________________________________________
______________________________________________________

Discharge analgesic prescription:

Acetaminophen (300mg) + codeine (30mg) + caffeine (15mg) □
Acetaminophen (300mg) + codeine (15mg) + caffeine (15mg) □
Acetaminophen (300mg) + codeine (7.5mg) + caffeine (15mg) □
Acetaminophen (325mg) + oxycodone (5mg) □
Acetaminophen (325mg) + tramadol (37.5mg) □
Appendix I

Analgesics and Adverse Effects Questionnaire

List the pain medicine and how much medicine that you have used in the previous 24 hours to manage your pain:

_____________________________________________________________________________
_____________________________________________________________________________

Circle the number that describes how, during the past 24 hours, how much pain medicine has caused the following adverse effects:

<table>
<thead>
<tr>
<th>0 = not present</th>
<th>10 = present and very bothersome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
</tr>
<tr>
<td>Sedation</td>
<td></td>
</tr>
<tr>
<td>Urinary Retention</td>
<td></td>
</tr>
</tbody>
</table>

Other (please describe)
Appendix J

Non-Pharmacological Intervention Inventory (NPI)

Place a check mark in the box(es) next to the modalities used to manage pain in the previous 24 hours.

☐ Rest

☐ Exercise (please describe: ____________________________)

☐ Massage

☐ Pillows to support incisions

☐ Relaxation/ meditation

☐ advice on how to move, turn and sit up

☐ Distracting activities:

☐ watching television

☐ music

☐ reading

☐ other: ______________________________________________________
## Appendix K

Patient Concerns Regarding Pain Management Individual Items (Barriers Questionnaire - SF)

<table>
<thead>
<tr>
<th>Items</th>
<th>Usual care group</th>
<th>Intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td>(0-10)</td>
<td>n = x</td>
<td>n = x</td>
</tr>
<tr>
<td>Pain medicine cannot really control pain</td>
<td>1.8 (1.6)</td>
<td>1.6 (1.7)</td>
</tr>
<tr>
<td>Addicted to pain medicine easily</td>
<td>2.0 (1.5)</td>
<td>2.0 (1.6)</td>
</tr>
<tr>
<td>Good patients avoid talking about pain</td>
<td>1.2 (1.6)</td>
<td>1.3 (1.2)</td>
</tr>
<tr>
<td>Easier to put up with pain than side effects</td>
<td>2.0 (1.5)</td>
<td>2.1 (1.4)</td>
</tr>
<tr>
<td>Distract a physician from treating my illness</td>
<td>1.1 (1.6)</td>
<td>1 (1.2)</td>
</tr>
<tr>
<td>Pain medicine should be ‘saved’</td>
<td>1.8 (1.8)</td>
<td>1.6 (1.6)</td>
</tr>
<tr>
<td>Pain is a sign that the illness has gotten worse</td>
<td>2.0 (1.7)</td>
<td>1.8 (1.6)</td>
</tr>
</tbody>
</table>
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