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ORIGINAL ARTICLE

Increased preoperative knowledge reduces surgery-related anxiety: a randomised clinical trial in 100 spinal stenosis patients

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Abstract
Purpose To assess the impact of preoperative knowledge on anxiety, health-related quality of life (HRQoL), disability, and pain in surgically treated spinal stenosis patients.
Methods One hundred patients were randomised into an intervention group (IG, $n = 50$) or control group (CG, $n = 50$). Both groups received routine preoperative patient education. IG additionally underwent a feedback session based on a knowledge test. Primary outcome measure was anxiety at the time of surgery. HRQoL, disability, and pain constituted the secondary outcome measures during a 6-month follow-up.
Results In IG, a significant reduction in anxiety was noted after the intervention, whereas in CG, anxiety reduced only after the surgery. In both groups, a significant improvement in HRQoL, disability, and pain was noticed at the 6-month follow-up, but there were no between-group differences.
Conclusions Higher knowledge level may reduce preoperative anxiety but does not seem to affect the self-reported clinical outcomes of surgery.

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Keywords Knowledge level · Spinal stenosis surgery · Anxiety · Health-related quality of life · Disability

Introduction

Spinal stenosis is a common health problem in the aging population with a significant burden on quality of life in a subset of patients. With increasing longevity, the need for surgical treatment will likely grow in the future. Knowledge expectations of spinal stenosis patients are high [1]. In general, surgical patients expect more knowledge than they actually receive [2]. For the patient to be able to give an informed consent, he/she has to master a broad understanding of the risks and benefits, as well as the likely outcomes of the different treatment options [3]. In addition to the bio-physiological factors of multidimensional knowledge, patients require knowledge in the functional (e.g., mobility, rehabilitation, rest, nutrition), social (family, work), experiential (emotions, attitude), ethical (patient rights, participation in decision-making, and confidentiality), and financial (costs and social benefits) aspects of surgical treatment [4, 5].

To date, a few studies have described or assessed preoperative education interventions in spine surgery. The reported outcomes of patient education include increased knowledge level [6] and improved patient involvement in decision-making [6–8]. However, the effect of preoperative patient education has not been studied from the perspective of the entire surgical pathway with special emphasis on clinical outcome.

A previous study showed that a specific preoperative patient education intervention (Knowledge Test Feedback Intervention, KTFI) increases the patient́s preoperative knowledge level significantly compared to routine patient

education [9]. The current study was designed to assess the impact of preoperative knowledge on perioperative anxiety and self-reported clinical outcomes (HRQoL, disability, and pain) in patients with spinal stenosis.

Materials and methods

Hypothesis

We hypothesized that higher knowledge would reduce preoperative anxiety and improve clinical outcomes after surgery. Research questions were as follows: (1) What is the impact of preoperative knowledge on perioperative anxiety? (2) What is the impact of preoperative knowledge on postoperative HRQoL, disability, and pain?

Design and participants

Patients for this randomised, controlled, double-blinded, parallel-group study were recruited from April 2011 to May 2012. The follow-up period of 6 months ended in January 2013. Inclusion criteria were: (1) planned surgery for spinal stenosis with or without degenerative spondylolisthesis, (2) age 18 years or older, (3) sufficient skills in the local language, (4) ability to use a telephone, and (5) patient informed consent. Exclusion criteria included inability to self-care or to use a telephone.

The sample size calculation was based on Spielberger's State Anxiety Inventory (STAI) [10], the primary outcome of this study. For the study to be able to detect a three-point difference in state anxiety [11] between the study groups with an 80% power, allowing a 15% drop-out rate, 100 patients were needed. After the decision for surgical treatment, the research nurse or the principal investigator (JK) recruited the patients at the outpatient clinic or by telephone. 132 eligible patients were approached to ensure 100 study patients (Fig. 1). The mean age, gender ratio, or education level of those patients who refused to take part in the study was not significantly different from the study participants.

After written informed consent, the research nurse who would later conduct the intervention randomised the patients into an intervention group (IG, $n = 50$) or a control group (CG, $n = 50$)) by the minimization method (MINIM-software©, https://www-users.york.ac.uk/~mb55/guide/minim.htm). We chose this covariate adaptive randomisation technique to ensure balance of specific covariates among the two study groups. In the minimization method, each new participant is sequentially assigned to a study arm by considering the predefined covariates and the previous assignments of participants [12]. As covariates (balancing factors), we used age, gender, and education level. In practice, the research nurse marked each patient's allocation on a password protected research file and conducted the intervention or the control procedure accordingly. Both participants and care providers were blinded to the group allocation throughout the study period. The nurse conducting the intervention did not take part in the patients' surgical care.

Intervention

A knowledge test (KNOWBACK Test) designed for this study was used to measure the patient's knowledge level in both study groups [9]. The KNOWBACK test is a self-report questionnaire with 27 'true–false-do not know' items in bio-physiological (9 items; e.g. aetiology, symptoms, treatment, and complications), functional (6 items; e.g., mobility, rehabilitation, rest, and nutrition), social (3 items; patient unions, family, and work), experiential (3 items; emotions, attitude), ethical (3 items; patient rights, participation in decision-making and confidentiality), and financial (3 items; costs and social benefits) domains. A correct answer gave one point with no points for false or "do not know" answers. Thus, the scale for the test ranged from 0 to 27.

Knowledge Test Feedback Intervention (KTFI) consists of an educational telephone discourse that aims to support the patient's cognitive empowerment through strengthening his/her knowledge of surgery-related issues [4, 13, 14]. The patients in the IG received their corrected KNOWBACK Test before the intervention. During the telephone discourse, the nurse encouraged the patients to take an active role and reflect on their answers to the test questions, as well as provided feedback on their existing knowledge. The telephone discourse consisted of three phases. First, an open atmosphere was created with small talk. The discourse proper utilized open-ended questions and active listening. The correct KNOWBACK Test answers were noted; the depth of the discourse on the incorrect items was according to the patient's preference. Finally, the discourse was summarized. The mean duration of discourse was 21 min (range 8–65).

To blind the patients in the CG, they received a general telephone discussion (mean duration 14 min, range 4–29) about their health history with the same nurse.

In addition, patients in both study groups received routine preoperative education. The surgeon informed the patient about the disease, different treatment options, the surgery, possible complications, and expected outcomes. A staff nurse gave instructions on how to prepare for surgery, and dealt with any possible concerns the patient may have had. At admission to the hospital, the patient met an anaesthesiologist and a physiotherapist.

In the first phase of our study, we assessed the impact of KTFI on the patients' knowledge level in the two study

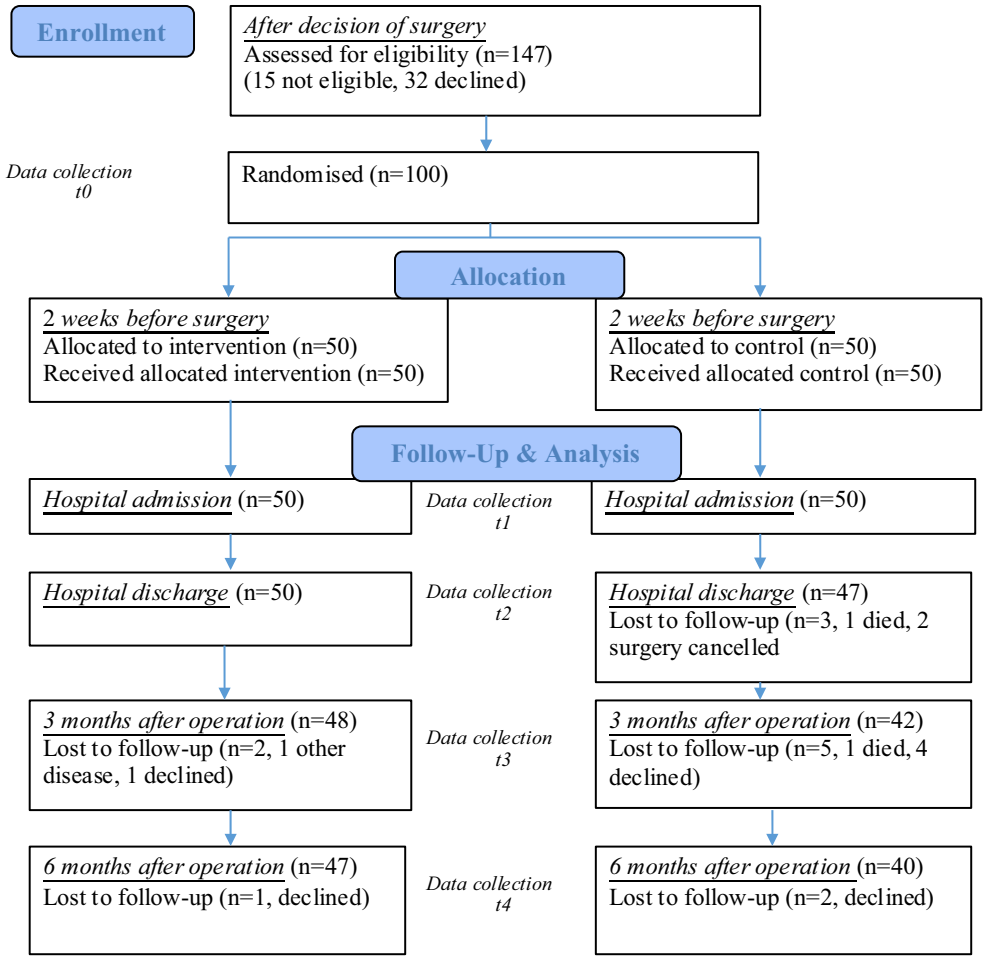

Fig. 1 Consort flow diagram

groups. In the IG, the knowledge level increased significantly more than in the CG (29 vs. 0%). The knowledge level in the IG remained stable throughout the follow-up, as did the difference between the study groups [9].

Data collection

The demographic and clinical characteristics (age, gender, education level, civil status, hospital stay, type of surgery, and duration of surgery) and the baseline data (t0) were collected after the decision for surgery (Fig. 1). The KTFI took place on an average 9 days before surgery (range 3–32 days). Outcome data collection points were at admission to the hospital (t1), discharge (t2) from hospital, three (t3), and 6 (t4) months after surgery (Table 1).

Our primary outcome was situational anxiety related to surgery measured by the state anxiety scale of Spielbergeŕs State Trait Anxiety Inventory (STAI Form Y-1), a 20-item self-report scale defining how the individual feels at the moment. The items are rated on a 4-point Likert scale with responses ranging from 1 (not at all) to 4 (very much). The sum scores have been categorized into low (20–39), medium (40–59), and high (60–80) levels of anxiety [10].

Our secondary outcomes were HRQoL, disability, and pain. A validated Rand 36-Item Health Survey 1.0 (RAND-36) with eight separate subscales was used to measure HRQoL. The results can be expressed by a single score ranging from 0 to 100 with higher scores indicating better HRQoL. [15] Disability was assessed using the Oswestry Disability Index (ODI, version 1.0) with a score range from 0 (no disability) to 100 (maximum disability) [16]. Back and leg pain were assessed by a 10 cm visual analog scale (VAS).

Statistics

Patient demographics were presented as frequencies or means and SDs. The differences between IG and CG were analyzed with *t* test for numeric variables. Chi-square test was applied for categorical variables. The outcome variables were analyzed with two-way repeated-measures analysis of variance (ANOVA) with the group (IG, CG) as

Table 1 Outcomes and instruments of the study

Time	t0 (Baseline) Decision of surgery	Intervention			
		t1 Hospital admission	t2 Hospital discharge	t3 3 months after surgery	t4 6 months after surgery
Data collection site	Home	Hospital	Hospital	Home	Home
Knowledge measures	Knowledge level	Knowledge level	Knowledge level	Knowledge level	Knowledge level
Outcome variables (instruments)	Anxiety (STAI-S)	Anxiety (STAI-S)	Anxiety (STAI-S)		
	HRQoL (RAND-36)			HRQoL (RAND-36)	HRQoL (RAND-36)
	Disability (ODI)			Disability (ODI)	Disability (ODI)
	Pain (VAS)			Pain (VAS)	Pain (VAS)

a between-subject factor, and time point (t0, t1, t2, t3, and t4) as a within-subject factor. Pairwise comparisons between the time points were performed using Tukey–Kramer adjustment. Internal consistency was evaluated using Cronbach's alpha coefficient. The data were analyzed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA). p values less than 0.05 were regarded as statistically significant.

Ethics

The ethical committee of the hospital district accepted the study design. All relevant permissions from copyright owners of the outcome instruments were obtained. The participants were provided oral and written information about the study before their written informed consent. The study was conducted according to the Declaration of Helsinki. This study was registered at Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12611000417987.

Results

At baseline, there were no statistically significant differences in the demographic or clinical characteristics between the study groups (Table 2). In both groups, one patient suffered from depression, and in the control group, one patient had been diagnosed with a bipolar mental disorder. The preoperative ODI was 42.3 (SD 16.6) in the IG and 44.7 (SD 15.5) in the CG indicating severe disability in both groups. 94% of the IG and 80% of the CG patients completed the 6-month follow-up.

At baseline, the anxiety level was moderate [10] in both groups (IG 44.0 vs. CG 41.9, $p = 0.985$). A statistically significant decrease of 5.1 points on STAI (95% CI 0.7–9.5, $p = 0.011$) was seen in the IG after the intervention (t1). A further decrease was noticed after the surgery. In the CG, a significant decrease of 4.8 points on STAI (95% CI 0.1–9.7, $p = 0.044$) was detected after the surgery (t2) (Fig. 2). However, the differences between the groups were not significant ($p_{\text{interaction}} = 0.265$) (Table 3).

Table 2 Background factors of participants

	IG ($n = 50$)	CG ($n = 50$)	p value
Gender (male/female)	17/33	19/31	0.677*
Age (years)[a]	61.9 (12.5)	63.0 (11.9)	0.654†
Professional education			0.792*
Primary	13	11	
Secondary	13	16	
Tertiary	24	21	
Chronic disease(s)	37	38	0.478*
Mental health problem	1	2	
Hospital stay (days)[a]	7.1 ± 2.4	7.5 ± 2.6	0.446†
Range days	3–16	3–15	
Previous surgeries			
Spine surgery (yes/no)	17/33	16/32	0.986*
Other surgery (yes/no)	39/10	45/4	0.100*
Surgery type			
Decompression	32	33	0.520*
Fusion	1	0	
Decompression with fusion	17	15	0.725*
Duration of surgery (minutes)[a]	148 (71)	145 (63)	0.839†
Range (minutes)	36–408	45–315	

IG intervention group, *CG* control group

* Pearson Chi-square for comparing proportions

† Student's t test for independent samples

[a] Mean values (standard deviation)

At baseline, there were no statistically significant differences between the groups in HRQoL. During follow-up, all dimensions of HRQoL improved significantly in both study groups ($p_{\text{group}} \leq 0.0002$); the improvement was beyond the suggested minimal clinically important difference for RAND [15]. Although no statistically significant differences between the groups emerged ($p_{\text{interaction}} \geq 0.11$), some subscales of RAND-36 showed a trend in

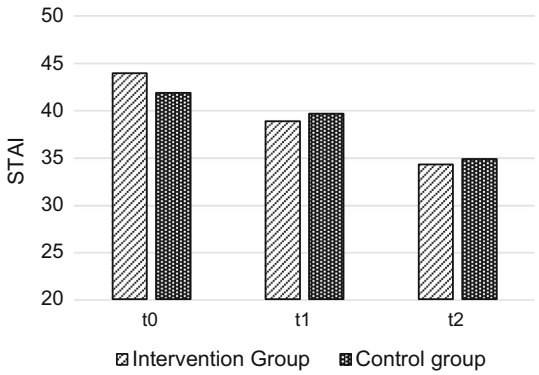

Fig. 2 Means of anxiety on Spielberger's State Anxiety Inventory (STAI-S Form Y1), scale 20–80. t0 = baseline, t1 at admission to hospital, and t2 at discharge from hospital

favor of the IG (social functioning, vitality, and emotional role functioning) (Fig. 3; Table 4). Furthermore, between the 3- and 6-month follow-up (from t3 to t4), a significant improvement was noted in both groups in the domains "physical functioning", "physical role functioning", and "social functioning".

The ODI decreased at follow-up significantly within the groups ($p_{group} < 0.0001$) (Fig. 4), but no significant difference between the groups was detected ($p_{interaction} = 0.95$) (Table 4).

The VAS scores for back and leg pain decreased during follow-up within the groups ($p_{group} < 0.0001$), but no significant between-group differences were detected ($p_{interaction} = 0.78$; 0.98, respectively). Pain relief was most noted during the first 3 months after surgery (t3), with a slight trend for increased pain by t4 (6-month follow-up) (Fig. 5).

Age, gender, education level, duration of hospital stay, or the previous spine surgery did not demonstrate any significant effect on anxiety, HRQoL, disability, or pain (p for all tests ≥ 0.06).

Discussion

In this randomised controlled trial, preoperative anxiety was significantly reduced after an educational intervention based on a knowledge test and an empowering telephone discourse that was shown to increase the patients' knowledge level. In the CG, preoperative anxiety was not relieved until after the surgery. The previous studies have shown that a preoperative education video on anesthesia [17], patient́s knowledge about the surgical procedure [18], or enhanced patient education [19] reduce preoperative anxiety. To our knowledge, the current study is the first to show that a specific preoperative patient education reduces

Table 3 Changes of the means of STAI within and between the groups

Group	t0		Change t0–t1			Change t1–t2		
	Mean (SD)	*n*	Mean (95% CI)	*n*	p_{t0-t1}	Mean (95% CI)	*n*	p_{t1-t2}
Intervention	44.0 (11.9)	49	−5.2 (−7.7, −2.6)	48	0.0011	−4.6 (−7.2, −2.1)	47	0.0053
Control	41.9 (12.3)	47	−1.9 (−4.5, 0.6)	46	0.6759	−5.4 (−7.9, −2.8)	45	0.0008
p_{group}	0.2388		0.7404			0.9910		
$p_{interaction}$	0.1790							

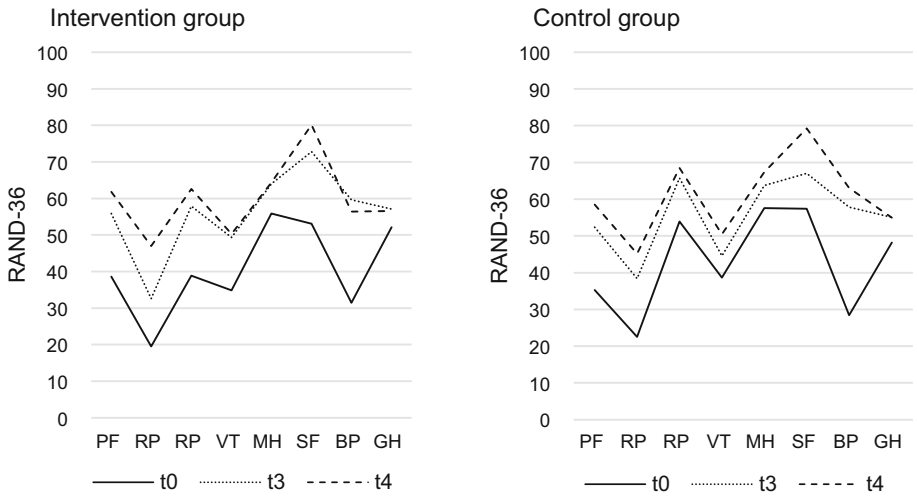

Fig. 3 Means of domains of HRQoL (RAND-36). *PF* physical functioning, *RP* physical role functioning, *RP* emotional role functioning, *VT* vitality, *MH* mental health, *SF* social functioning, *BP* bodily pain, and *GH* general health. *t0* baseline, *t3* 3 months after surgery, and *t4* 6 months after surgery

Table 4 Changes of dimensions of HRQoL (RAND-36) and disability (ODI) in groups and differences between the groups

Variable		Baseline t0		Change t0–t3		Change t3–t4			
Scale	Group	Mean (SD)	*n*	Mean (95% CI)	*n*	Mean (95% CI)	*n*	p^{a}_{time}	$p^{b}_{interaction}$
HRQoL									
General health	Intervention	52.1 (17.8)	50	5.8 (0.7, 10.9)	45	−1.3 (−5.7, 3.1)	42	0.0002	0.6562
0–100	Control	48.2 (21.8)	49	8.7 (3.1, 14.4)	39	−0.9 (−5.8, 4.1)	35		
	Difference	3.9		−2.9		−0.5			
	p_{group}	0.3439		0.4376		0.8836			
Physical functioning	Intervention	38.6 (24.0)	50	18.2 (11.1, 25.3)	45	6.7 (0.9, 12.6)	42	<0.0001	0.925
0–100	Control	35.3 (21.4)	49	17.3 (10.3, 24.4)	40	4.5 (−2, 1, 11.1)	36		
	Difference	3.3		0.9		2.2			
	p_{group}	0.4700		0.8550		0.6093			
Role functioning/physical	Intervention	19.5 (33.7)	47	17.1 (4.4, 29.7)	42	14.3 (0.6, 19.3)	39	<0.0001	0.653
0–100	Control	22.5 (35.2)	46	12.3 (−1.5, 26.0)	36	8.6 (−2.1, 19.3)	32		
	Difference	−3.0		4.8		5.8			
	p_{group}	0.6694		0.6053		0.5208			
Role functioning/emotional	Intervention	39.9 (42.9)	48	19.0 (2.2, 35.9)	42	9.3 (−5.7, 24.2)	36	0.0002	0.477
0–100	Control	53.9 (45.9)	47	11.5 (−4.5, 27.5)	34	−1.1 (−13.1, 10.9)	30		
	Difference	−7.7		7.5		10.3			
	p_{group}	0.4295		0.5217		0.2877			
Vitality	Intervention	34.9 (19.6)	49	13.7 (18.6)	43	1.6 (16.9)	41	<0.0001	0.111
0–100	Control	38.7 (20.0)	49	6.7 (17.9)	40	4.3 (16.3)	36		
	Difference	3.9		7.1		−2.7			
	p_{group}	0.3368		0.0950		0.3300			
Mental health	Intervention	55.9 (15.8)	49	8.0 (3.3, 12.5)	43	−0.2 (−4.0, 3.7)	41	<0.0001	0.762
0–100	Control	57.6 (18.7)	49	7.4 (2.4, 12.5)	40	2.6 (−0.1, 5.4)	36		
	Difference	−1.7		0.5		−2.8			
	p_{group}	0.6313		0.8766		0.2479			
Social functioning	Intervention	53.1 (28.1)	49	19.9 (10.5, 29.3)	44	7.1 (1.6, 12.7)	43	<0.0001	0.122
0–100	Control	57.4 (31.1)	49	9.3 (0.5, 18.1)	39	8.0 (1.0, 14.9)	35		
	Difference	−4.3		10.6		−0.8			
	p_{group}	0.4760		0.1030		0.1310			
Bodily pain	Intervention	31.5 (18.6)	50	29.1 (21.1, 37.1)	45	−2.8 (−10.1, 4.5)	42	<0.0001	0.284
0–100	Control	28.4 (24.1)	49	29.7 (20.3, 39.1)	39	2.8 (−3.8, 9.4)	35		
	Difference	3.1		−0.6		−5.6			
	p_{group}	0.5203		0.9258		0.2625			
Disability	Intervention	42.3 (16.6)	50	−16.8 (−22.5, −11.2)	45	−2.5 (−4.7, 2.7)	42	<0.0001	0.946
0–100	Control	44.7 (15.5)	49	−17.9 (−17.9, −12.0)	39	−1.0 (−6.6, 1.6)	35		
	p_{group}	0.4668		0.7942		0.6041			

[a] Difference within the group over time

[b] Difference between the groups over time

preoperative anxiety in spinal stenosis patients. None of the collected demographic or clinical patient characteristics explained our finding. Even patients with previous surgeries seemed to benefit from improved patient education in terms of relieved preoperative anxiety.

We hypothesized that higher preoperative knowledge would improve the clinical outcome of spinal stenosis surgery. Among joint replacement patients, the extent of patient education has been connected to postoperative HRQoL [20]. In our spinal stenosis patients, a significant improvement in HRQoL, disability, and pain was noticed during the 6-month follow-up, but there were no significant differences between the two study groups. In spinal stenosis, the overall clinical improvement is most probably due to decompression and thus unrelated to preoperative knowledge or anxiety. However, from a patient's

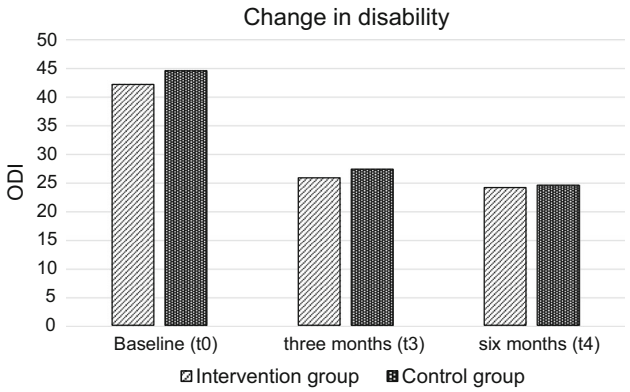

Fig. 4 Means of disability (Oswestry disability Index, ODI) with a score range from 0 (no disability) to 100 (maximum disability). At the follow-up, the change within the group was statistically significant in both groups but not between the groups

perspective, the reduction of preoperative anxiety may have value per se, even without an effect on the surgical outcome.

Preoperative patient education has reduced postoperative pain after total knee replacement [19]. There is no way of knowing, but our intervention might have reduced the need of postoperative pain medication or otherwise affected the immediate postoperative recovery. However, these outcomes were outside the scope of this study.

Our results suggest that patient education alone does not significantly impact postoperative HRQoL, disability, or pain. Effective methods to support patient recovery after surgery are clearly needed. Some specific postoperative rehabilitation interventions have resulted in faster recovery in terms of HRQoL and disability [21] and overall improvement in HRQoL [21, 22] after spinal stenosis surgery, although this finding has not been corroborated in other studies [23]. Furthermore, repeating and deepening the preoperative patient education during the postoperative phase have been suggested to satisfy the patient́s individual knowledge needs [24].

Our study has several strengths. The study protocol was rigorous: the patients and the care providers were blinded regarding the group allocation; the intervention was conducted by a research nurse trained in the technique and experienced in nursing spine surgery patients. The study groups were homogeneous, and the overall drop-out rate (13%) was lower than the sample size calculation allowed (15%). We used validated and reliable outcome measures that are commonly used in spine surgery and research [25]. The Gronbach's alpha of this study at the baseline was for STAI 0.94, ODI 0.85, and on the subscales of RAND-36 from 0.72 to 0.88.

Our study has some limitations. To the authorś knowledge, no minimal clinically important difference (MCID) for STAI exists. We chose the difference of three in the state anxiety scale for our sample size calculation based on a previous study [11]. Furthermore, we did not measure the trait anxiety scale of the STAI. It is possible that the baseline trait anxiety level would have been higher in one of the study groups, i.e., the patients in that group would have been more prone to anxiety. However, we would expect the randomization procedure to balance this baseline characteristic. Furthermore, whereas state anxiety scores have been shown to rise prior to surgery and decline as patients recuperate, trait anxiety scores do not appear to be influenced by the stress of surgical procedure [10]. As the study was conducted within routine clinical practice, we could not control the time interval between the intervention and admission to hospital. The length, depth, or content of the telephone discourse was not standardized, but rather according to each patient́s need of support for his/her cognitive empowerment; thus, the telephone discourse differed from patient to patient. Although the knowledge level was our outcome measure in assessing the effect of the educational intervention, it is highly likely that other factors besides the increased knowledge reduced the preoperative anxiety in the IG, e.g., the empowering discourse with the research nurse per se conducted in a

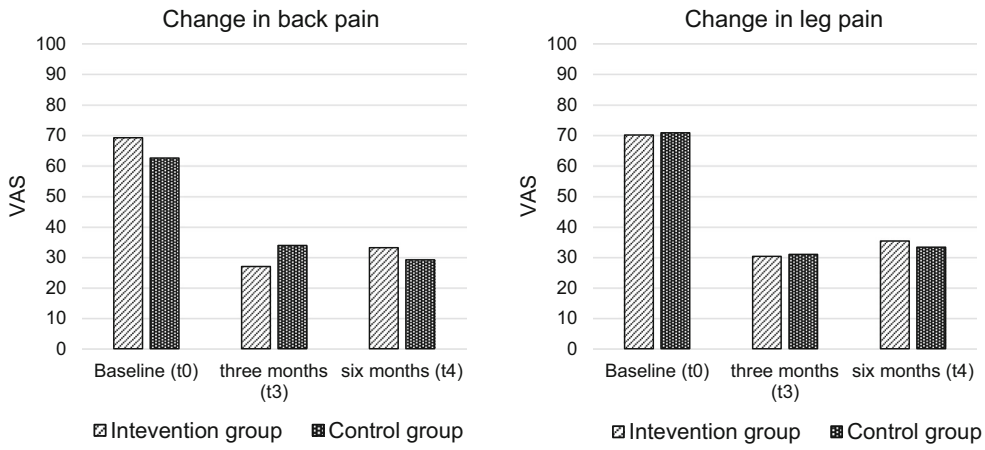

Fig. 5 Means of back and leg pain (Visual Analog Scale, VAS) with a scale from 0 (no pain) to 100 (extreme pain). At the follow-up, the change within the group was statistically significant in both groups but not between the groups

trusting and encouraging atmosphere, the attention given to the patient before surgery, and the interest demonstrated by the research nurse on the patient's situation. We also conducted a telephone discussion with the CG on their general health status, but these discussions were shorter and not as structured as the empowering discourse in the IG. All these factors may have contributed to the difference in the preoperative anxiety noticed between the groups.

Our educational intervention was conducted by a research nurse specifically trained with the technique. Although the KTFI is an easily implemented method in any clinical setting, it is dependent on the communication skills of the educator, which may introduce variability into the intervention. We could not control whether the patients looked for additional information, e.g., from the Internet, and interactions during the hospital stay may have created collaborative learning opportunities amongst fellow patients. However, this would be true for both study groups, and suggests that the reduction in preoperative anxiety would result from the intervention. Finally, the 6-month follow-up is relatively short for a clinical study, but has been considered long enough for spinal stenosis surgery [21].

Conclusions

Increased knowledge after the KTFI probably contributed to the reduction of preoperative anxiety in our spinal stenosis patients. However, this did not seem to affect the self-reported surgical outcome.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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