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RESEARCH ARTICLE

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A randomized clinical trial of a new perioperative practice model on anxiety and health-related quality of life in arthroplasty patients

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Abstract

Aims: To explore the effectiveness of a new perioperative practice model on anxiety and health-related quality of life in patients undergoing total hip arthroplasty and total knee arthroplasty under spinal anaesthesia.

Design: A randomized clinical trial.

Methods: Control group participants (N = 222) received standard perioperative care, meaning they were cared for by various nurses during their perioperative process without postoperative visits. Intervention group participants (N = 231) were assigned one named anaesthesia nurse during their entire perioperative process who visited them postoperatively. Both groups responded to two self-reported questionnaires: the generic 15D health-related quality of life instrument and the State-Trait Anxiety Inventory (STAI) measuring anxiety two to three weeks pre-operatively and three months postoperatively.

Results: There were no statistically significant differences between the groups at baseline or at follow-up in health-related quality of life or anxiety.

KEYWORDS

anxiety, continuity, health-related quality of life, nursing, perioperative practice model, randomized clinical trial

1 | INTRODUCTION

People globally suffer from osteoarthritis (OA), a chronic disease listed among the ten most disabling diseases in developed countries (WHO, 2001). Usually, OA causes pain, deformity of the joints, fatigue and anxiety, reducing both physical and psychological functioning. These symptoms influence health-related quality of life (HRQoL) in persons suffering from OA. Total hip arthroplasty (THA)

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and total knee arthroplasty (TKA) are highly effective surgical treatments for end-stage OA with the intent to improve both HRQoL and functional status (Specht et al., 2015). Advanced surgical and anaesthetic techniques have shortened arthroplasty patients' length of stay in hospitals (LOS). Other reasons for shorter LOS include increasing outpatient surgery activity and fast-track protocols comprising standardized pre-operative information, education, special anaesthetic techniques, multimodal pain management, early mobilization and active patient participation (Husted et al., 2011). Despite these medical advances, the perioperative practice model delivered by nurses has not changed over the years. The shortened LOS might be challenging both for patients and perioperative nurses because the shared time between patients and nurses is even more limited; still, the emphasis on perioperative nursing is on supporting the recovery and self-management of the patient. Patients do not form a uniform group; they are individuals with specific care needs and resources. All patients might not fit into the fast-track protocols without extra encouragement and emotional support for timely recovery and self-management.

An operation is a unique situation with an unknown outcome that may create insecurity, nervousness and a feeling of loss of control over one's life. These psychological factors cause anxiety and may result in decreased ability to concentrate and difficulties in comprehending information concerning care (Vaughn, 2007). They might even affect patients' responses to anaesthetic and analgesia intraoperatively. Patients' discharge from hospital might be delayed due to increased pain and delayed wound healing caused by anxiety (Pritchard, 2009). Up to 75% of patients undergoing surgery are reported to suffer from surgery-related anxiety (Kühlmann et al., 2018; Montin et al., 2008). Regarding the shortened LOS for patients undergoing arthroplasty, anxiety is a serious phenomenon to take into consideration. To meet the current demands of nurse-delivered perioperative care, new interventions focusing on continuity and quality of care are needed (Eurostat, 2017). As a standard in current perioperative nursing practice, the patient is cared for by several nurses in the operating department (i.e. in an operating room and post-anaesthesia care unit, PACU). The information obtained by the patient might be fragmented in terms of being received from multiple nurses. This might cause confusion, insecurity, lack of confidence, and even increased anxiety, resulting in decreased HRQoL. The new perioperative practice model (NPPM) proposed in this study focusing on continuity of care could be useful in diminishing anxiety and improving HRQoL in patients undergoing THA and TKA.

1.1 | Background

Untreated OA causes pain and reduces physical and social functioning, increasing the need for help in daily life and support from family members while waiting for surgery. The constant pain and restricted physical functioning causes anxiety and a decreased HRQoL. Bachrach-Lindström et al. (2008) evaluated the impact of the waiting time on HRQoL and concluded that a long waiting time (three to twelve months) for THA may harm patients' HRQoL. Another study's findings indicated that long waiting time for surgery may reduce HRQoL for years. This study showed that THA resulted in pain relief, improved physical function, and enhanced HRQoL regardless of patients' characteristics or type of operation. Patients' poor pre-operative function was found to affect outcomes; these patients were more likely to have postoperative pain and low postoperative physical function (Montin et al., 2007). In a randomized controlled trial by Hirvonen et al. (2007), the findings showed the opposite; a long waiting time in TKA patients did not influence their HRQoL.

Patient satisfaction might also be affected by anxiety. In one study of patients undergoing THA and TKA, findings showed that the prevalence of anxiety and depressive symptoms was high pre-operatively but decreased at three to twelve months postoperatively. However, patients with pre-operative anxiety and depressive symptoms had worse patient-reported outcomes at three and twelve months postoperatively, and they were less satisfied than patients without anxiety or depressive symptoms (Duivenvoorden et al., 2013). Negative emotional state seemed to be related to poorer recovery, and greater satisfaction with nursing care was associated with better quality of recovery (Johansson Stark et al., 2016).

Various interventions have been conducted aiming to diminish anxiety in patients undergoing surgery, with varying success. A recent systematic review of music interventions concluded that music might have the potential to improve outcomes in patients undergoing hip or knee surgery (Sibanda et al., 2019). Pre-operative visits can diminish anxiety prior to surgery and decrease postoperative complications, according to earlier studies (Gürsoy et al., 2016; Sadati et al., 2013).

Nurse–patient communication has been reported to impact positive patient experiences and could be enhanced by noticing the individual needs of anxious patients (Johansson Stark et al., 2014; Lane et al., 2016; Mitchell, 2012; Rodríguez-Martín et al., 2019; Sjøveian & Leegaard, 2017). Individualized and person-centred nursing interventions are reported to be valuable in assessing anxiety in patients undergoing THA or TKA, reducing their anxiety, and improving HRQoL (Djukanovic et al., 2011; Olsson et al., 2014). Patients experience good surgical care when they have been treated as active partners in their care and the nurse has educated and informed the patients, giving them the opportunity to affect their own care (Johansson Stark et al., 2016; Mako et al., 2016). Interventions enabling continuity of care have been reported efficient among patients in day surgery (Suominen et al., 2014), midwifery (McInnes et al., 2018; Perriman et al., 2018; Viveiros & Darling, 2018), and primary care (Bazemore et al., 2018; Wright & Mainous, 2018) but have not been reported in perioperative environments with arthroplasty patients.

To synthesize: According to earlier research findings, anxiety has many side effects that delay recovery from THA and TKA, affecting HRQoL and overall patient satisfaction. Patient-centred and individual nursing interventions have been reported efficient in diminishing anxiety and enhancing recovery in arthroplasty patients. The common factor for these interventions

is communication, person-centredness, patient involvement, and emotional support. What is not known is how effective continuity-enabling interventions are on anxiety and HRQoL in arthroplasty patients.

This randomized clinical trial (RCT) aimed to explore the effectiveness of the NPPM on anxiety and HRQoL in patients undergoing THA or TKA under spinal anaesthesia. The RCT was based on a pilot study in which the NPPM was tested with a qualitative approach with patients (n = 19) undergoing either THA or TKA under spinal anaesthesia (Pulkkinen et al., 2016). The NPPM emerges from the model of perioperative dialogue (Lindwall & Von Post, 2009; Lindwall et al., 2003), developed from a caring science perspective as an ideal model for organizing perioperative care from a philosophical point of view (Eriksson, 2002).

The perioperative dialogue was operationalized as the NPPM with the aim of focusing on the continuity of patients' care by assigning a patient to the care of the same anaesthesia nurse (AN) throughout the perioperative process. In this study, the perioperative process refers to pre-, intra-, and postoperative phases spent in the hospital in connection to the actual arthroplasty. The NPPM is a theoretical framework guiding perioperative nurses to meet and to care for the individual patient in practice.

The concept of "continuity" in the NPPM encompasses person-centredness and individual care, while the patient has access to their own assigned anaesthesia nurse physically and emotionally. Three types of continuity have been identified by Haggerty et al. (2013): informational, management and relational. These types of continuity exist in all settings, but the emphasis on specific types of continuity varies with the setting. Our study deals with relational continuity (Haggerty et al., 2013), meaning that patients interact with their assigned nurse throughout their perioperative process. The mutuality of the patient–nurse relationship was expected to foster patients' involvement, trust, comfort, and sense of emotional support, resulting in diminished anxiety and improved HRQoL. The pilot study findings showed that the patients experienced the NPPM as beneficial; patients felt that they were taken seriously and that they had the opportunity to participate in their own care. They also experienced emotional support as crucial (Pulkkinen et al., 2016). The continuity created by the NPPM is part of high-quality patient care, the encouraging findings of the pilot study led to the current RCT.

The problem addressed in this study was anxiety, which is known to diminish HRQoL in arthroplasty patients. Our intention was to investigate the effectiveness of the NPPM, which enabled relational continuity of care, in turn expected to diminish anxiety and thereby improve HRQoL for patients. Patients undergoing THA and TKA need to feel safe and confident with early discharge from the hospital. Since anxiety seems to influence patient outcomes severely and might even jeopardize timely discharge, we found the RCT to be justified.

The research questions of the study were as follows:

- What is the effectiveness of the NPPM on anxiety and HRQoL compared to the standard perioperative nursing practice measured with STAI and 15D instruments?
- How does the NPPM influence anxiety and HRQoL from baseline to follow-up three months postoperatively?

2 | THE STUDY

2.1 | Aim

To explore the effectiveness of the NPPM on anxiety and HRQoL in patients undergoing THA or TKA under spinal anaesthesia.

2.2 | Hypotheses

We hypothesized that the intervention group would have statistically significantly higher mean improvements in anxiety and HRQoL compared to the control group.

2.3 | Design

A two-group parallel, single-blind, randomized clinical trial. The randomized participants in the study were masked. They did not know to which group they were recruited and did not meet the participants from the other group. None of the researchers participated in the randomization or care of the study participants. The named anaesthesia nurses were not masked due to the nature of the intervention, so that they could care for the patient according to the protocol.

2.3.1 | Participants and setting

The study was performed at one operating department in a university hospital in southern Finland. The bed capacity in this hospital is 380, and the average number of operations performed per year is over 9000, out of which over 6000 is orthopaedic operations. The number of healthcare professionals working in this hospital is 2900.

The study population consisted of adult female and male patients scheduled for either THA or TKA. The participants were recruited at their pre-operative visits to the outpatient clinic two to three weeks prior to their scheduled operations. The inclusion criteria for the patients were: 18 years of age or older, able to comprehend the study information and complete the questionnaires, and operation being performed under spinal anaesthesia. One exclusion criterion for the intervention group was the planned surgery on Friday, because the postoperative visits could not be performed during the weekend.

The sample size requirement for comparing two means was checked with power analysis (2-sided test) with $\alpha = 0.05$, $\beta = 0.9$, 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 et al., 2015). The randomization ratio was 1:1. A sufficient sample size was determined to be 152 per group.

2.3.2 | Randomization

Randomization of participants was performed by independent third parties (two nurse assistants at the outpatient clinic). All patients scheduled for THA and TKA attending the outpatient clinic were considered eligible and invited to participate in randomization if they met the inclusion criteria. Eligible patients drew one of two cards; one indicated an invitation to participate the study and the other was blank, indicating no participation in the study. Patients in the control group were recruited every other week and patients for the intervention group every week between. This pattern was repeated until the desired number of patients was recruited. This stratification ensured that patients in different groups did not exchange information in the postoperative ward.

2.3.3 | Intervention

Intervention group (NPPM care)

The NPPM included an assigned AN meeting the patient at his or her arrival to the operating department and caring for the patient both in the operating room (OR) and in the PACU. The patients in both groups received the same medical care, nursing care, postoperative pain control, rehabilitation, exercise, and wound care. Nursing care in the OR and the PACU remained the same but was organized in a new way to focus on patients' continuity of care. Furthermore, the assigned AN visited the patients in the surgical unit on the first postoperative day. At the postoperative visit, each nurse had an opportunity to evaluate the perioperative care together with the patient. Working hours for the ANs were arranged so that they worked in the OR and moved with the patient to the PACU after the operation. After the patient was discharged from the PACU to the ward, the AN returned to the OR. One AN started at 7:30 in the morning and was assigned to the OR. Another assigned AN started at 10:00 in the morning and took care of the patient who was scheduled second in the OR while the first patient moved with his or her AN to the PACU, thus carrying out the NPPM.

Control group (standard perioperative nursing practice)

In the standard perioperative nursing practice, the patient is cared for by several nurses during the perioperative process. For example, an AN care for the patient in the OR, and a recovery nurse attends the patient in the PACU. Furthermore, pre- and postoperative visits to surgical patients are rare in the unit where the study was performed, mainly due to the present way of organizing the work and the quick surgical processes (the patient arrives in the hospital on the morning of the scheduled procedure). The patients in the control group received standard perioperative nursing practice without postoperative visits.

2.3.4 | Outcome measures

Two instruments were used for data collection. The 15D instrument was used to measure HRQoL. The 15D is a generic, standardized, self-administered, fifteen-dimensional instrument that can be used both as a single-scored measure and a profile. The questionnaire comprises the following dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental functioning, discomfort and symptoms, depression, distress, vitality, and sexual activity. The respondent chooses one of five levels for each dimension that best describes his or her state of health at present; the best level is 1 and the worst is 5. The valuation system of the 15D is based on an application of the multi-attribute utility theory. The single index score (15D score), representing the overall HRQoL on a 0–1 scale (1 = full health, 0 = being dead) and the dimension level values reflecting the levels relative to no problems on the dimension (=1) and being dead (=0), are calculated from the health state descriptive system using a set of population-based preference or utility weights. Mean dimension level values are used to draw 15D profiles for groups (Sintonen, 2001). The minimum clinically important change or difference in the 15D score has been estimated to be ± 0.015 on the basis that people can, on average, feel such a difference (Alanne et al., 2015).

The other instrument used in this study was the State-Trait Anxiety Inventory (STAI), which measures situational anxiety (state anxiety, STATE) and anxiety tendency (trait anxiety, TRAIT); that is, the individual tendency to experience anxiety. This instrument is composed of STATE and TRAIT scores, each of which having twenty items. The STATE items evoke feelings on a 4-point Likert scale, with responses ranging from 1 (*not at all*) to 4 (*very much*). The TRAIT items evoke general feelings on a frequency scale ranging from 1 (*hardly ever*) to 4 (*almost always*). The scores from the both STATE and TRAIT scales are obtained by totalling the ratings (range 20 to 80 on both scales); (Koivula et al., 2002, 2010); Spielberger et al., 1983; Spielberger et al., 2010). Permission to use the 15D and STAI instruments was obtained from the stakeholders.

The data collected from the participants included age, gender, surgical procedure, and ASA score (Doyle & Garmon, 2018); (Table 1).

2.4 | Data collection

Data collection began in September 2016 and was completed in December 2017. Two nurse assistants at the outpatient clinic were supervised and trained by the first author to inform eligible candidates about the study and invite them to participate. The first author prepared envelopes containing the two questionnaires (15D and STAI), written research information, and the informed consent form in duplicate (one for the participant and one for the first author to keep in a locker). The envelopes were labelled indicating either the intervention group or control group and brought to the outpatient clinic in advance during the first week (control group recruitment) and the second week (intervention group recruitment) of recruitment.

2.5 | Validity and reliability

Both instruments used in this study were validated and reliable. They have been used worldwide and translated into several

TABLE 1 Characteristics of the study participants (total $n = 453$)

Intervention group	Age (mean, *SD*) 67 (*SD* 10.41)	ASA 1 $n = 30$	ASA 2 $n = 102$	ASA3 $n = 97$	ASA 4 $n = 2$	Total $n = 231$
Female THA	67.2 (8.79)	12	44	32	1	89 (38.5%)
Male THA	62.9 (11.52)	9	23	22	1	55 (23.8%)
Female TKA	71.4 (10.99)	6	23	28	0	57 (24.7%)
Male TKA	66.1 (8.53)	3	12	15	0	30 (13.0%)
Control group	**Age (mean, *SD*) 68 (*SD* 10.48)**	**ASA 1 $n = 33$**	**ASA 2 $n = 108$**	**ASA 3 $n = 78$**	**ASA 4 $n = 3$**	**Total $n = 222$**
Female THA	65.8 (10.87)	17	41	22	0	80 (36.0%)
Male THA	68.1 (9.70)	6	32	19	2	59 (26.6%)
Female TKA	70.3 (10.10)	9	23	26	1	59 (26.6%)
Male TKA	70.2 (10.98)	1	12	11	0	24 (10.8%)

Note: ASA 1: A normal healthy individual. Fit, non-obese (BMI under 30), nonsmoker with good exercise tolerance.

ASA 2: A patient with mild systematic disease. Individual with no functional limitations and well-controlled disease (e.g. treated hypertension, obesity with BMI under 35, frequent social drinker or is a cigarette smoker).

ASA 3: A patient with severe systematic disease that is not life-threatening. A patient with some functional limitations as result of disease (e.g. poorly treated hypertension or diabetes, morbid obesity, chronic renal failure a bronchospastic disease with intermittent exacerbation, stable angina, implanted pacemaker).

ASA 4: A patient with a severe systematic disease that is a constant threat to life. A patient with functional limitation from severe, life-threatening disease (e.g. unsuitable angina, poorly controlled COPD, symptomatic CHF, recent (less than three months ago) myocardial infarction or stroke (Doyle & Garmon, 2018)).

languages. The 15D instrument has been developed in Finland with Finnish population (Sintonen, 2001; Sintonen 1995). The State-Trait Anxiety Inventory for Adults used in this study was a licensed, translated version obtained with permission from Mind Garden, Inc. (Spielberger, 2010). The STAI inventory has been used with Finnish population earlier (e.g. Koivula et al., 2002, 2010; Montin et al., 2007). The results of the study are reported in accordance with the CONSORT 2010 Statement (Moher et al., 2012).

2.6 | Ethical considerations

Study participants got written and oral information about the study, and a written informed consent was obtained from each participant. They were informed about their right to withdraw from the study at any time, which would not affect their care in any way. The physical documents (questionnaires) were stored in a locker by the first author. The study was approved by the Ethical Committee at the University Hospital (decision number §114/11.5.2016, Dnr. 157/13/03/02/16). The study permission was obtained from the hospital authorities (decision number §16/215/2016).

2.7 | Data analysis

Descriptive statistics were used to present characteristics of the study participants. One- and multi-factor ANOVAs were used to compare means of the groups. Interaction terms were used to compare means of the groups defined by combinations of categorical independents. Tukey's adjustment was used to account for multiple comparisons if necessary. Statistical significance of potential differences between the groups in the distributions of categorical variables was tested using chi-square tests. Statistical analysis was performed using SAS® version 9.4.

At randomization, no subgroups were fixed. According to a bibliometric analysis by Mansukhani et al. (2016), gender has often been ignored in human surgical clinical research. Thus, in post hoc analysis, the outcomes were tested for gender and the type of surgical procedure (THA versus TKA).

3 | RESULTS

3.1 | Demographic characteristics

The final sample size was 222 participants in the control group and 231 in the intervention group. Out of the 453 participants, 63% ($n = 285$) were females. The patients' ages ranged from 29 to 92 years (mean 67 years, *SD* 10.44). No significant differences were found between the participants in the control and intervention groups in baseline characteristics (Table 1). The response rate of the 15D questionnaire in the intervention group was 91% at baseline and 65% at follow-up and 85% and 61%, respectively, in the control group. The response rate for the state anxiety questionnaire was 86% at baseline and 67% at follow-up in the intervention group and 86% and 61%, respectively, in the control group. A comparison of the baseline characteristics of the respondents and non-respondents in the follow-up questionnaires showed that the dropout was random (Figure 1).

3.2 | Changes in the HRQoL from baseline to follow-up

No statistically significant difference between the intervention and control groups could be detected in the mean 15D scores. At baseline, the difference (intervention versus control group) of means between the groups was −0.019, *SD* 0.08, 95% CI [−0.040, 0.001] and at follow-up, −0.016, *SD* 0.08, 95% CI [−0.041, 0.008]. Furthermore, no statistically significant difference between baseline and follow-up was seen in either THA or TKA patients. The HRQoL total index scores of 15D at baseline and follow-up, with means and SDs are presented in Table 2. There was no statistically significant difference

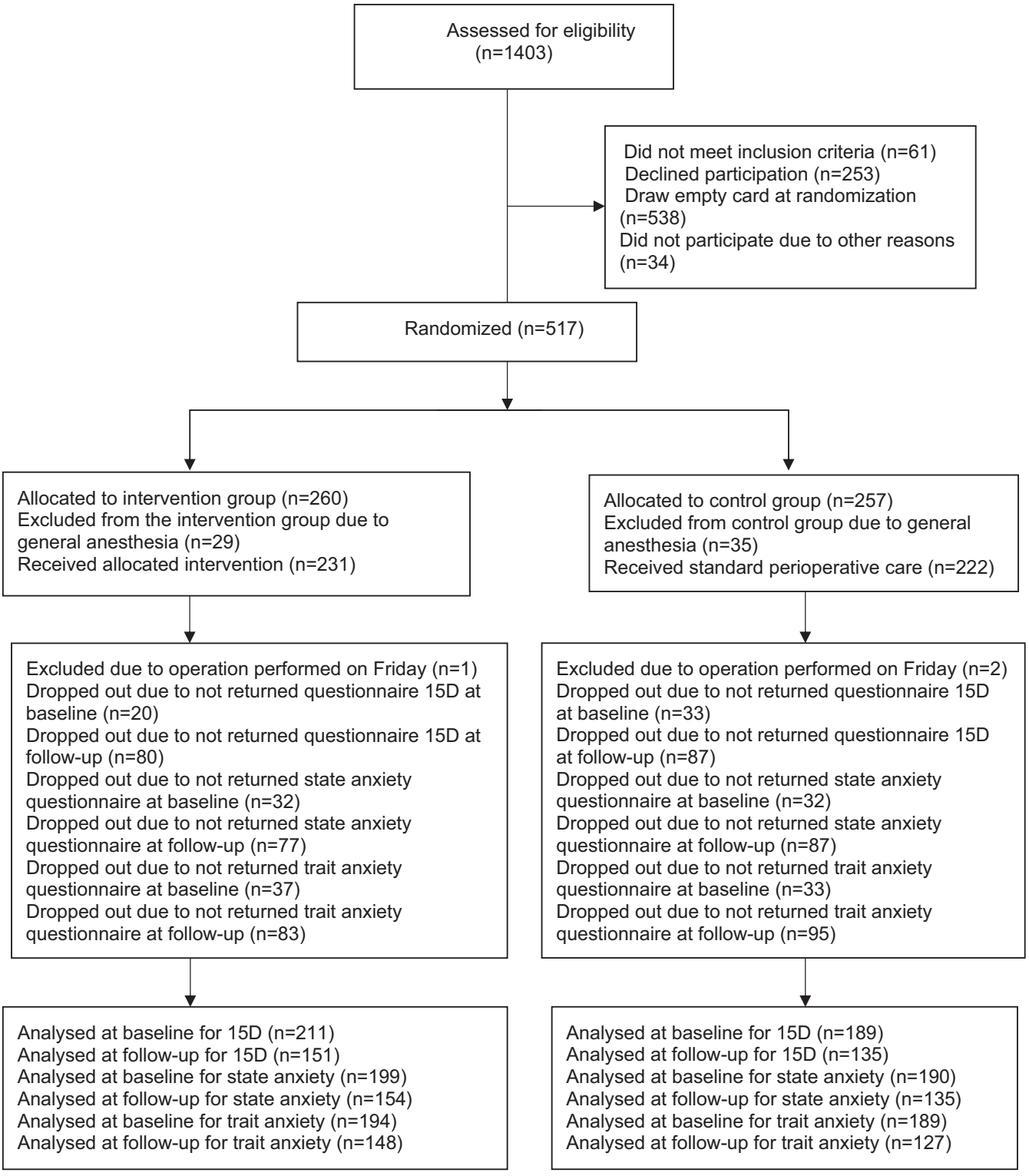

FIGURE 1 Flow chart of the study participants and reasons for exclusion and dropout

between the groups in patients' distribution into global assessment categories based on the limits for change in the 15D score (Table 3).

In both groups, there was a statistically significant mean improvement in the 15D dimensions of moving, usual activities, vitality, distress and discomfort, and symptoms. In the intervention group, the mean improvement in moving was 0.171, *SD* 0.16, 95% CI [0.127, 0.213], in usual activities 0.110, *SD* 0.16, 95% CI [0.062, 0.158], in discomfort and symptoms 0.207, *SD* 0.19, 95% CI [0.152, 0.261], in distress 0.061, *SD* 0.15, 95% CI [0.019, 0.102], and in vitality 0.078, *SD* 0.15, 95% CI [0.035, 0.120].

In the control group, the mean improvement in moving was 0.163, *SD* 0.17, 95% CI [0.116, 0.207], in usual activities 0.082, *SD* 0.16, 95% CI [0.031, 0.132], in discomfort and symptoms 0.192, *SD* 0.20, 95% CI [0.134, 0.249], in distress 0.049, *SD* 0.14, 95% CI [0.005, 0.092], and in vitality 0.056, *SD* 0.15, 95% CI [0.011, 0.100] (Figure 2).

3.3 | Changes in state anxiety and trait anxiety from baseline to follow-up

State anxiety scores decreased in both groups from baseline to follow-up; the improvements were statistically significant. The most significant decreases in the state anxiety score were seen in THA female intervention and control groups: Mean changes were −8.09, *SD* 10.10, 95% CI [−2.27, −13.92] and −7.82, *SD* 11.41, 95% CI [−1.44, −14.21], respectively. There was no statistically significant difference between the groups in the mean scores at baseline or follow-up. The male patients in both groups demonstrated no significant improvement in state anxiety scores from baseline to follow-up. Trait anxiety scores in all patients showed no significant improvement (Table 4).

4 | DISCUSSION

To our knowledge, this is the first RCT to explore the effectiveness of a perioperative nursing intervention on anxiety and HRQoL in patients undergoing THA or TKA under spinal anaesthesia. The first research question explored the effectiveness of the NPPM on anxiety and HRQoL compared to the standard perioperative practice. We did not find any statistically significant difference between the intervention and control groups in mean anxiety or 15D scores, either at baseline or follow-up.

State anxiety scores improved from baseline to follow-up in both groups, and these improvements were statistically significant. Slight improvements were found in the trait anxiety scores, but they were not statistically significant. According to Spielberger (1966, 1972, 1977), trait anxiety scores are essentially the same pre-operatively and postoperatively and do not appear to be influenced by the stress of the surgical procedure. Although trait anxiety scores do not predict differences in emotional reactions to physical threats, individuals with high trait anxiety scores usually respond with higher elevations in state anxiety to threats to self-esteem than individuals

TABLE 2 HRQoL total index scores of 15D at baseline and follow-up

	HRQoL mean, (*SD*) at baseline	HRQoL mean, (*SD*) at follow-up	Difference of means	95% CI	*p*-value*
Intervention group all	0.827 (0.08)	0.886 (0.08)	0.059	[0.036, 0.081]	<0.001
THA all (female + male)	0.826 (0.09)	0.894 (0.08)	0.068	[0.048, 0.087]	<0.001
THA female	0.814 (0.08)	0.886 (0.08)	0.072	[0.032, 0.111]	<0.001
THA male	0.844 (0.09)	0.898 (0.08)	0.054	[0.003, 0.105]	0.026
TKA all female + male)	0.830 (0.08)	0.876 (0.08)	0.046	[0.018, 0.074]	<0.001
TKA female	0.826 (0.08)	0.873 (0.07)	0.047	[0.014, 0.108]	0.271
TKA male	0.837 (0.08)	0.883 (0.09)	0.045	[−0.031, 0.123]	0.615
Control group all	0.847 (0.07)	0.902 (0.08)	0.055	[0.031, 0.078]	<0.001
THA all (female + male)	0.849 (0.07)	0.920 (0.06)	0.071	[0.049, 0.092]	<0.001
THA female	0.835 (0.07)	0.922 (0.06)	0.086	[0.041, 0.132]	<0.001
THA male	0.863 (0.07)	0.917 (0.07)	0.053	[0.004, 0.102]	0.021
TKA (female + male)	0.842 (0.07)	0.872 (0.10)	0.029	[0.000, 0.058]	0.046
TKA female	0.840 (0.07)	0.882 (0.10)	0.041	[−0.021, 0.104]	0.465
TKA male	0.857 (0.06)	0.847 (0.10)	−0.010	[−0.097, 0.076]	1.000
HRQoL total index scores of 15D baseline between intervention group and control group					
Intervention group	0.827 (0.08)		−0.019	[−0.040, 0.001]	0.075
Control group	0.847 (0.07)				
HRQoL total index scores of 15D follow-up between intervention group and control group					
Intervention group	0.886 (0.08)		−0.016	[−0.041, 0.008]	0.343
Control group	0.902 (0.08)				

*t-test of a multivariate model with Tukey–Kramer adjustments.

TABLE 3 Classification of the changes in the 15D scores from baseline to follow-up into global assessment scale categories and the distribution of patients into these categories

Global assessment category	Limits for change in the 15D score (Alanne et al. 2015)	Distribution of patients (%)	
		Intervention group	Control group
Much better	>0.035	60.3	62.6
Slightly better	0.15–0.035	14.4	11.4
Much the same (no change)	>−0.015 and < 0.015	13.0	13.0
Slightly worse	−0.015 to −0.035	7.5	7.3
Much worse	<−0.035	4.8	5.7

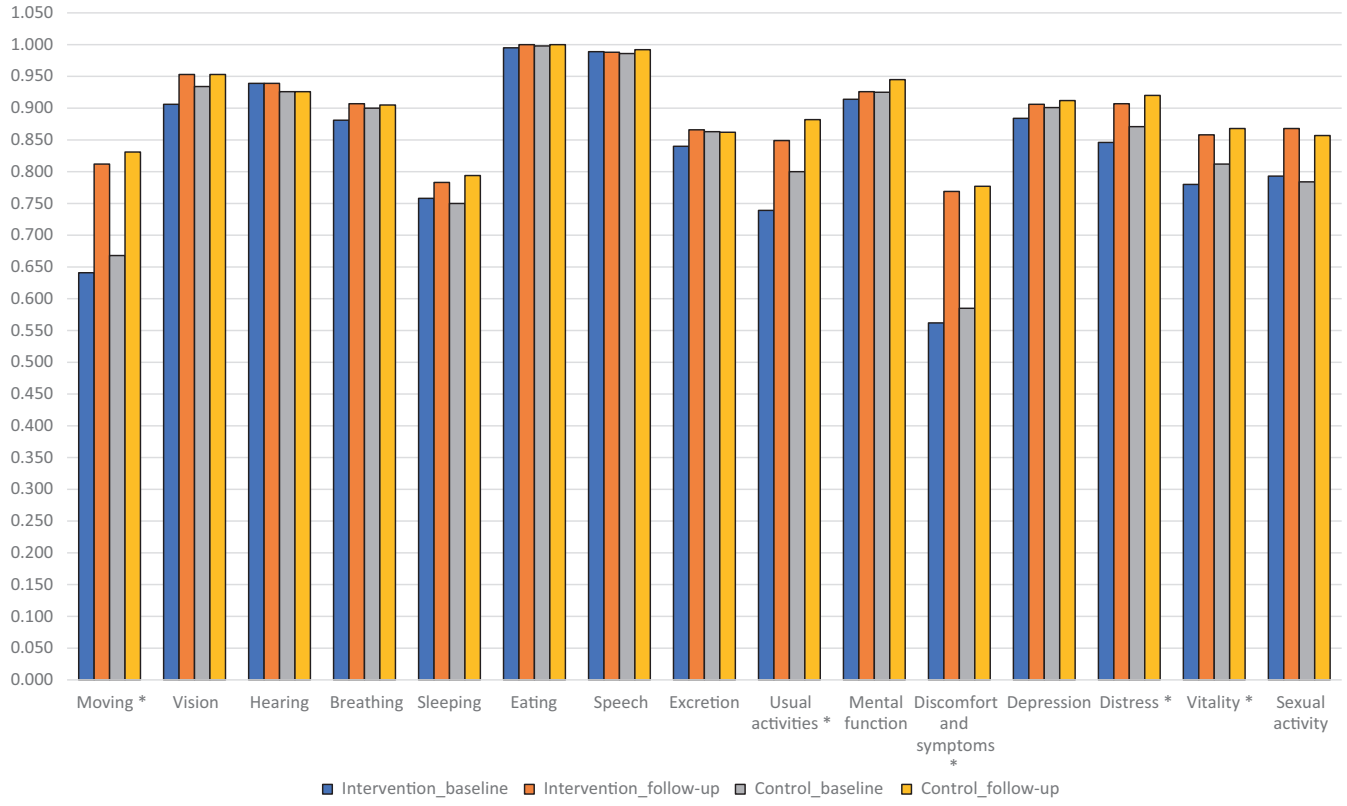

FIGURE 2 The mean 15D profiles of both groups at baseline and at follow-up. The dimensions with a statistically significant improvement (p <.05) are marked with an asterisk*

with low trait anxiety scores (Spielberger, 1966, 1972, 1977). We did not find such an association in our study. None of the patients in our study reported high levels of state anxiety at baseline; moderate state anxiety (41.13) was seen at baseline only in the female intervention group undergoing THA. These findings are in line with an earlier study (Montin et al., 2007). According to the raw score, anxiety is classified as low (20–39), moderate (40–59) or high (60–80) (Spielberger, 2010). In the female intervention and female THA control groups, improvement from baseline to follow-up in state anxiety scores was statistically significant. In patients undergoing TKA, no statistically significant improvements in state anxiety or trait anxiety scores were seen in either group.

The main findings of our research concerning HRQoL and its dimensions showed that on average, improvements from baseline to follow-up could be seen in both groups. The improved dimension scores of the 15D were moving, usual activities, discomfort and symptoms, distress, and vitality.

The female THA intervention group experienced a statistically significant improvement in the 15D dimensions of moving, usual activities, depression, distress, and vitality. Similar results were reported in earlier studies (Montin et al., 2007; Räsänen et al., 2007). This could be explained by the fact that the female THA intervention group was in a poorer condition than the other participants in the study. This can be seen from the mean baseline 15D score of this group (Table 2).

When examining the results of all patients undergoing TKA, improvement could be seen in the 15D dimension of moving. Recovery from TKA takes more time than recovery from THA; earlier research

TABLE 4 The mean state anxiety (STAI-S) and trait anxiety (STAI-T) scores at baseline and follow-up

	STAI-S Baseline mean (*SD*)	STAI-S Follow-up mean and (*SD*)	Difference of means	95% CI	*p*-value*
Intervention group all	38.06 (11.40)	33.14 (10.63)	−4.91	[−8.02, −1.79]	<0.001
Female THA	41.12 (12.07)	33.03 (10.10)	−8.09	[−13.92, −2.27]	<0.001
Male THA	36.39 (9.14)	33.17 (11.88)	−3.22	[−10.55, 4.11]	0.884
Female TKA	36.11 (12.02)	32.27 (10.83)	−3.85	[−11.53, 3.82]	0.787
Male TKA	35.51 (10.64)	35.33 (9.55)	−0.16	[−10.53, 10.21]	0.000
Control group all	36.98 (11.80)	31.77 (11.37)	−5.21	[−8.47, −1.95]	<0.001
Female THA	39.28 (12.85)	31.46 (11.41)	−7.82	[−14.21, −1.44]	<0.05
Male THA	33.51 (11.60)	29.00 (10.25)	−4.51	[−11.71, 2.67]	0.543
Female TKA	36.80 (10.71)	34.67 (13.07)	−2.12	[−9.86, 5.61]	0.991
Male TKA	38.72 (9.10)	34.20 (9.25)	−4.52	[−16.37, 7.33]	0.940
STAI-S Baseline scores between the intervention group all and control group all					
Intervention group	38.06 (11.40)		1.07	[−1.95, 4.10]	0.799
Control group	36.98 (11.80)				
STAI-S Follow-up scores between the intervention group all and control group all					
Intervention group	33.14 (10.63)		1.37	[−1.96, 4.70]	0.714
Control group	31.77 (11.37)				
	STAI-T Baseline mean (*SD*)	**STAI-T Follow-up mean (*SD*)**	**Difference of means**	**95% CI**	***p*-value***
Intervention group all	33.70 (9.42)	32.93 (10.39)	−0.76	[−3.54, 2.02]	0.896
Female THA	35.84 (10.41)	34.61 (10.78)	−1.22	[−6.36, 3.91]	0.996
Male THA	32.29 (8.43)	31.40 (9.80)	−0.88	[−7.50, 5.73]	0.999
Female TKA	32.86 (8.03)	32.25 (10.62)	−0.61	[−7.94, 6.72]	0.000
Male TKA	31.34 (9.40)	31.45 (9.82)	0.10	[−8.83, 9.04]	0.000
Control group all	33.83 (9.81)	31.77 (9.82)	−2.05	[−4.98, 0.88]	0.274
Female THA	34.35 (9.70)	32.48 (10.72)	−1.86	[−7.71, 3.30]	0.975
Male THA	32.14 (10.26)	29.35 (7.49)	−2.79	[−6.96, 1.37]	0.891
Female TKA	33.84 (9.58)	32.35 (10.79)	−1.48	[−8.63, 5.65]	0.998
Male TKA	36.78 (9.31)	34.76 (9.63)	−2.02	[−12.87, 8.83]	0.999
STAI-T Baseline scores between the intervention group all and control group all					
Intervention group	33.70 (9.42)		−0.13	[−2.66, 2.40]	0.999
Control group	33.83 (9.81)				
STAI-T Follow-up scores between the intervention group all and control group all					
Intervention group	32.93 (10.39)		1.15	[−1.99, 4.31]	0.780
Control group	31.77 (9.82)				

*t-test of multivariate model with Tukey–Kramer adjustments.

findings show that patients suffering from knee arthrosis, especially females, suffer from severe pain and inability to mobilize and take part in everyday activities caused by fatigue and thus tended to recover more slowly (Engström et al., 2017; Mandzuk et al., 2015). This could be a reason that patients undergoing TKA in our study did not improve in the 15D dimensions as much as patients who underwent THA. Another reason might be that the patients undergoing TKA were in better health pre-operatively and might show better outcomes but less improvement, as can be seen from the HRQoL total index scores (Table 2). This is supported in a study by Hofstede et al. (2018) in which patients who had worse functioning pre-operatively showed more improvement. The following changes occurred within the groups by gender: Female intervention group patients undergoing THA improved in the 15D dimensions of moving, usual activities, discomfort and symptoms, distress, and vitality. Female control group patients undergoing THA improved in the dimensions of moving, usual activities, discomfort and symptoms, and sexual activity but demonstrated only a slight improvement in the dimension of vitality. In contrast to female patients, male patients undergoing THA in the intervention and control groups reported

improvements only in the 15D dimensions of moving and discomfort and symptoms. One reason for this could be that the male patients undergoing THA may have been in a better condition at baseline than the female patients undergoing THA, as the mean baseline 15D score suggests (Table 2). According to an earlier investigation, female patients are more likely to delay arthroplasty, but male patients seek arthroplasty at an earlier stage of arthrosis. This might cause female patients to demonstrate lower initial function compared with male patients (Mora et al., 2012).

It is difficult to speculate about which improvements in anxiety and HRQoL were achieved by the intervention and which were results of the surgical procedure. The results of our study indicate the need for more extensive studies concerning HRQoL and anxiety in arthroplasty patients. The timing of the measurements of anxiety and HRQoL must be rescheduled; we do not know how anxious the patients really were on the day of the operation or their levels of anxiety during the intraoperative phase. In a study by Mitchell (2008), findings indicated that the OR environment and local anaesthesia influenced patients' anxiety during the intraoperative phase. It could be essential to reschedule the time points for the measurements. For instance, the first measurement could be taken when the decision for an operation is made, usually six months or one year prior to the operation. The second measurement could be scheduled during the waiting time for surgery, for example three months prior to the scheduled operation, and the third measurement could be taken on the day of operation prior to entering the OR. Postoperative measurements could take place on first postoperative day and at three, six, and twelve months. The new time points for measurements might reveal different results than the current study. In recent studies, findings indicate that anxiety and depressive symptoms in patients undergoing TKA increases every year. This has been found to impact the rate of complications postoperatively caused by chronic pain (Klement et al., 2016; Pan et al., 2019). This was not evaluated in our study but remains to be explored in a future investigation with the above-mentioned premises.

However, the NPPM may enhance patient safety by reducing delays, errors in communication, and handovers, empowering patients in self-management of pain and recovery after continuously shortening hospital stays. These potential advantages of NPPM were not addressed in this study but need to be explored in future research. Furthermore, this study showed the NPPM to be feasible from the resourcing perspective. No extra nurses were needed, the only change related to their work shifts. As a future task, it could be useful to develop a simple instrument/checklist for measuring anxiety in advance to target patients who could benefit from the NPPM.

The strength of this study was its large sample size. Another strength was the high response rate. The somewhat lower response rate at follow-up is probably because only completed sets of questionnaires were taken into account. The similarity of the intervention group and control group at baseline can also be considered a strength of this study.

4.1 | Limitations

There are some limitations of our study which are discussed with the help of the tool for assessing risk of bias (Sterne et al., 2019). Bias from the randomization is regarded minimal as the allocation sequence was random due to patients arriving to the operation consideration totally randomly. All patients were randomized during their first visit to the hospital and did not meet patients in the other group neither got any information concerning the other group, so we regarded no timing concerned bias in the identification. Both groups finished the intended intervention, and there were no deviations from the protocol. NPPM nurses knew if the patient was in the intervention group but otherwise the personnel did not know about the study group.

Missing outcome data was at an acceptable level at three months questionaries. The outcome results were checked only after the study was completed and could thus not intervene to the results. We used the per protocol analysis, and also conducted an analysis by GEE estimation with and without imputation of missing values (two different missing value regression models where diagnosis, gender and 15D/STAI-S and STAI-T were used as covariates). These estimations provided equal results compared with original ones using ANOVAs.

Follow-up at three months could be regarded as an overall risk, especially among patients undergoing TKA. It is known from earlier research that recovery from TKA is somewhat slower than recovery from THA in terms of pain, wound stiffness, mobilization, and overall patient satisfaction; it may take six months to one year to recover from TKA (Szöts et al., 2015). The patients had their postoperative visits to the outpatient clinic three months postoperatively; we assumed this time point would be most convenient to gather as many responses as possible as opposed to mailing questionnaires to the patients' homes.

Another overall limitation was that the baseline measurements of anxiety and HRQoL were carried out two to three weeks pre-operatively, during waiting time. According to Hodges and Spielberger (1966), state anxiety scores have been reported to be highest just prior to a surgical procedure. Our baseline measurement showed only moderate levels of state anxiety in female intervention group patients waiting for THA. Trait anxiety scores do not essentially vary pre- and postoperatively and do not appear to be influenced by stress caused by the surgical procedure (Hodges & Spielberger, 1966), which was also the case in our study.

5 | CONCLUSIONS

This study provides new knowledge of a perioperative nursing intervention hypothesized to diminish anxiety and increase HRQoL in patients undergoing THA and TKA. The NPPM is an intervention offering person-centred, continuous nursing care, although our study did not find it superior to standard perioperative care in increasing

HRQoL or reducing anxiety. In future studies, the variables will be examined over at least three times (baseline, at least 4 weeks, and the third shift) to further discuss the effect of time on a variable such as anxiety by comparing the results. According to our results, men and women responded differently. However, this result was found in ad hoc analysis. Thus, further testing of gender differences needs to be conducted in future perioperative nursing research using randomized gender stratification.

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CONFLICT OF INTEREST

Professor Harri Sintonen is the developer of the 15D inventory and obtains royalties from its electronic versions. The other authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTIONS

Study design: MP, IJ, SS and KJ; Data collection/analysis: MP; drafting of the manuscript: MP, IJ, HS and KJ; Statistical analysis: JE and HS; Critical revisions for intellectual content: IJ, HS, SS and KJ; Supervision: IJ and KJ.

DATA AVAILABILITY STATEMENT

The data sets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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