Title page:

Title of the study:

The effect of A New Perioperative Practice Model on Patient, Nursing and Organisational Outcomes

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The online addresses of the publications concerning this study:

Study Protocol:

Background

Earlier research findings show that when a caring encounter is established where the nurse informs the patient about the perioperative process and its proceedings and educates the patient, a significant impact on both postoperative pain and the recovery from surgery can be achieved (Bager et al. 2015, Bailey 2015, Johansson et al. 2014). Also, anxiety increases the postoperative pain and slows down the recovery from surgery (Marks 2015). An earlier investigation comparing recovery of general surgery patients to orthopedic patients showed that overall, the orthopedic patients were less recovered in the acute recovery phase as well as after one month postoperatively. The most common reason for slow recovery was pain, which was ranked high in the acute recovery phase for both orthopedic and general surgery patients. The authors state that support for the orthopedic patients must be improved (Forsberg et al. 2015).

An investigation conducted by McHugh et al. (2013) revealed that patients experience improvement in psychosocial and biomedical outcomes at six months after hip replacement. The strongest predictors of recovery were anxiety and depression, pain, previous joint surgery and taking pain medication. By recognizing these factors nurses are able to identify and provide more support for patients at risk of poor recovery after hip replacement.

Mandzuk et al. (2015) conducted a longitudinal retrospective study with total hip replacement and total knee replacement patients (N=851). The study examined self-reported quality of life and functional status over the preoperative and postoperative periods: the measurements were taken 12 months prior to surgery, one month prior to surgery and 12 months postoperatively. The results revealed that patients who had a total hip replacement tended to demonstrate higher improvement than total knee replacement patients. Male patients reported higher levels of physical and mental quality of life as well as functional status than women. Mental health scores were consistently lower in both hip replacement and knee replacement patients across the perioperative period and up to one year postoperatively compared to the reference values utilizing the SF-12 instrument (Ware et. al 1996). Thus, there is an opportunity for health care providers to proactively address the mental health of hip and knee replacement patients throughout their joint replacement trajectory. The nurses' preoperative assessment may be useful in identifying and defining patients' risk factors not only for surgery but for the entire perioperative care. The nurse's role in the preoperative assessment is that of an advocate who identifies the patient´s needs and risk factors that may be affected by the surgical experience (Malley et al. 2015). The shortened hospital stays nowadays require optimizing assessment and care management by focusing on patients' greater health care needs and by tailor made care information and skills to patients' individual needs (Su et al. 2010).

This research follows a pilot study, where a new perioperative model of caring was tested with patients (n=19) undergoing a hip or a knee replacement surgery under spinal anesthesia (Pulkkinen et al. 2015). In this new model the one and same anesthesia nurse took care of the patient during the entire perioperative process (pre-, intra- and postoperative phase) and visited the patient to the surgical ward the next day after surgery. The study findings showed that the patients experienced the new model of perioperative care as beneficial. Patients experienced that they were taken seriously and that they had the opportunity to participate in their own care. They also experienced the emotional support important. Thus, the new model had influence on patient satisfaction and on the individual care. The patient safety was even

ensured; no complications or medical errors were reported concerning the patients in the study sample. The same nurse cared for the patient during the entire perioperative process, and this might have diminished the possibilities for occurring errors. For example, the reduced information transfer increases the patient safety (WHO 2007).

There are several concerns in current specialized health care that this research will address. The length of hospital stay has shortened; thus, the patients must feel safe to cope with their recovery at home. Earlier research findings show that when a caring encounter is established where the nurse educates the patient about the perioperative process has significant impact on both postoperative pain and the recovery (Bager et al. 2015, Bailey 2015, Johansson et al. 2014. Also, the new health care legislation in Finland gives the patients right to choose the place of care. Therefore, patient satisfaction is an important part of organizations' competitiveness. This research deals with a high-volume hospital service. Altogether the amount of surgical procedures performed in Finland during 2015 was 362 552 (Sjöholm/Kuntaliitto 2016). Further, the health care organizations have to deal with lack of nursing resources. This new practice may influence engagement of nurses.

Aim and objectives

The aim of this study is to improve the surgical patients' care process. The objective is to explore the effect of a new perioperative practice model on 1) patient outcomes (satisfaction, surgery-related anxiety and quality of life), 2) nursing outcomes (organizational engagement), and 3) organization outcomes (timeline of surgical care process).

The study is part of Dr. Junttila's Post doc research project "Knowledge-based management in perioperative nursing". At the same time it links to professor Lindwall's research projects concerning the Perioperative Dialogue.

Methods

Study design

A longitudinal untreated control group design with pre- and posttests will be followed.

Study sample and setting

The study will be conducted at the Helsinki University Hospital; more specifically at the operating department K of the Peijas Hospital. The study population consist of adult female and male patients scheduled for either total hip arthroplasty (THA) or total knee arthroplasty (TKA). A control group and an experimental (intervention) group will be formed. The participants are recruited at their preoperative visits to the outpatient clinic two to three weeks prior to their scheduled operations. The inclusion criteria: 18 years of age or older, able to comprehend the study information and complete the questionnaires, and operation being performed under spinal anesthesia. One exclusion criterion for the intervention group is that the planned surgery is performed on Friday, because the postoperative visits cannot be performed during the weekend.

Randomization and sample size

Randomization of participants is performed by independent third parties (two nurse assistants at the outpatient clinic). All patients scheduled for THA and TKA attending the outpatient clinic are considered eligible and invited to participate in randomization if they meet the inclusion criteria. Eligible patients will draw one of two cards; one indicate an invitation to participate the study and the other is blank, indicating no participation in the study. Patients in the control group will be recruited every other week and patients for the intervention group every week between. This pattern will be repeated until the desired number of patients are recruited. This stratification will ensure that patients in different groups do not exchange information in the postoperative ward. The sample size requirement for comparing two means was checked with power analysis (2-sided test) with α = 0.05, β = 0.9, standard deviation 0.08, and differences of means 0.03 in 15D scores, which is within the slight difference of 0.015-0.035 (Alanne, Roine, Räsänen, Vainiola, & Sintonen, 2015). A sufficient sample size is determined to be 152 per group.

Intervention

Traditionally during the intra- and postoperative phases of surgical care, the patient is cared for by several nurses; i.e. by an anesthetic nurse in the operating room and by a recovery room nurse in the Post Anesthesia Care Unit (PACU). Furthermore, the pre- and postoperative visits to the surgical patients are rare in Finland; mainly due to resources and new surgical processes where patients arrive to the hospital in the morning of the scheduled procedure.

The new perioperative practice model denotes that the one and same nurse will meet the patient at his/her arrival to the operating department, and will care for the patient both in the operating room and in the PACU. Thus, the nursing care in the operating room and in the PACU remains the same but will be organized in a new way which focuses on the patient centered individual care and the continuity of care. Furthermore, the same nurse will visit the patient at the surgical unit on the first postoperative day.

Data collection and Outcome Measures

The demographic data of the participants includes age, gender, diagnosis, procedure, and ASA class (ASA Physical Status Classification 2014). Further patient data will be collected by 1) The Good Perioperative Nursing Care Scale (Leinonen & Leino-Kilpi 2001) measuring the quality of perioperative care; 2) 15D instrument measuring the health-related quality of life among adults (Sintonen 2001) and 3) STAI, the State-Trait Anxiety Inventory; measuring anxiety in adults (Spielberger et al. 2010). The schedule for patient data collection is presented in Table 1.

Table 1. Schedule of patient data collection

Instrument	Baseline (preoperative visit 2-3 weeks prior to surgery)	Cross-section (at discharge)	Post-test (three months after discharge)
15 D	x		x
STAI	x		x

		x	
Good Perioperative Nursing Care Scale			

Primary Outcome Measures

1. Change from baseline Health Related Quality of Life (HRQoL) at three months after the surgical procedure. Time Frame: Baseline 2-3 weeks prior to, and post-measurement 3 months after the procedure (The 15D instrument)

Secondary Outcome Measures

1. Change from baseline Surgery-related anxiety at three months after the surgical procedure. Time frame: Baseline 2-3 weeks prior to, and post-measurement 3 months after the procedure (The State-Trait Anxiety Inventory (STAI)

2. Quality of perioperative care as experienced by surgical patients. Time frame: On average the third postoperative day, depending the time of discharge (Good Perioperative Nursing Care Scale)

<u>**Ethical considerations**</u>

The ethical codes and good scientific practice (TENK 2012) will be followed throughout the research. Participants will get written and oral information about the study, and a written informed consent will be asked. The participants will be informed about their right to decline from the study at any time, and they are told that this will not affect their care in any way. They also have the right to withdraw their consent in which case their data will not be used in the study. This clinical trial has been approved by the Operative (surgical) Ethical Committee of Helsinki University Hospital (decision number §16/27.7.2016). Permissions to use instruments (15D, STAI, Good Perioperative Nursing Care Scale) have been asked from the copyright holders.

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Statistical Analysis Plan:

Descriptive statistics will be used to present characteristics of the study participants. One- and multi-way analysis of variance will be used to compare means of groups. Interaction terms will be used to compare means of the groups defined by combinations of categorical independents. Tukey's adjustment will be used to account for multiple comparison if necessary. Statistical significance of dependencies between categorical variables are tested using Chi-square tests. SAS® statistical software, version 9.4 (SAS Institute Inc., Cary, NC, USA) will be used in statistical analysis.

In the analysis of the patient data, collected with the GPNCS, if a respondent answers to less than 50% of the quality statements, his or her response will be excluded from the analysis. Frequencies and percentages obtained with the Pearson chi-square test are calculated for the background data. Non-parametric tests are used when comparing background factors with quality categories. The reliability of the scale is checked with a Cronbach's alpha coefficient. In the analysis of data sets, the non-parametric tests will include the Kruskall-Wallis test and Mann Whitney U-test with Bonferroni corrections. A p-value of 0.05 is considered statistically significant.