

ORIGINAL ARTICLE

The effects of a psycho-educational intervention to improve pain management after day surgery: A randomised clinical trial

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Abstract

Aims and objectives: To evaluate the effectiveness of a psycho-educational intervention for shoulder and breast day surgery patients in decreasing pain intensity and pain interference with function and strengthening adherence with the analgesic regimen; and further to identify factors that influence average pain intensity and pain interference with function.

Background: Pain is one of the most prevalent symptoms after day surgery. However, pain management is left to the patients and family, and interventions to help patients are needed.

Design: Randomised clinical trial with an intervention ($n = 101$) and a usual care group ($n = 119$) using multiple measurements during 6 months postoperatively. The CONSORT checklist is used.

Methods: Patients in the intervention group received a booklet about pain and pain management and coaching by research nurses on postoperative days 2, 3 and 7. Differences between groups were identified using the chi-squared analysis and t tests. Changes with time were identified using a linear mixed model with repeated measures.

Results: After controlling for covariates, group differences at any time in average pain intensity and pain interference with function were not statistically significant. Changes over time within any one group in average pain intensity and pain interference with function were statistically significant and decreased with time. Higher levels of average pain intensity and pain interference over time were associated with shoulder surgery, female, younger, pain expectation, preoperative pain and poorer adherence.

Conclusions: No group differences related to the intervention were revealed, and pre-operative teaching together with a pain management booklet and coaching may help to strengthen the intervention's effects. Further research on interventions directed towards pain management is needed.

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Relevance to clinical practice: Day surgery patients' postoperative pain and pain management is not satisfactorily handled. To encourage and educate patients to use the prescribed analgesics in the immediate postoperative days may be necessary to enhance pain management.

Clinical trial registration: ClinicalTrials.gov (NCT01595035).

KEYWORDS

ambulatory surgical procedures, clinical trial, mammoplasty, pain, postanesthesia nursing, postoperative, randomised controlled trial, shoulder

1 | INTRODUCTION

In day surgery, the patient is discharged from hospital on the day of surgery. The use of day surgery is increasing and currently comprises 50%–60% of all Norwegian elective surgical procedures (Ræder & Nordentoft, 2010). Early discharge means that the responsibility for pain management during the recovery period has been transferred from the hospital to the patient and their family (Berg et al., 2013). Postoperative pain management at home is a challenge because of the need for patients to receive complete information and to understand how to manage their pain. However, with day surgery, the nurse–patient interaction is brief, and information given before discharge is not always adequate (Mattila et al., 2005). Moreover, patients are still recovering from anaesthesia and might not be able to understand or remember the information given or ask for information at discharge (Berg et al., 2013), or to foresee problems that may occur in the first days after surgery (Dewar et al., 2003).

Postoperative pain management after day surgery requires the use of analgesics that are safe, easy to manage by the patients themselves and have minimal side effects. Even though patients are prescribed sufficient doses of analgesics, pain relief is dependent on their adherence with the analgesic regimen. Gramke et al. (2007) found that almost 50% of patients do not use any of the recommended analgesics despite the provision of written instructions and a box of tablets. The reported reasons for nonadherence are uncertainties about how to use the prescribed pain medication (Berg et al., 2013), fear of addiction, and prior or current constipation or nausea even when in moderate pain (Watt-Watson, Chung, et al., 2004). Others patients may see pain as natural and the use of pain medication as unnatural (Older et al., 2010), whereas others may wish to experience the pain as a means of protecting themselves from being too active, and to use their pain as a way of monitoring their recovery (Older et al., 2007, 2010).

2 | BACKGROUND

Pain is one of the most prevalent symptoms after day surgery, and recovery from orthopaedic surgery can be especially painful (Campagna et al., 2016; Fahmy et al., 2016; Nishimori et al., 2007). When evaluating the effects of a multimodal perioperative pain protocol in patients undergoing ambulatory shoulder surgery, patients

What does this paper contribute to the wider global clinical community?

- No difference was found using a psycho-educational intervention to patients after surgery compared with usual care for average pain intensity or pain interference with function at any time postoperatively.
- Compared with the usual care group, patients in the psycho-educational intervention group answered significantly more often that they took analgesics as prescribed after surgery.
- Day surgery patients' postoperative pain and pain management is not managed satisfactorily. Further research on interventions directed at pain management is needed. Better methods for pain management are needed to encourage and educate patients to use the prescribed analgesics in the immediate postoperative days.

treated by the protocol had lower worst pain intensity 24 h postoperatively compared with patients treated without the protocol. However, patients in both groups had moderate to strong worst pain 48 h after surgery on a scale from 0 (no pain)–10 (worst pain imaginable): 7.2 ($SD = 3.0$) and 6.7 ($SD = 2.6$) in the control and intervention groups, respectively (Elkassabany et al., 2019).

Breast reconstruction surgery is another common surgical procedure performed as day surgery (Barker et al., 2018). Breast reconstruction is often performed after mastectomy surgery for cancer but may also be performed to enlarge or minimise the breasts without any former disease. In one study that evaluated chronic post-surgical pain after breast reconstruction, patients had a mean pain score of 3.9 ($SD = 2.1$) 1 week after surgery on a scale from 0 (no pain)–10 (worst pain imaginable) (Roth et al., 2018). Kulkarni et al. (2017) examined the factors associated with acute postoperative pain after breast reconstruction and found that younger age, bilateral reconstruction, severity of preoperative pain, and anxiety and depression were associated with greater acute postoperative pain. Another study that examined pain after autologous breast reconstruction found that patients had the most severe pain on the

second postoperative day, with a mean pain score of 4.1 ($SD = 2.4$) (Armstrong et al., 2016).

Few randomised clinical trials (RCTs) have been conducted to evaluate the effects of the provision of information about pain management and nurse-led support following day surgery. Dewar et al. (2003) assessed the effect of preoperative teaching using a pamphlet about pain management and follow-up by telephone on postoperative days 1, 2 and 3 in patients who had undergone arthroscopic knee surgery, breast reduction, hernia repair or anal surgery. All patients were telephoned on postoperative day 5 and asked about their pain and other symptoms. The intervention group had significantly less pain than the usual care group on postoperative day 5. The intervention group also reported significant reductions in pain interference with mood, walking, relationships with others and concentration on postoperative day 3 (Dewar et al., 2003).

A more recent RCT evaluated the effectiveness of an educational intervention on pain management in day surgery patients undergoing hernia repair (Sawhney et al., 2017). All patients received the usual preoperative information at the preadmission clinics before surgery. In addition, patients in the intervention group received a booklet about pain and pain management followed by an individual face-to-face educational session during which the content of the booklet was discussed. The patients in the intervention group also received a support telephone call the day before surgery and a second support telephone call 24 h after surgery, which replaced the usual call provided by the surgery nurse to the patients in the usual care group. In Sawhney et al.'s study (2017), patients in the intervention group had significantly lower pain intensity scores both at rest and during movement, and pain-related interference during general activity and walking compared with the usual care group on postoperative day 2. Patients in the intervention group also used significantly fewer oral opioids than those in the usual care group on postoperative day 2. No significant differences were found between groups on postoperative day 7 for any of the pain intensity scores (Sawhney et al., 2017).

Both of the studies mentioned above reported some improvement in pain intensity and pain-related interference after use of the booklet and phone calls.

In a nonrandomised experimental study with orthopaedic patients, Rahmani et al. (2020) found that patients given educational intervention together with a family member before and after surgery had significantly less pain compared with the usual care group. The intervention consisted of bedside education of patient and family members the day before surgery. A booklet comprising information about pain physiology, pain medication and their complications, and nonpharmacological methods such as expressing fear and concerns, and relaxation methods was the topic of the education. A second session of education was given postoperatively after the patients had been alert. The topics in this session was on the use of the pain measurement tool, discussing unrealistic expectation about pain, reviewing, reinforcing and encouraging nonpharmacological pain relief used by patient and family. The usual care group got routine care and

the same instructions to use the pain measurement. Patients in the intervention group had significant reduction in pain severity compared with the control group in every 3 days after surgery (Rahmani et al., 2020).

Considering the findings of these prior studies, we sought to evaluate whether the use of similar interventions could improve pain management in patients undergoing shoulder and breast reconstruction surgery.

The main purposes of this RCT were to evaluate the effectiveness of a psycho-educational intervention for day surgery patients following shoulder and breast reconstruction surgery on (1) pain intensity and pain interference with function during the first 7 days and 3 and 6 months after surgery, and (2) adherence with the analgesic regimen compared with usual care. A secondary aim was to identify factors that influence average pain intensity and pain interference with function, such as age, sex, type of surgery, pain before surgery, barriers to pain management, adherence with pain medication, pain expectation and time.

3 | METHOD

3.1 | Sample

All patients scheduled for shoulder surgery at a university hospital in the western part of Norway and patients scheduled for breast reconstruction surgery in a university hospital in the east of Norway were invited to participate in this RCT during 2014 if they were older than 18 years of age, able to read, write and understand Norwegian, and had a telephone line. Some patients had their last following up telephone in 2015. Patients were excluded from the study if they were not discharged on the same day as surgery. A total of 110 patients undergoing shoulder surgery participated, all but four of whom had arthroscopic surgery. Of these patients, 79% had surgery as defined by the surgeon as "not so painful," such as subacromial decompression (SCD), and 21% had surgery defined as "moderate or most painful," such as SCD and suture of the supraspinatus or subscapularis muscles. Of the 110 patients who had breast reconstruction surgery, two thirds received the breast reconstruction after previous breast cancer surgery.

3.2 | Design and setting

The patients were asked to participate in the study through the admission clinics together with their appointment date for day surgery. All patients received written information about the study and a written consent form to complete along with the usual information from the day surgery clinic. At the same time, the patients received a questionnaire to fill in and were asked to return it together with the written consent in a prepaid envelope before surgery. The written consent and the questionnaire were returned to the main researcher (BTV) or the research nurse (AOE) at the two hospitals.

TABLE 1 Content given to the intervention and usual care group

Time	Intervention group	Usual care group
Preadmission information	Standard preadmission information	Standard preadmission information
Written information on pain management before discharge as a booklet "Pain relief after day surgery"	<ul style="list-style-type: none"> • why pain relief is important • common concerns about pain and pain management • examples of pain relief methods 	
Pain diary filled in once a day for 7 days postoperatively	Worst and average pain intensity scores in past 24 h during rest and activity, pain interference with daily activity	Same as the intervention group
Telephone call on postoperative day 1	Usual call from the day surgery clinic	Same as the intervention group
Telephone call from researcher to patients at home on postoperative days 2, 4 and 7	<p>Academic detailing and coaching</p> <ol style="list-style-type: none"> 1. Determine the patient's baseline knowledge and motivation by reviewing the answers to questionnaires answered preoperatively: <ul style="list-style-type: none"> • adherence with pain medication (previous patterns of pain medication use) • pain expectations after surgery • beliefs and misconceptions about pain and pain management (i.e. addiction, side effects) 2. Define educational and behavioural objectives 3. Coach patients according to their answers to the questionnaires 4. Review pain scores and medication use in the past 24 h. Coach patients about the optimal administration of pain medication 5. Highlight and repeat key information and providing positive reinforcement in the follow-up about use of analgesics, management of side effects and other concerns 	Reminder to fill in the pain diary
Telephone call from researcher to patients at home 3 and 6 months after surgery	Assess pain intensity and pain interference with function	Same as the intervention group

After returning the baseline questionnaire and providing consent, the patients were randomised into the intervention or usual care group by means of premade concealed envelopes by BTV or AOE separately at the two study sites. Both the patients, the surgeons, the anaesthesia personnel and other health personal at the day surgery clinic were blinded to the group allocation.

After surgery, all patients in both groups were asked to complete a pain diary once a day for the next 7 days. All patients were contacted by telephone at home and reminded to fill in the diary on postoperative days 2, 4 and 7.

Patients who were randomised to the intervention group received written information about pain and postoperative pain management in a booklet entitled "Pain relief after day surgery" to take home after the surgery. This booklet was a revised version of that originally written by Watt-Watson, Stevens, et al. (2004) and contained information about why pain relief is important postoperatively, how to assess pain using a numeric rating scale (NRS) and the recommendation to take analgesics at fixed hours. The booklet also contained examples of noninvasive pain alleviation techniques such as using a pillow to support the wound and listening to music or watching television as a distraction. The booklet also addressed frequently asked questions and concerns about pain and postoperative pain management.

A researcher contacted patients by telephone on postoperative days 2, 3 and 7 and coached them in pain management. The academic detailing and coaching consisted of the following steps: determination of baseline knowledge and motivation by reviewing the answers to the preoperative questionnaire; adherence with pain medication (previous patterns of pain medication use); pain expectations after surgery; and beliefs and misconceptions about pain and pain management (e.g. addiction, side effects). The patients were coached according to their answers about their baseline knowledge, pain scores and medication used in the preceding 24 h. The patients were also coached about optimal administration of pain medication, key information was highlighted and repeated, and positive reinforcement was provided about use of analgesics, management of side effects and other concerns. Table 1 includes an overview of the content of the intervention.

Patients in the usual care group did not receive the booklet or coaching in pain management as described above but were instead contacted by telephone on the same days as the intervention group and reminded to fill in the pain diary. The intention of these telephone calls was to ensure the collection of data on pain and to compensate for the general positive effect of attention in clinical trials (i.e. the "Hawthorn effect"). For patients in the usual care group with concerns they wanted to discuss, the investigator only advised contacting the hospital.

All patients in both groups were contacted by telephone 3 and 6 months after the operation to collect data about persistent pain and pain interference with function after surgery.

CONSORT 2010, for reporting parallel group randomised trials checklist from the Enhancing the Quality and Transparency Of health Research (EQUATOR) guidelines, is used (File S1).

3.3 | Data collection

Before surgery, demographic and clinical characteristics such as age, sex, education level, income, ethnicity and previous surgery were collected. Other data on present pain, duration of pain, use of analgesic medications and pain expectation after surgery were also obtained from all patients. Further, prior to surgery barriers to pain management were collected.

3.3.1 | Barriers to pain management

Concerns and knowledge of pain and pain management were assessed in a questionnaire composed of eight statements derived from the Barriers Questionnaire (Gunnarsdottir et al., 2002; Valeberg et al., 2009) and the Family Pain Questionnaire (Ferrell et al., 1993). This questionnaire covered statements about the importance of waiting as long as possible before taking pain medication, being able to endure strong pain after surgery, taking pain medication as needed, the belief that only strong pain requires pain medication, addiction, enduring pain rather than experiencing side effects, importance of "saving" pain medication in case the pain gets worse and being inactive rather than taking pain medication. An NRS from 0 (completely disagree)–5 (completely agree) was used as a response for each item.

3.3.2 | Pain expectation

A rating of how much pain the patients expected to have after surgery was obtained using an NRS from 0 (no pain)–10 (worst pain imaginable). Patients' pain expectations have been shown to predict postoperative pain after elective surgery (Gramke et al., 2009; Sommer et al., 2010).

After surgery, data on pain characteristics, adherence with pain medication and satisfaction with the booklet were assessed.

3.3.3 | Pain characteristics

Patients in both groups were asked to fill in a diary once a day after surgery. The diary was a modified version of the Brief Pain Inventory (BPI) short form (Daut et al., 1983; Klepstad et al., 2002). Pain intensity scores (i.e. the average and worst pain intensity at rest and during activity that lasted 24 h) were obtained using an NRS from 0 (no pain)–10 (worst pain imaginable). Pain interference with daily

activity, mood, walking ability, relationships with others and sleep was measured using an NRS from 0 (does not interfere)–10 (interferes completely). Pain interference was analysed after collapsing all of the interference items into one pain interference score. This modified BPI was used to measure postoperative pain and has been shown to be valid and reliable in surgery patients (Dihle et al., 2006).

3.3.4 | Adherence with pain medication

The overall adherence with pain medication was assessed during the last telephone call on postoperative day 7 by asking all patients whether they had taken the pain medication as recommended when discharged from the hospital. The choice of answers was "yes" or "no." If no, the reasons for not adhering were assessed.

3.3.5 | Satisfaction with the booklet

Patients in the intervention group were asked whether they had read the booklet (yes or no) and, if they had not, the reason why. The patients who read the booklet were asked whether they found the booklet useful and, if so, to describe in what ways it was.

3.4 | Statistical analysis

A prior power analysis was conducted by using an anticipated difference in average pain intensity. A sample size of 100 patients in each surgery group would achieve at least 80% power to detect a 25% reduction of average pain intensity on an NRS from 0–10 with an SD of 2 at the 5% significance level. A 25% reduction in pain intensity is assumed to be a clinically significant change (Farrar et al., 2003). We further anticipated a drop out of 20% and thus aimed to include 120 in each group. In the final sample, we included 101 and 119 individuals, so we consider our study sufficiently powered. The power analysis was conducted using statistical software Stata, vers, 14. The power calculation was based on the anticipated differences between the means in both groups. This is a standard formula based on the normal distribution assumption and a difference between two means (Rosner, 2015).

An intention-to-treat analysis was performed. Interval variables are described as mean and SD, and categorical data are presented as number and percentage. Differences between the two groups were analysed using independent-samples *t* test for interval data or Pearson's chi-square test for categorical variables. Linear mixed models (LMM) for repeated measures were used to identify changes over time and at given time points using average pain intensity during activity and pain interference with function as the dependent variables. LMM do not require full data sets and no imputation of missing data is thus necessary. These models use all available information, so all included patients were entered.

To account for statistical dependencies—as the same individuals were assessed at several time points—we used unstructured

covariance matrix. This matrix does not impose any structure on the data, so it is considered the best option if it is possible to get the models to converge. Covariates, such as time, group (intervention and usual care), sex, age, type of surgery, barriers to pain management, pain before surgery, pain expectation and adherence, were controlled for and entered into the model as fixed effects. We have estimated the models using time, group and time*group interaction. The interaction was not statistically significant; thus, it was omitted from the final model. There were no random effects to be considered in the mixed model. p -Values $<.05$ were considered to be significant. All analyses were performed using the SPSS version 24 (IBM) and STATA 15 (STATACorp).

3.5 | Ethical considerations

The present study was approved by the Regional Ethics Committee for Medical Research (2011/1984B), Norway, and the Data Inspectorate (2012/4054), and conforms to the principles outlined in the Helsinki Declaration (Rickham, 1964). This RCT was registered with ClinicalTrials.gov (NCT01595035).

All patients provided written informed consent before surgery to ensure that they were fully aware and capable of making decisions. All patients received at least the standard information and follow-up after day surgery, as the goal was to test an intervention to increase their preparedness and ability to deal with postoperative pain at home.

4 | RESULTS

In total, 220 patients agreed to participate: 101 were randomised to the intervention group and 119 to the usual care group. As our intention was to include 240 patients, 240 envelopes were pre-made for the randomisation to either control or intervention group. As only 220 patients agreed to participate, 19 envelopes left were envelopes marked for the intervention group and one envelope for the usual care group. The same patients were invited to participate several times because of cancellations and rescheduling of surgery, and we were unable to calculate response rate. Most (83%) of the included patients answered the follow-up telephone call at 3 months and 75% at 6 months after surgery. Patients who did not answer the telephone call were contacted several times at different times of the day, and the reasons for patients not responding are not known. Nearly all (98%) of the patients in the intervention group had read the booklet, although nine had not before postoperative day 2, when the research nurse phoned the patients in the intervention group. Of the patients who had read the booklet, 80% thought that the information was informative and easy to read, it gave information about what was not known before and gave practical suggestions to ease the pain. The reasons given for not reading the booklet were "could not concentrate," "could not find it," "forgot," "have much experience from prior surgery," "too much information" and "was not necessary because I had the pain under control."

4.1 | Demographic and clinical characteristics of the patients and barriers to pain management at baseline

The patients' demographic and clinical characteristics are shown in Table 2. No significant differences were found in demographic or clinical characteristics between the two groups before surgery. The sex distribution did not differ between groups. The patients' mean age was 51 years (SD 12.1; range 18–80 years). Most (84%) lived with another adult.

The patients expected to have moderate pain after surgery; the mean pain intensity was 5.9 (SD 2.1) (Table 2). The mean score for barriers to pain management was 2.8 (SD 1.2), and 73% of the patients perceived that it is better to take pain medication as needed rather than on a schedule. The preoperative barriers score did not differ between groups (Table 3).

4.2 | Pain intensity and pain interference with function after surgery in the two groups

No significant difference was found between the intervention and usual care group for average pain intensity during activity or pain interference with function at any time points postoperatively. The trajectory of average pain intensity during activity and pain interference with function from after surgery to 6 months after the operation showed that the pain scores were highest the day of surgery for both patient groups (Table 4). After controlling for other covariates, the changes over time within any one group in average pain intensity and pain interference with function were significant ($B = -0.314$ and $B = -0.276$, both $p < 0.01$) for pain intensity and pain interference, respectively, and those two outcomes decreased with time, whereas the group differences at any time in average pain intensity and pain interference with function were not significant ($B = 0.111$, $p = 0.31$ and $B = 0.134$, $p = 0.19$) for pain intensity and pain interference, respectively. Younger, female patients, those who underwent shoulder surgery, had pain before surgery and were nonadherent with pain medication experienced both higher pain intensity during activity and pain interference with function during the postoperative period and at 3 and 6 months after surgery. Barriers to pain management did not influence the trajectory of average pain intensity during activity and pain interference with function (Table 5).

4.3 | Prescription of pain medication and adherence with prescribed medication in the two groups

Patients in the intervention group took pain medication as prescribed after surgery more often than those in the usual care group ($p = <.01$). Overall, 48% of all patients were not adherent with the suggested pain medication after surgery: 37% in the intervention group and 57% in the usual care group. The nonadherent patients

	Total sample n (%)	Usual care group n = 119 n (%)	Intervention group n = 101 n (%)	p-Value ^a
Sex				
Male	56 (25.5)	30 (25.2)	26 (25.7)	.93
Female	164 (74.5)	89 (74.8)	75 (74.3)	
Living conditions				
Living alone	34 (15.7)	16 (13.6)	18 (18.2)	.35
Living with family	183 (84.3)	102 (86.4)	81 (81.8)	
Education				
Primary school	14 (6.5)	9 (7.6)	5 (5.1)	.74
Secondary school	96 (44.2)	51 (43.2)	45 (45.5)	
College/university	107 (49.3)	58 (49.2)	49 (49.5)	
Pain other than usual before surgery				
Yes	110 (50.7)	62 (52.5)	48 (48.5)	.055
No	107 (49.3)	56 (47.5)	51 (51.5)	
	Mean (SD)	Mean (SD)	Mean (SD)	
Age	50.6 (12.1)	52.3 (12.0)	50.0 (12.2)	.46
Average pain before surgery	5.0 (2.0)	2.8 (3.1)	3.6 (1.89)	.12
Pain expectation before surgery	5.9 (2.1)	6.0 (2.2)	5.9 (2.1)	.92
Total pain interference with function before surgery	3.9 (1.9)	4.0 (2.1)	3.6 (1.8)	.29
Barrier to pain management (0-5)	2.8 (1.2)	2.9 (1.1)	2.8 (1.2)	.39

^aChi-square test was used for categorical variables and independent sample t test for interval variable.

TABLE 2 Demographic and clinical characteristics and barriers to pain management at baseline among the patients (N = 220)

	Mean (SD)	Low barriers score (1-3) n (%)	High barriers score (4-5) n (%)
It is important to wait as long as possible before taking pain medication	3.0 (1.6)	103 (52.6)	93 (47.4)
Must endure strong pain after surgery	2.6 (1.5)	128 (64.6)	70 (35.4)
Better to take pain medication as needed rather than on a schedule	3.7 (1.5)	55 (27.0)	149 (73.0)
Take pain medicine only when pain is strong	3.2 (1.6)	85 (42.7)	114 (57.3)
It is easy to become addicted to pain medicine	3.0 (1.6)	91 (46.2)	106 (53.8)
It is easier to endure pain than to experience the side effects of pain medicine	2.6 (1.6)	116 (62.0)	71 (38.0)
Pain medication should be saved in case the pain gets worse	2.3 (1.6)	119 (67.2)	58 (32.8)
It is better to be inactive than to take pain medication	2.1 (1.5)	138 (78.4)	38 (21.6)

TABLE 3 Patients barriers to pain management (N = 220)

Abbreviation: SD, standard deviation.

gave a variety of reasons for nonadherence when asked in the telephone call on postoperative day 7. The most common reasons were as follows: "Did not have much pain," "took pain medication when I needed it" and "fear of side effects."

Most patients (76%) received a prescription for analgesics before leaving the hospital. The type of medication prescribed differed according to the type of surgery (shoulder and breast reconstruction). For the shoulder patients, the most frequent medication class prescribed was nonsteroidal anti-inflammatory drugs (NSAIDs), either alone or in combination with other pain medication. NSAIDs were prescribed alone for only one breast reconstruction patient and together with another pain medication for six patients who underwent shoulder surgery. The most frequent prescription given to the patients undergoing breast reconstruction surgery was paracetamol with codeine, either alone or in combination with another pain medication. Paracetamol with codeine was prescribed to only seven shoulder patients and in combination with another pain medication to six patients. No patients reported filling a prescription for oxycodone, but 15 breast reconstruction surgery patients and 11 shoulder patients took it on the day of surgery.

5 | DISCUSSION

In this RCT, no significant differences in pain intensity or pain interference with function were found between the usual care and

intervention groups at any time points after the intervention. These findings are not in accordance with prior RCTs, which found significant differences in pain intensity and pain interference with function between the groups on particular days after surgery (Dewar et al., 2003; Rahmani et al., 2020; Sawhney et al., 2017). One difference between our study and these previous studies is that they offered preoperative instruction about pain and pain management. One study provided this 10–15 min before surgery (Dewar et al., 2003), the other the day before surgery together with a family member (Rahmani et al., 2020), and the third offered an individual teaching session at the preadmission clinics (Sawhney et al., 2017). All three studies gave the patients a pain management pamphlet, and two studies (Dewar et al., 2003; Sawhney et al., 2017) gave a follow-up by telephone support as we did in the present study. The preoperative instruction may have reminded the patients about the importance of pain management before their surgery, and this extra reminder may have made their intervention more individualised and effective than ours.

Another reason for the lack of significant differences between the two groups in this study may be that the patients in the intervention group received the pain management booklet at home before surgery together with the preoperative questionnaire. The patients were expected to read the booklet before surgery. The time frame from receiving the booklet to the actual surgery (several weeks) may have been too long. The patients may not have been interested in reading the booklet at that time, and it may not have been the ideal time to provide information about what to do and expect after

TABLE 4 Comparison of intervention and control group on average pain intensity in activity and pain interference with function across time ($N = 220$)

Average pain in activity	Intervention group Mean (SD)	<i>n</i>	Usual care group Mean (SD)	<i>n</i>	<i>p</i> -Value
Preoperative	3.6 (1.8)	97	2.8 (3.1)	116	.12
0 day	5.0 (2.6)	95	4.5 (2.8)	102	.21
2 postoperative day	4.0 (2.5)	95	3.6 (2.5)	102	.34
5 postoperative day	2.7 (2.3)	92	2.6 (2.3)	101	.84
7 postoperative day	2.6 (2.5)	87	2.1 (2.0)	100	.19
3 months of average pain	1.3(2.0)	85	1.5 (3.0)	89	.58
6 months of average pain	1.2 (1.8)	79	0.5 (1.5)	85	.02
Pain interference with function					
Preoperative	3.6 (1.8)	47	4.0 (2.1)	62	.29
0 day	3.7 (2.3)	96	3.7 (2.3)	106	.87
2 postoperative day	2.8 (2.1)	96	2.8 (2.2)	106	.76
5 postoperative day	1.9 (2.0)	96	1.8 (2.0)	105	.79
7 postoperative day	1.7 (1.9)	92	1.6 (1.8)	104	.68
3 months	2.2 (2.0)	31	2.6 (2.3)	36	.48
6 months	1.8 (1.7)	28	2.1 (2.3)	13	.73

Average pain intensity during activity	B coefficient	95% CI of mean difference ^a Lower and upper limit	p-Value
Group difference—intervention group	0.111	-0.105 to 0.328	.31
Type of surgery—shoulder surgery	2.016	1.704 to 2.329	<.01
Sex—female	1.053	0.756 to 1.350	<.01
Time	-0.314	-0.355 to -0.272	<.01
Age	-0.013	-0.022 to -0.004	<.01
Total barriers	0.014	-0.116 to 0.088	.78
Pain expectation	0.254	0.202 to 0.306	<.01
Pain before surgery	-0.770	-1.035 to -0.505	<.01
Adherence to pain medication	-0.213	-0.431 to 0.005	.06
Pain interference with function			
Group difference—intervention group	0.134	-0.334 to 0.067	.19
Type of surgery—shoulder surgery	1.050	0.759 to 1.342	<.01
Sex—female	0.765	0.491 to 1.038	<.01
Time	-0.276	-0.315 to -0.238	<.01
Age	-0.004	-0.013 to 0.004	.34
Total barriers	0.032	-0.063 to 0.126	.51
Pain expectation	0.142	0.094 to 0.190	<.01
Pain before surgery	-0.470	-0.716 to -0.223	<.01
Adherence to pain medication	-0.460	-0.661 to -0.257	<.01

TABLE 5 The main effects of group and time in average pain intensity during activity and pain interference with function using a linear mixed model with repeated measures ($N = 220$)

^aConfidence interval.

surgery. Whether they had read the booklet or understood the content was not apparent before postoperative day 2 during the follow-up telephone call. In previous intervention studies (Dewar et al., 2003; Sawhney et al., 2017), the information was given either just before the surgery or at the presurgical clinic. In this situation, the entire purpose of the visit was to prepare the patients for day surgery. In addition to an information booklet, the patients were also given individualised instruction, which included an explanation of the topics in the booklet at the presurgical clinic.

Another reason for the lack of significant differences between the groups in this study may be that patients in both the intervention and usual care group filled in a daily pain diary during the first 7 days after surgery. A pain diary may be an intervention by itself because it prompts patients to pay extra attention to pain and pain management and evokes awareness about pain management. Research has shown that the use of a pain diary may improve pain management in palliative care (Lind et al., 2007) and in cancer patients with pain (Allard et al., 2001; Schumacher et al., 2002). Moreover, filling in a pain diary gives the patient a sense of control and may therefore be an intervention in itself (Aguirre et al., 2008).

The patients in the intervention group were coached about pain treatment by telephone on postoperative days 2, 4 and 7. Many of these patients had questions and needed guidance about how to

treat pain. We do not know whether patients in the usual care group sought and received guidance from other sources.

A significant difference in adherence with pain medication was observed between the intervention and usual care group, but this did not appear to influence the differences between the groups in pain intensity or pain interference with function. It is possible that patients in the intervention group answered more positively to the question about adherence than the control patients because the research nurse highlighted the importance of taking pain medication regularly to the intervention group. Overall, as many as 48% of the patients did not adhere to the recommended pain medication after surgery, which is consistent with values reported previously (Gramke et al., 2007). Research shows that patient decision-making is a complex process that is strongly influenced by past experience, personal beliefs, and culture, and relies on more than information and access to effective prescription analgesics (Older et al., 2007, 2010).

The recommended pain management regimen is to take pain medication at scheduled times and not only as needed (Pasero, 2010). As described by Older et al. (2010), many patients prefer to take medication when needed and to wait until the pain is severe. In this study, 73% of the patients noted that they would rather take pain medication as needed, and 57% would rather wait until the pain was severe. For patients who do not take analgesics at scheduled times and wait until the pain is severe, the pain medication prescribed may not be

sufficient to ease the pain. In the postoperative telephone interview, the patients stated that side effects such as nausea, diarrhoea, sore eyes and stomach ache were also reasons for nonadherence. Other patients stopped taking their pain medication, but then had to resume. This underpins the importance of educating all patients and their family caregivers about the need to take pain medication regularly to ensure a steady level of medication in the bloodstream. All of these reasons for nonadherence are consistent with the findings of the qualitative studies by Older et al. (2007, 2010), which described the different reasons patients give for not taking pain medication and enduring greater pain intensity than needed.

The individual and diverse reasons for nonadherence suggest that interventions to improve pain management at home need to be more individually targeted for both patients and their family caregivers.

5.1 | Limitations

One limitation of the present study is that we were unable to estimate the response rate and the data may not be generalised to other day care patients. Due to technical difficulties when including the patients, we were not able to collect any information on how many patients were invited and declined to participate; thus, unfortunately we were not able to compare responders and nonresponders.

It is difficult to generalise to all day surgery patients as only two patient groups participated, and pain intensity differed due to different types of surgery. Information concerning the anticipated level of pain due to surgery type could have moderated the effect of the intervention. However, such information was only available for about half of the included patients (shoulder surgery patients). Moreover, a great majority of the included patients were expected to have "not so painful surgery"; thus, we would not be able to control for level of anticipated pain as there was not enough variation in this variable to perform any meaningful statistical analyses.

The number of patients who participated provided sufficient power to detect significant differences between the intervention and usual care group. However, due to the lack of statistical power, we were not able to fit a model with all the possible interactions. Therefore, the conclusion exploring the effects of group, time, and covariates on dependent variables may be changed when the sample size is enlarged and the model can consider the interactions between group and covariates, and interactions between time and covariates.

We found that many patients had not read the study information sheet at home or had forgotten to return the informed consent form. A better approach would be to address the patients directly when they arrive at the day surgery clinic and provide more information about the study in addition to what they receive at home. Although the booklet emphasised the use of nonpharmacological strategies to alleviate pain, we did not assess the patients' use of these strategies, and we do not know whether the patients in the intervention group used these strategies more often than those in the usual care group.

A bias could also be that we do not know whether patients in the usual care group sought and received guidance from other sources.

6 | CONCLUSIONS

6.1 | Relevance to clinical practice

Even though the intervention was given to only one group of patients, the average pain intensity during activity and pain interference with function postoperatively did not differ between the two groups. A psycho-educational intervention that also includes preoperative instruction may be one way of strengthening the effects of the intervention, another may be to include a family member in the preoperative preparation. Overall pain management is not satisfactory in these patients, and further research on interventions directed at pain management in day surgery is needed. Adherence with the recommended pain regimen was significantly improved in patients in the intervention group, but only 63% of those in the intervention group stated that they took pain medication as prescribed after surgery. Further exploration of reasons for nonadherence is warranted.

7 | CONTRIBUTIONS

Conception and design: B. T. V., Tone Rustøen; acquisition of data: B. T. V., A. D., A. O. E.; data analysis: B. T. V., M. C. S.; interpretation of data: B. T. V., A. D., M. C. S.; manuscript writing: B. T. V.; revision of the manuscript critically: B. T. V., A. D., M. C. S., A. O. E., T. R.; final approval of the version to be published: A. D., M. C. S., A. O. E., T. R.; agreement to be accountable for all aspects of the work: B. T. V., A. D., M. C. S., A. O. E., T. R..

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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