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Clinical Study

A web-based platform to accommodate symptoms of anxiety and depression by featuring social interaction and animated information in patients undergoing lumbar spine fusion: a randomized clinical trial

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Abstract

BACKGROUND: Approximately one-third of patients undergoing spine surgery have symptoms of anxiety and depression that correlate with pain, disability, and lower health-related quality of life. The use of web-based informative strategies before surgery and principles from cognitive behavioral therapy, have been applied in other patient groups, facilitating mobility and encouraging beneficial coping behavior.

PURPOSE: To examine the effect of a web-based Spine Platform featuring Interaction and Information by Animation (w-SPIINA) on symptoms of anxiety and depression, pain, disability, and health-related quality of life.

STUDY DESIGN: A single-center, two-arm, randomized controlled trial

PATIENT SAMPLE: One hundred fourteen consecutive patients scheduled for instrumented lumbar spine fusion due to degenerative disc disease or spondylolisthesis.

OUTCOME MEASURES: Primary outcome was the change in self-reported Hospital Anxiety and Depression Scale (HADS) scores from baseline to 3-month follow-up. Secondary outcomes were change in HADS 1-day before surgery 2 days and 6 months after and changes in self-reported disability measured on the Oswestry disability index (ODI), quality of life (EQ-5D-5L questionnaire), and the low back pain rating scale (LBPRS) 2 days and 3 and 6 months after surgery.

METHOD: Patients were randomized to either a control group receiving a standard information regimen or an intervention group gaining access to w-SPIINA in addition to the standard regimen. The independent charity Helsefonden contributed $45,000, the Health Research Fund of the Regional Hospital Central Jutland contributed $10,000, and the Toyota foundation contributed $10,000 to remunerate a dedicated investigator. The authors have no conflict of interest to declare.

RESULTS: There was no statistically significant difference within the w-SPIINA group and the control group regarding changes in HADS at 3-month follow-up ($p \geq .37$). Approximately 40% reached minimum clinically important difference (MCID) in the w-SPIINA group on the HADS at 3 months. In the control group 50% reached MCID on anxiety subscale and 35% on the depression subscale at 3 months. No statistically significant differences were found between groups with regard to the overall outcomes at any of the predefined time points.

FDA device/drug status: not applicable.

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CONCLUSION: Providing patients with access to w-SPIINA in addition to a standard information regimen had no additional effect on HADS and patient-reported outcomes1 day before, 2 days, 3 or 6 months after surgery. However, a high compliance and degree of interaction with w-SPIINA indicates that this mode of web-based support could be applicable in this group of patients.

Keywords: Lumbar spine fusion; Anxiety; Depression; Web-based platform; Randomized trial, Information; Animation

Background

During the last decade, symptoms of anxiety and depression have been found to be important predictors of spine surgery outcome and to correlate with greater pain, disability, and lower health-related quality of life [1–5]. Patients with chronic back pain are commonly found to have symptoms of both anxiety and depression, with a prevalence that is two to three times greater than in the general population [6,7]. Furthermore, approximately one-third of patients with degenerative disorders undergoing surgery have similar symptoms before surgery [8,9], and approximately one of every five patients have these symptoms 1 year after surgery [10]. In addition, new onset of depression is more often found in patients after spine surgery, especially lumbar spine fusion (LSF), compared to patients with other surgical or medical diagnoses [11].

This correlation may be explained by the theoretical standpoint expressed in WHO's *International Classification of Functioning, Disability and Health* (ICF) where a reduced ability to function is defined as a consequence of a complex and dynamical interaction between states of health and functioning and contextual factors [12]. Thus, pain, disability, and health-related quality of life may be perceived as a composite phenomenon, influenced by the individual's comorbidity, reaction, ability to cope, and the environment [13]. Consequently, in addition to important biomedical/mechanical issues, a wider approach is needed in these patients in order to improve postsurgical outcome [13].

Web-based informative strategies before surgery and principles from cognitive behavioral therapy (CBT) have been applied in this patient group in recent years [14,15]. A rationale is found in using information and elements from CBT in order to reduce pre- and postoperatively symptoms of anxiety [16] and depression [6,17]. Educative methods together with cognitive methods, hence elements from CBT, presented on a web-based solution have not yet been evaluated in patients undergoing LSF. In this study, a web-based Spine Platform featuring Interaction and Information by Animation (w-SPIINA) was used in the attempt to reduce symptoms of anxiety and depression in patients undergoing instrumented LSF due to disc degeneration or spondylolisthesis. The aim is to explore the effect of alternative educative and cognitive methods in LSF patients given access to w-SPIINA, primarily with regard to symptoms of anxiety and depression 3 months after surgery and secondarily on symptoms of anxiety and depression the day before surgery and symptoms of anxiety, depression, back and leg pain, disability, and health-related quality of life 2 days and 3 and 6 months after surgery.

Materials and methods

Participants

Patients were enrolled at a single-center orthopedic spine department in Denmark from September 2015 to May 2017. The inclusion criterion was patients scheduled for first-time elective one-three level lumbar spine fusion, that is, instrumented posterolateral fusion (PLF) or transforaminal interbody fusion (TLIF), attending baseline visit 1 to 5 weeks prior surgery.

Exclusion criteria were age below 18, patients with psychotic disease, schizophrenia or other psychotic disorder, inability to communicate in Danish, patients without an internet connection.

Patients were randomized to either a control or an intervention group at baseline. Block randomization was performed using random block sizes of four or six, with equal numbers of "intervention" and "control". Assignments were obtained using a simple "shuffling envelope" procedure by an independent secretary. Due to the nature of the intervention, neither the patients nor the researchers were blinded to allocation. Data security and management was approved by the Danish Data protection agency (J.no. 2014-41-3583), and the trial was registered at Clinical Trials.gov (record NCT02615483). In line with the Helsinki Declaration [18], patients were informed about the study both in writing and verbally and had at least 24 hours to consider their participation.

Control group

Patients in the control group received the standard course of treatment, rehabilitation, and information, which consisted of a 2-hour joint session 1 to 5 week before surgery. In this session patients and their support person were given information on the operative and anesthetic procedure, the course of treatment, medication, postoperative training, and restrictions. Information was provided orally and supported by slides and written handouts by nurses, physiotherapists, and occupational therapists. Supervised physical rehabilitation began 12 weeks after surgery.

Intervention group

In addition to the standard course, patients and their support person received access to w-SPIINA from any browser with an individual password through a designated website closed for public access. Patients and support persons went through a 15-minute introduction to w-SPIINA at baseline. To promote implementation and easy access, tablets were provided for those not in possession of such a device.

W-SPIINA consisted of animated information, an internet support group (ISG) and a diary. The animated narratives attempted to influence the ability to recall information by reducing the complexity to accommodate the possible challenges of a low degree of health literacy. The information was animated based on the current literature stating that pictographs and animations optimize patients' acquisition of knowledge [19–23]. Animations also included noncatastrophic images that sought to influence, change, or modify patients' beliefs, feelings, and consequently their behavior [17]. In line with the internet provision of computerized cognitive behavioral therapy, the approach was designed to reduce anxiety, catastrophic thoughts, and misconceptions in relation to surgery [24–26]. The animation displayed was divided into chapters mirroring the chronology of the treatment and comprised of 16-minute, two-dimensional animations, in 17 sequences explaining the course of treatment from initial preparation to surgery to postsurgical rehabilitation the first 3 months at home. The second element of the w-SPIINA featured an ISG that attempted to increase patients' satisfaction with their social life and thus, decrease their experience of solitude [27,28] and provided the possibility of exchanging experiences and thus, hopefully better their everyday abilities [29,30]. To avoid there being only one or two patients in the ISG at the beginning of the study, six former patients were invited to participate as facilitators, providing peer support, answering questions and creating activity. These six were not included in the analysis.

W-SPIINA featured a diary in which development of pain and physical ability could be tracked by the patients every day, supporting management of analgesics, and visualizing the progress in pain and activity.

Providing w-SPIINA, geography was taken out of the equation, patients were offered the possibility of gaining knowledge in familiar surroundings in their own home, and at a pace matching their needs and wishes [31]. Technical support could be provided if needed, and a researcher was to mediate whether any offensive remarks or aggressive tone was used. No support or mediation of such behavior was ever needed.

Outcomes

At baseline, demographic characteristics were collected (gender, age, body mass index [BMI], smoking, educational, employment and marital status, primary diagnosis) and symptoms of anxiety and depression, back and leg pain, disability, and health-related quality of life were collected by self-reporting questionnaires.

Primary outcome was the change in self-reported symptoms of anxiety and depression from baseline to 3 months follow-up. Secondary outcomes were the change in symptoms of anxiety and depression 1-day before surgery, 2 days and 6 months after surgery and furthermore, changes in low back and leg pain, in self-reported disability and in quality of life 2 days, 3 and 6 months after surgery

From baseline until 6 months after surgery, patients' activity on w-SPIINA was monitored manually by tracking the use from Google Analytics, including location data, browser data, device type, event type and event time; user-generated c data, and personal data, including location, access date, date of operation, and from which device the patient gained access.

Primary outcome

Symptoms of anxiety and depression were evaluated using the Hospital Anxiety and Depression Scale (HADS), a self-reported questionnaire. HADS is a 14-item scale, with seven items related to anxiety (HADS-A) and seven items to depression (HADS-D) [32], with a maximum score of 21 for each. A high score indicates a high level of symptoms of anxiety and depression in nonpsychiatric hospital patients. Using a score of 8+ on each subscale to identify symptoms of anxiety and depression has in other studies been shown to provide the optimal balance between sensitivity and specificity [33]. Based on previous studies, the minimum clinically important difference (MCID) of HADS is set at 1.5 [34].

Secondary outcome

The Low Back Pain Rating Scale (LBPRS) was used to evaluate back and leg pain [35]. A difference of at least 1.2 for backpain and 1.6 for leg pain must be present for the difference to reach MCID [36]. Disability was graded and evaluated by the Oswestery Disability Index (ODI) [37,38]. A change in ODI of at least 15 points must be presented in order for the change to reach MCID [37,39]. Health-related quality of life was measured by the use of EQ-5D 5L questionnaire. The health states were assigned an index score between 1, representing the best health, and −0.624 representing the worst health [40]. The index score must have a change of at least 0.08 in order to reach MCID [41].

Sample size

The sample size calculation was based on the evaluation of the primary outcome measure, HADS. The minimal important difference in the HADS score was set at 1.5 [34] and the standard deviation on the change in HADS was set to 2.5 [34]. With a significance level at 0.05 and a power of 0.80, the study needed 88 patients. In effort to minimize and meet the risk of losing study power due to, loss to follow-up, rescheduled and cancelled surgery, an additional 30% were included. Thus, 114 patients were included in the study.

Statistical methods

Data were managed using REDCap electronic data capture tools hosted at Aarhus University, Denmark [42]. All data were entered twice, and any divergence was corrected according to source data. Statistical calculations were performed using the software program STATA 15. Data were analyzed according to the as treated principle. The difference from baseline to 3 and 6 months follow-up is presented with the use of medians and percentiles. Comparisons of difference between the two groups were completed using Mann-Whitney test or in order to test for trends using chi-square. Due to the nonparametric distribution of parameters, nonparametric statistics were applied. A post-hoc sensitivity analysis was performed. Due to the unequal distribution of gender in the two groups, the comparison of each of the two primary endpoints were stratified on gender and combined to a test adjusted for gender [43].

Results

Participant flow

A total of 212 consecutive patients were assessed for eligibility; 98 did not enter the study (Fig. 1). The excluded patient group contained a slightly lower proportion of woman (5%) and a slightly older population with a mean age of 62 years (range 31–79). A total of 114 patients fulfilled the in- and exclusion criteria. Fifteen (7%) additional patients were excluded due to changed or cancelled surgery or they withdrew consent. In total, 99 patients were included in the analysis, 51 in the control group and 48 in the intervention group (Fig. 1).

Cancelled or moved surgery and withdrawal based on medical reason was considered a random event. A total of five patients withdrew their participation because they lost motivation. This was presumably not random as all withdrawals had been randomized to the intervention group. All were women with a mean age of 65 (range 37–80), three presenting a caseness of depression and two of anxiety. Thus, in the group of patients who withdrew, the occurrence of depression was higher, they were slightly older, and all were women.

The overall mean number of days from baseline to surgery was 18 (range 7–36). The two groups were comparable at baseline (Table 1). However, by chance there was a difference in the distribution of gender (p=.03). In both groups at baseline, approximately one-third scored 8+ on the anxiety subscale indicating anxiety, and on depression subscale indicating depression, approximately one-third of the intervention group and one in five in the control group scored 8+.

Five patients in both groups had complications. In the intervention group, three had a dura lesion versus two in the control group. Additional complications comprised kidney failure, infection without focus, severe pain, and respiratory problems; no differences were found between the two groups in terms of patient characteristics, baseline measurements, length of stay, or outcome changes.

Interaction with intervention

All patients accessed w-SPIINA more than once. A total of 90% of the patients accessed the ISG embedded in w-SPIINA, and of these 48% (n=23) were active users who contributed posts or comments. The animated information has been viewed a total of 656 times. The dairy was used a total of 293 times, and 3,357 events were registered in the ISG, thus a total of 4,306 interactions were registered on w-SPIINA.

Clinical outcome measures

There were no significant differences between improvements in the two groups according to the primary outcome HADS at 3 months after surgery, neither 1 day before surgery or 2 days or 6 months after surgery as displayed in Table 2. Exploratory analysis concerning an MCID of 1.5 points on the *HADS-A subscale* at 3 months was carried out and revealed that in the intervention group 19 patients (42%) improved and 9 (20%) worsened. In the control group 23 patients (50%) improved and 6 (13%) worsened. Test for trends showed no significant differences (p=.62). At 6 months, also with no differences between groups (p=.27) in the intervention group 17 patients (40%) improved and 9 (21%) worsened. In the control group 17 patients (38%) improved, 4 (9%) worsened.

Exploratory analysis concerning an MCID of 1.5 points on the *HADS-D subscale* at 3 months showed that in the intervention group 20 patients (44%) improved and 13 (29%) worsened. In the control group 16 patients (35%) improved and 8 (17%) worsened. Tests for trends found no differences between groups (p=.10). At 6 months in the intervention group 15 patients (35%) improved and 10 (23%) worsened. In the control 14 (31%) improved and 12 (27%) worsened, tests for trends found no differences between groups (p=.9).

Looking at the caseness of both anxiety and depression in the total group of patients in dichotomized data (≥8) [33], there is a decline from baseline to 3-month follow-up, and with an increase again from 3 to 6 months (Table 3). Fig. 2 presents box plots of the performance of HADS at all predefined time points in both groups.

The patients presenting caseness of anxiety and/or depression across groups at baseline also presented worse ODI and EQ-5D-5L index score at baseline (p for all tests ≤.05) but presented no significant difference in pain when comparing those with or without symptoms of anxiety or depression (p for all tests >.05).

The result of the post hoc sensitivity analysis of the two primary endpoint shoved for the anxiety score a nonsignificant (p=.85) difference between the two groups in favorite of the intervention group for the women and a nonsignificant (p=.20) difference between the two groups in favorite of the control group for the men. The combined test showed no significant difference between the two groups (p=.54).

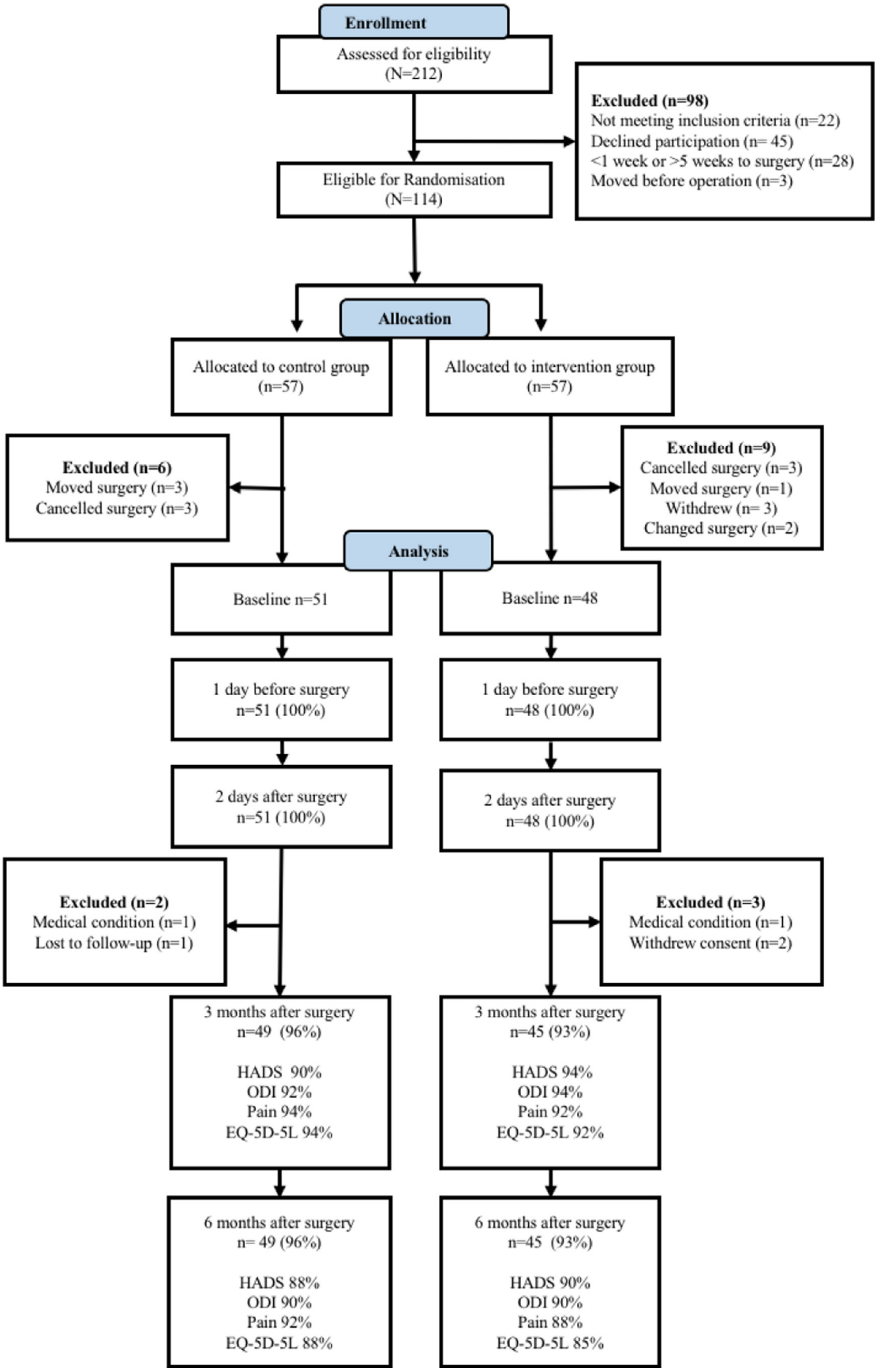

Fig. 1. Patient recruitment and flow.

Table 1
Background patient data

Patient characteristics	Total (n=99)	Intervention group (n=48)	Control group (n=51)	p
Female, n (%)	64 (65)	26 (54)	38 (75)	.03
Age, mean yr. (range)	54 (29-79)	53 (29-77)	55 (30-79)	.20
BMI > 30, n (%)	26 (26)	15 (31)	11 (22)	.27
Smoking, n (%)	19 (19)	7 (15)	12 (24)	.26
Marital status, n (%)				
Married/cohabitating	81 (82)	41 (85)	40 (78)	
Living alone*	18 (18)	7 (15)	11 (22)	.37
Education, n (%)				
Basic education†	22 (22)	12 (25)	10 (20)	
Secondary education‡	73 (74)	33 (69)	40 (78)	
Higher education§	4 (4)	3 (6)	1 (2)	.41
Employment status, n (%)				
Employed	33 (33)	15 (31)	18 (35)	
Sick leave/disability pension/unemployed‖	39 (39)	23 (48)	16 (31)	
Retirement/student	27 (27)	10 (21)	17 (33)	.58
Indication for fusion, n (%)				
Spondylolisthesis	35 (35)	16 (33)	19 (37)	
Degenerative disease	64 (65)	32 (66)	32 (63)	.68
Anxiety and depression (HADS)				
Anxiety (HADS-A) (≥8), n (%)	32 (33)	14 (29)	18 (37)	.43
Depression (HADS-D) (≥8), n (%)	26 (27)	17 (35)	11 (22)	.28
HADS-A score, median (IQR¶)	6 (4 to 9)	6 (4 to 8)	6 (4 to 9)	
HADS-D score, median (IQR)	5 (3 to 8)	5.5 (3 to 8.5)	5 (2 to 7)	
Disability (ODI)				
Median (IQR)	48 (32 to 56)	48 (30 to 54)	49 (32 to 60)	.21
Pain – median (IQR)				
Back pain right now	6 (4 to 7)	6 (4 to 7)	6 (4 to 7)	.50
Leg pain right now	5 (3 to 7)	5 (3 to 7)	5.5 (3 to 8)	.68
Worst back pain within the last 14 days	8 (7 to 9)	8 (7 to 9)	8 (7 to 9)	.66
Worst leg pain within the last 14 days	8 (5 to 9)	8 (6 to 9)	8 (5 to 9)	.66
Mean back pain within the last 14 days	6 (5 to 7)	6 (5 to 7)	7 (5 to 7)	.21
Mean leg pain within the last 14 days	6 (4 to 8)	5.5 (4.5 to 7)	6 (3 to 8)	.07
Quality of life (EQ-5D 5L), index score median (IQR)	0.56 (0.46 to 0.68)	0.59 (0.42 to 0.68)	0.56 (0.48 to 0.64)	.60
Length of stay, mean (range)	5.1 (2 to 18)	4.9 (2 to 18)	5.3 (2 to 13)	.24
Surgical procedure, n (%)				
Posterolateral fusion (PLF)	94 (95)	46 (96)	48 (94)	1.0
Transforminal interbody fusion (TLIF)	5 (5)	2 (4)	3 (6)	1.0
Complications, n (%)	10 (10)	5 (10)	5 (10)	1.0
Dural lesion, n (%)	5 (5)	3 (6)	2 (4)	1.0
Length of stay within this group, mean (range)		8.2 (4 to 18)	9.8 (3 to 13)	.25

* Includes widows, single or divorced,
† Basic education level comprised ISCED levels 0–2 (early childhood education, primary education, and lower secondary education)
‡ Secondary education comprised ISCED levels 3 (upper secondary education),
§ Higher education level comprised ISCED levels 4–8 (post-secondary non tertiary education, short-cycle tertiary education, bachelors or equivalent, masters or equivalent, doctoral or equivalent level) [44],
‖ Includes patients not employed for other reasons than illness or unemployment, such as housewife, on leave, or student.
¶ IQR indicates interquartile range (25th and 75th percentile).

The analysis of the depression score shoved a nonsignificant (p=.43) difference between the two groups in favorite of the intervention group for the women and a nonsignificant (p=.54) difference between the two groups in favorite of the control group for the men. The combined test showed no significant difference between the two groups (p=.77).

Comparing the two groups, no significant differences were found between the groups in the overall changes of ODI, LBPRS, and EQ-5D-5L at 2 days or 3 or 6 months after surgery (Table 2). However, with one exception, "leg pain right now", which presented a significantly better change 2 day after surgery in the control group than in the intervention group (p=.01).

Exploratory analysis on secondary outcome focusing on the reach of MCID *only at 6 months* after surgery. The MCID of 15 points on the ODI, was reached by 19 patients (44%) and 4 (9%) worsened in the intervention group. In the control group 20 patients (43%) improved and 10 (21%) worsened. There were no differences between groups (p=0.26). Focusing on *average back* pain score the MCID (1.2 points) was reached by 31 patients (74%) in the intervention and 31 patients (66%) in the control group.

Table 2
Effect of w-SPIINA on symptoms of anxiety and depression, disability, pain, and health-related quality of life

	Intervention group Change from baseline Median [IQR]	Score at follow-up Median [IQR]	N	Control group Change from baseline Median [IQR]	Score at follow-up Median [IQR]	N	Between-group diff. p
HADS-A							
1 day before surgery	1 (3.5 to 2)	7 (4 to 10)	48	0 (1 to −1)	6 (4 to 8)	48	.12
2 days after surgery	1 (3 to −1)	7 (4 to 10)	47	0 (2 to −2)	6 (3 to 9)	42	.18
3 months after surgery	−1 (1 to −3)	5 (3 to 7)	45	−1.5 (0 to −3)	4 (1.5 to 7)	46	.37
6 months after surgery	−1 (1 to− 3)	5 (2 to 8)	43	−1 (1 to −3)	4 (1 to 8)	45	.78
HADS-D							
1 day before surgery	0 (2 to −1)	6 (3 to 9)	47	1 (2 to −1)	6 (3 to 8)	48	.67
2 days after surgery	2 (4 to 1)	8 (5 to 12)	47	1 (3 to 0)	6 (3 to 9)	41	.15
3 months after surgery	−1 (2 to −3)	3 (1 to 6)	45	−1 (0 to −3)	3 (1 to 5)	46	.78
6 months after surgery	0 (1 to −2)	5 (2 to 8)	43	0 (2 to −2)	3 (1 to 8)	45	.97
Back pain − back pain right now							
2 days after surgery	1 (2 to −2)	6 (5 to 7)	47	0 (−2 to 2)	5 (3.5 to 7)	44	.42
3 months after surgery	−2 (−1 to −4)	3 (1 to 5)	45	−3 (−1 to −4)	3 (1 to 4)	49	.38
6 months after surgery	−3 (−1 to −4)	3 (2 to 4)	43	−2 (−1 to −4)	3 (1 to 5)	47	.51
Back pain − the worst back pain within the last 14 days							
2 days after surgery	1 (2 to 0)	9 (8 to 10)	46	1 (2 to 0)	9 (8 to 10)	43	.78
3 months after surgery	−2 (−4 to 0)	6 (3 to 8)	44	−3 (−5 to 0)	5 (2 to 8)	48	.24
6 months after surgery	−3 (−4 to 0)	5 (3 to 7)	42	−3 (−5 to 0)	5 (2 to 7)	47	.59
Back pain − median back pain within the last 14 days							
2 days after surgery	0 (1 to −1)	6 (5 to 7)	45	0 (1 to −1)	8 (5 to 8)	42	.79
3 months after surgery	−2 (−0.5 to −3.5)	3 (2 to 5)	44	−3 (−1 to −4)	3 (1.5 to 5)	48	.26
6 months after surgery	−2 (−1 to −4)	3 (2 to 5)	42	−2 (−1 to −4)	4 (2 to 5)	47	.98
Leg pain − leg pain right now							
2 days after surgery	1 (3 to 2)	3 (2 to 6)	46	3 (5 to 0)	2 (0 to 4)	43	**.01**
3 months after surgery	−2 (−5 to 0)	2 (0 to 5)	44	−3 (−5 to−1)	1 (0 to 3)	48	.17
6 months after surgery	−2.5 (−5 to 0)	1 (0 to 5)	42	−3 (−5 to −1)	1 (0 to 4)	46	.38
Leg pain − the worst leg pain within the last 14 days							
2 days after surgery	1 (0 to 3)	7 (6 to 9)	46	1.5 (0 to 4)	7.5 (5.5 to 9)	42	.40
3 months after surgery	−1.5 (−4 to 0)	3 (1 to 7)	44	−2 (−4 to 0)	1 (0 to 5)	47	.73
6 months after surgery	−2 (−4 to −1)	4 (1 to 8)	42	−2 (−4 to 0)	2 (0 to 6)	46	.62
Leg pain - median leg pain within the last 14 days							
2 days after surgery	0 (−2 to 0)	5 (5 to 7)	46	0 (1 to −2)	5 (3 to 7)	43	.20
3 months after surgery	−3 (−5 to −1)	2 (1 to 5)	45	−3 (−5 to −1)	1 (0 to 3)	49	.55
6 months after surgery	−2 (−5 to −1)	2 (1 to 6)	43	−3 (−5 to 0)	1 (0 to 5)	47	.51
ODI							
2 days after surgery	34 (17 to 43)	80 (63 to 87)	47	26 (11-40)	76 (59 to 87)	43	.25
3 months after surgery	−10 (0 to −23)	32 (16 to 47)	45	−15.5 (0 to −27.5)	30 (15.5 to 47.5)	48	.42
6 months after surgery	−11 (0 to −30)	26 (11 to 46)	43	−9 (5 to −29)	39 (12 to 58)	47	.58
EQ-5D-5L							
2 days after surgery	−0.11 (0 to 0.22)	0.5 (0.37 to 0.58)	45	−0.09 (−0.03 to 0.17)	0.5 (0.37 to 0.62)	42	.52
3 months after surgery	0.12 (0.20 to 0.02)	0.69 (0.59 to 0.78)	44	0.13 (−0.06 to 0.23)	0.7 (0.64 to 0.79)	48	.49
6 months after surgery	0.08 (0.24 to 0.01)	0.68 (0.59 to 0.75)	41	0.16 (0.24 to 0.06)	0.72 (0.63 to 0.8)	45	.25

IQR indicates the interquartile range (25th and 75th percentile); HADS-A, anxiety subscale on the Hospital Anxiety and Depression Scale; HADS-D, Depression Subscale on the Hospital Anxiety and Depression Scale; ODI, Oswestry Disability Index; Back and Leg pain; Low Back Pain Rating Scale (LBPRS); EQ-5D-5L, Health-related quality of life questionnaire.

Two (5%) patients in the intervention and 3 (6%) in the control group declined. No differences between groups (p=0.84). MCID (1.6 points) on *average leg* pain was reached at 6 months in 25 patients (58%) in the intervention and 30 patients (64%) in the control group. Four patients (9%) in the intervention and 3 patients (6%) in the control group declined (p=.24). Finally, the MCID of at least 0.08 point on the EQ-5D-5L index score at 6 months, was reached in 20 patients (49%) in the intervention group and 30 (67%) in the control group. Three (7%) and 4 (9%) patients in the intervention and control group declined. Tests for trends found no differences between groups (p=.16). Box plots displaying the performance of ODI, EQ-5D-5L, and LBPRS at all predefined time points in both groups are seen in Figs. 3–5.

Discussion

Adding w-SPIINA to a usual standard informational regimen did not significantly reduce symptoms of anxiety and depression in the intervention group compared with the control group at 3 months or at any of the predefined time

Table 3
Caseness of anxiety and depression at baseline, 3 and 6 months follow-up

HADS-A (≥8) n (%)	Intervention group	Control group
Baseline	14 (29%)	18 (37%)
3 months	11 (24%)	11 (22%)
6 months	12 (28%)	13 (28%)
HADS-D (≥8) n (%)		
Baseline	17 (35%)	11 (22%)
3 months	8 (18%)	8 (17%)
6 months	11 (26%)	12 (26%)

points. Adding w-SPIINA did not further improve achievements in ODI, LBPR, and EQ-5D-5L scores, thereby leaving areas for discussion concerning outcome parameters, setting, population, content, and context.

First of all the frequent use of w-SPIINA could indicate that it was found to have some value. All included patients used w-SPIINA, and there were approximately 4,300 events (ISG 3357, Animations 656, and Diary 293). However, this frequent usage did not affect the outcome parameters, and thus, there is a need to further explore the experiences of LSF patients. Such an exploration would clarify patient-perceived value and illuminate whether a possible effect of w-SPIINA could be captured using other outcome parameters. Examples of a possible value can be found in the literature. Qualitative studies have shown that patients who use an ISG, which is the most frequently used feature of w-SPIINA, receive useful information, gain social and emotional support, help others, and connect with peers in the same situation [45–48]. Collectively, this has been described as being empowering for patients [49].

The lack of effect on anxiety might be due to information overload. A study by Kesänen et al. (2017) [16] and one by Chuang et al. (2016) [50] both reduced surgery-related anxiety by optimizing preoperative information with focus only on surgery-related issues and key points of postoperative care. That more narrow focus is in contrast to w-SPIINA, where the information, in addition to being related to the surgery, was directed toward both the period before and until 3 months after surgery, and in addition contained an ISG, and a diary. Thus, an explanation for the lacking effect of w-SPIINA could be found in the so called "filter failure." From this perspective, the strategies for deciding which information is relevant for a certain situation have not evolved at the same pace as the production of information [51]. The challenge is the ability of the patient to select and use the information at their disposal, and thus, providing too much information can have a negative effect [51]. An inconsistency of findings regarding the reduction of anxiety when applying information is substantiated in a review, where the variation of results was attributed not only to the amount of information but also to the heterogeneity of informative interventions and content [52]. This review included 14 interventional trials, using different informative interventions (audio, audiovisual, leaflets, websites, imagery, and multimedia) preoperative, before various surgical procedures (orthopedic, coronary, abdominal, and urinary). Of these 14 studies, eight found a significant reduction in preoperative anxiety [52].

Two-thirds of the patients included in this study did not present (8+) caseness of anxiety or depression at baseline, which might influence the visibility of a potential effect. Furthermore, the fact that two thirds did not present caseness might give reason that 40% to 50% of the included patients experienced no change or a change below MICD on the HADS. Finally, also indicating that the study might

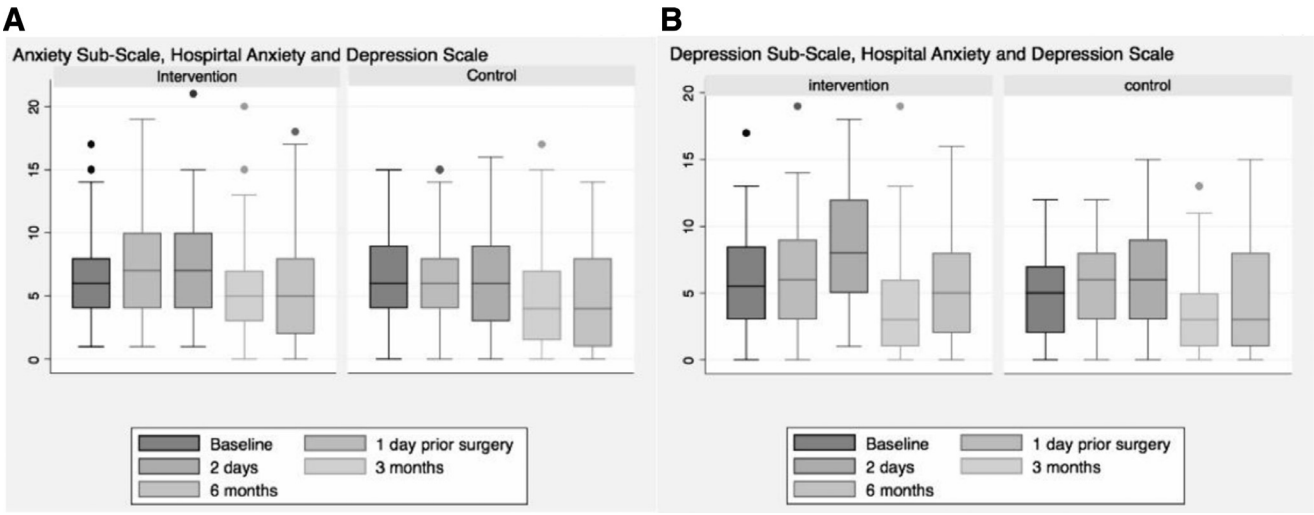

Fig. 2. Hospital Anxiety and Depression Scale, box plot at the predefined time points. Scoring 8+ on either of the subscales indicates caseness of (A) anxiety or (B) depression. Boxes illustrate medians with 25th and 75th percentiles and the whiskers illustration the 5th and the 95th percentiles. The dots outside the whiskers illustrate outliers.

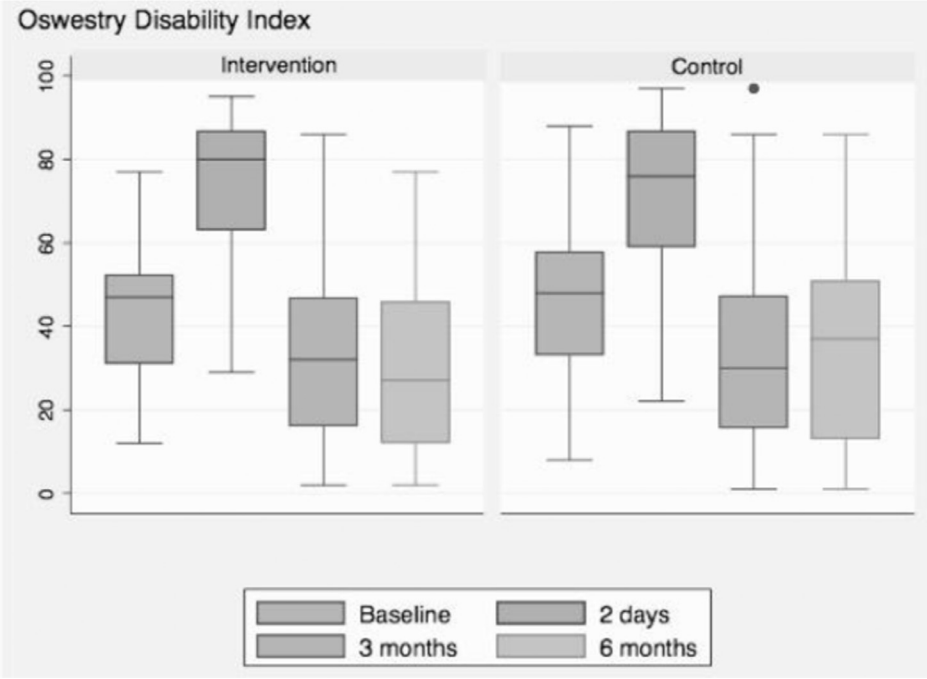

Fig. 3. Oswestry Disability Index, box plot at the predefined time points. Scoring from 0 to 100, 0 indicates no disability. Boxes illustrate medians with 25th and 75th percentiles and the whiskers illustration the 5th and the 95th percentiles. The dots outside the whiskers illustrate outliers.

be underpowered is the large spread in the HADS measures shown at the predefined time points in Fig. 2. In the current study the number of patients with caseness (8+) was too low for subgroup analysis.

The fact that w-SPIINA was an add-on intervention to an already existing 2-hour joint information session may have interfered with the evaluation and contributed to the reason that no effect was found. The 2-hour joint information session has been developed during the last decade, continuously evaluated and changed according to changes in the clinical setting or demands from patients or support persons. The constellation, the content, and the mode of this session were based on the same considerations as the development of w-SPIINA, providing verbal, visual, and written information seeking to enhance understanding, involving support persons, and optimizing support after discharge. Gathering patients in joint sessions has previously been found to have a positive effect on the everyday functioning of LSF patients [29]. Thus, seeking to explore the effect of the already existing joint information session could be an interesting perspective in future research to clarify whether w-SPIINA could replace it, and might even explain the lack of effect of w-SPIINA.

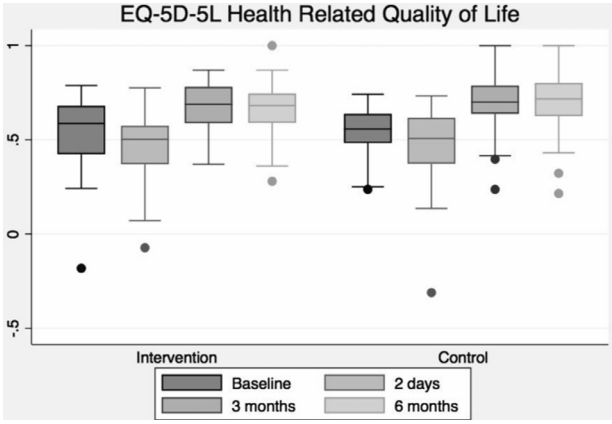

Fig. 4. EQ5D-5L index-score, box plot at the predefined time points. One representing the best health and −0.624, representing the worst health. Boxes illustrate medians with 25th and 75th percentiles and the whiskers illustration the 5th and the 95th percentiles. The dots outside the whiskers illustrate outliers.

The primary aim of w-SPIINA was to reduce anxiety and depression. However, with regard to the factors reported to be associated with anxiety and depression in a recently published review, w-SPIINA lacks focus on central factors [53]. This review uncovered five factors associated with anxiety and depression before and after spine surgery. First, patients' understanding of pain and their ability to cope with pain should be addressed. Second, patients' needs of individual information should be accommodated. Third, addressing every day activities and informing patients to be active to the limit of their abilities should be dealt with. Fourth, patients should be taught to adopt a new life trajectory or to adopt a realistic expectation concerning return to work possibilities, and fifth, if these factors are given priority, the risk of a new onset of psychological disturbances could be decreased [53]. Focus on coping with pain or with disability in everyday life could be increased and the perspective of returning to work or the support to adopt realistic expectations concerning future goals could be added to w-SPIINA.

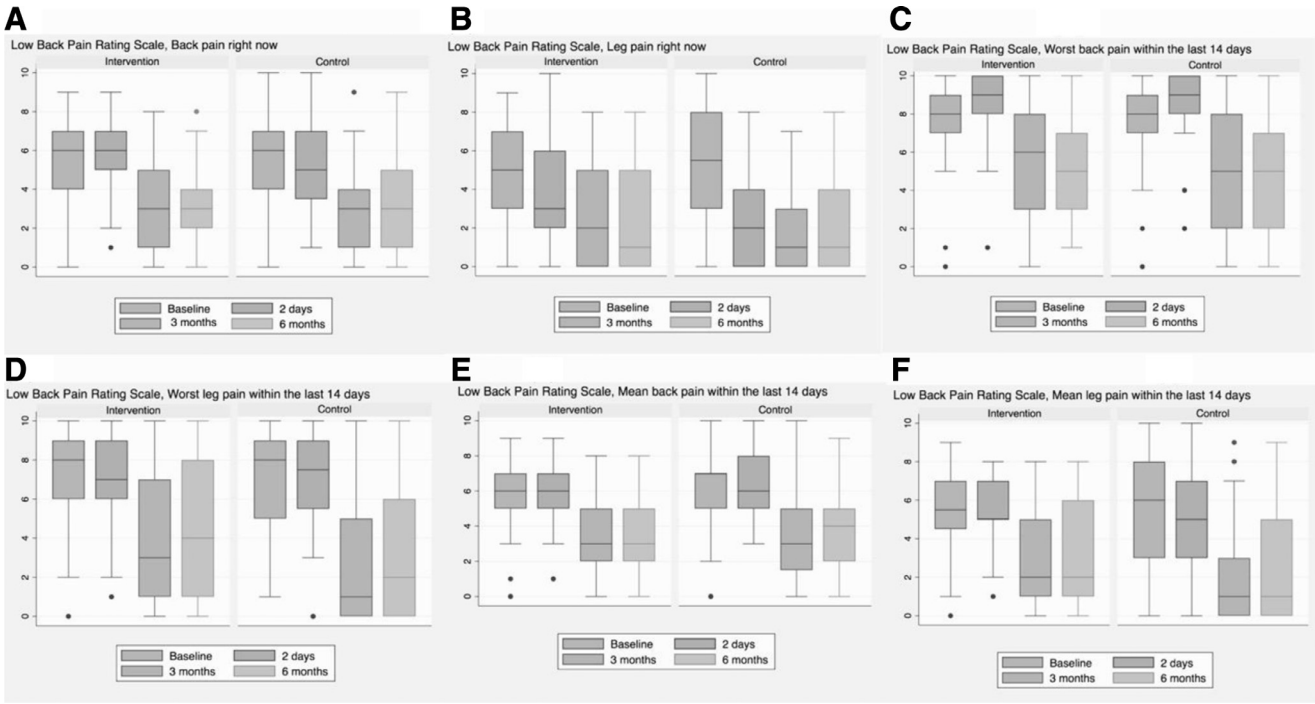

Fig. 5. Low Back Pain Rating Scale, box plot at the predefined time points. Teen indicates the worst pain and 0 no pain (A) + (B) Back and leg pain "right now", (C) + (D). The worst back and leg pain within the last 14 days and (E) + (F) Mean back and leg pain within the last 14 days. Boxes illustrate medians with 25th and 75th percentiles and the whiskers illustration the 5th and the 95th percentiles. The dots outside the whiskers illustrate outliers.

The content of w-SPIINA also included principles from CBT. Three studies presented positive results in outcome parameters when CBT sessions were added to the rehabilitation program after LSF [2,14,54]. Comparing w-SPIINA with the results from these studies, using face-to-face CBT sessions might seem questionable, as w-SPIINA lacks central elements from CBT (awareness of illness behavior, relearning of reactions, provision of means of reacting to frightening thoughts, and transferring attention from fear to positive elements) [17]. Our results regarding disability at 3 and 6 months could not match those of Abbott et al. or Monticone et al. [2,54], as they found that the provision of CBT was superior to an exercise program alone regarding reduction of pain, disability and negative thoughts and increasing health-related quality of life [2,54]. However, in the third study by Rolving et al. [14], a comparable population was used, and the study included patients from the same institution with similar diagnoses. The mean baseline ODI in the study by Rolving et al. was slightly lower than that in the present study; however, the magnitude of changes in ODI from baseline to 3 and 6 months in the present study reassembles the changes found in the intervention group in the study by Rolving et al. [14].

The primary follow-up was 3 months after surgery, the secondary 1 day before surgery and 2 days and 6 months after surgery. However, the effect of w-SPIINA may first have become apparent later. Imbedding an ISG in w-SPIINA was intended to provide patients with peer support and resemble the effects on daily functioning found by Christensen et al. [29]. However, in contrast to the short follow-up after w-SPIINA, positive results on daily functioning found by Christensen et al., presented themselves 2 years after surgery [29] and thus, the effects of w-SPIINA might still emerge. ISG was also added to w-SPIINA to accommodate patients' experience of solitude [27,28] and subsequently reduce symptoms of anxiety and depression. No data regarding patients' experience of solitude were collected, and the subsequent effect on symptoms of anxiety and depression failed to appear. Studies have previously been conducted that looked at the effect of ISG in cancer patients. These studies found an overall positive effect of an ISG on psychosocial outcomes [55-57]. There are, however, substantial differences between the ISG used in these studies and the one used in w-SPIINA. The number of patients who used w-SPIINA were low and there were no moderator-initiated dialogs or perusing topics, which might have influenced the results.

Finally, there still is a necessity for further research regarding interventions that accommodate symptoms of anxiety and depression within spine surgery. Anxiety and depression are found to account for 12% to 14% of the variance in pain and for 20% of the variance in disability, function, and general well-being in these patients [4]. Depression alone has been found to prolong return to work [58] and to increase dissatisfaction with outcomes independent of physical outcomes [59,60]. Furthermore, there still exists uncertainties regarding the most appropriate or the most effective way to provide patients with information.

Strength and limitations

In the current study, the focus and aim were to investigate the possibility of accommodating symptoms of anxiety and depression preoperatively, postoperatively and in the early rehabilitation period by featuring social interaction and animated information in a randomized controlled trial. In this setting, 40% of patients with degenerative spine disorders undergoing LSF achieved MCID in HADS 6 months after surgery, the majority reached MCID with respect to pain and health-related quality of life at 6 months and approximately 45% reached MCID in ODI 6 months after surgery. However patient-reported outcomes at 6 months follow-up cannot be taken as the final outcome of LSF surgery.

The key strength was the randomized controlled design, and furthermore w-SPIINA was the first of its kind investigating the effect of applying a web-based platform featuring social interaction in combination with animated information in patients undergoing LSF. Another strength was a 100% compliance in accessing w-SPIINA combined with frequent use and further with a higher usability than reported in other studies evaluating ISGs [61,62]. Thus, lack of differences in patient-reported outcomes within the two groups cannot be attributed to a lack of use. The high degree of usage could indicate that this mode of intervention is applicable within this group of patients, bearing in mind that the implementation was supported by tablets.

The current study has several limitations. The lack of blinding of patients, healthcare professionals, and researchers was a limitation. During screening, the group declining to participate contained a slightly lower proportion of woman and was slightly older. Even though women are found to present symptoms of anxiety and depression more often than men [63,64], it is doubtful that this small difference in the included and not included could have had an effect on the generalizability of the study. Furthermore, a total of five participants in the intervention group withdrew. The group of patients who withdrew, had a higher occurrence of depression, they were slightly older, and all were women. This cannot be perceived as random and might be of influence on the estimated effect.

Finally, a substantial limitation of the present study is the low number of patients with the caseness of anxiety and depression, as the power of the study is reduced and any effect of w-SPIINA on anxiety and depression might not be visible.

Conclusion

Providing patients with access to w-SPIINA in addition to a standard 2-hour patient information session had no additional effect on symptoms of anxiety and depression or on patient-reported outcome before surgery or 2 days, 3 or 6 months after LSF in this study. However, the high compliance and degree of interaction with w-SPIINA indicates that this mode of web-based support could be applicable in this group of patients.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.1016/j.spinee.2018.11.011.

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