Web-based support targeting anxiety and depression by featuring social interaction and animated information

A review of factors associated with anxiety and depression together with clinical evaluation

PhD dissertation

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### Abbreviation

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>CCBT</td>
<td>Computerised Cognitive Behavioural Therapy</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioural Therapy</td>
</tr>
<tr>
<td>CLBP</td>
<td>Chronic Low Back Pain</td>
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<tr>
<td>HADS</td>
<td>Hospital Anxiety and Depression Scale</td>
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<tr>
<td>ICF</td>
<td>International Classification of functioning</td>
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<tr>
<td>ISG</td>
<td>Internet Support Group</td>
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<tr>
<td>IQR</td>
<td>InterQuartile Range</td>
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<tr>
<td>LBP</td>
<td>Low Back Pain</td>
</tr>
<tr>
<td>LBPRS</td>
<td>Low Back Pain Rating Scale</td>
</tr>
<tr>
<td>LSF</td>
<td>Lumbar Spine Fusion</td>
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<tr>
<td>MCID</td>
<td>Minimal Clinically Important Differences</td>
</tr>
<tr>
<td>ODI</td>
<td>Oswestry Disability Index</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>PLF</td>
<td>Posterolateral Fusion</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Clinical Trial</td>
</tr>
<tr>
<td>REDCap</td>
<td>Research Electronic Data Capture</td>
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<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<tr>
<td>TLIF</td>
<td>Transforminal Interbody Fusion</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>WP</td>
<td>Web-based Platform</td>
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<tr>
<td>w-SPIINA</td>
<td>Web-based Spine Platform featuring Interaction and Information by Animation</td>
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1. Introduction

The present PhD dissertation applies both qualitative and quantitative methods in an attempt to address a clinical issue: the spine patient with symptoms of anxiety and depression. The studies within the dissertation investigate the factors associated with anxiety and depression in spine surgery, the usability of a web-based platform (WP) in patients undergoing one- to three-level instrumented lumbar spine fusion (LSF) and the effect of this WP on anxiety and depression.

The worldwide health care sector faces a wide range of economic challenges due to circumstances like the still ageing population, the ongoing development of new treatment possibilities, and the increased prevalence of chronically ill citizens in need of lifelong treatment. Estimates from OECD (The Organisation for Economic Co-operation and Development) indicate that healthcare expenditures will continue to grow at a steady pace [1]. All countries strive to find ways to increase healthcare efficiency, and hence there is a need for innovative thinking and new ways of treating, supporting, and rehabilitating patients in order to accommodate economic challenges [1,2]. One of the solutions is seen in the exploitation of new technologies where artificial intelligence and digitization are perceived to contain advantages that can bring better health for the individual and prevent sickness, with the reservation, that skills have to be developed in order to harvest the potential of these new technologies [3].

During the last ten years, the Elective Surgery Centre at Silkeborg Regional Hospital has developed new strategies for patient-treatment pathways, exploiting the strength of new information technologies and an ongoing interdisciplinary approach. Involvement of patients combined with the extensive interdisciplinary approach, i.e., secretaries, anthropologists, physiotherapists, doctors and nurses from the outpatient clinic, operating theatre, orthopaedic and anaesthesia wards, has led to pioneering work in patient support tools [4-6]. This will in short be presented in the following and further elaborated in Chapter 4.

Three former research studies performed at the same site as that of this dissertation lead up to the study presented here. Two of them explored the use of innovative solutions providing patients with information, one using a telemedicine solution placed in the home of patients [4] and one using a WP [5]. The third study explored the chosen visual approach [6]. Both the telemedicine solution and the WP were provided to patients undergoing fast track hip replacements. The end goal within fast track programmes was and continues to be to optimize recovery, reduce hospital stay, diminish postoperative morbidity, while reducing cost and without
compromising quality or patient satisfaction [7]. In order to accommodate these goals, the developed solutions contained educative, animated web-based support tools, developed in order to empower patients and their support persons with sufficient information to make it possible for them to take an active part in preparation, treatment, and rehabilitation. The results of first study were promising in terms of reducing the length of stay and at the same time still maintain quality and patient satisfaction [4]. The second study looked at the impact on psychosocial factors like anxiety and depression in patients undergoing a standard hip arthroplasty programme, with and without supplementation of a WP. Significant reductions in both symptoms of anxiety and depression were seen within groups from pre-admission to three months after surgery, but the study was not able to show differences between the groups [5]. A randomised evaluation of the WP on anxiety and depression was recommended. Thus, a new project was launched; the content from the previously used telemedicine solution and the web-based support tool were modified and further developed, aiming to accommodate symptoms of anxiety and depression in LSF patients and subsequently better surgical outcome.

This PhD dissertation is the next step in the accumulation of knowledge using informative and novel patient support tools in the preparation, treatment, and rehabilitation of patients.
2. Background presenting key topics of the dissertation

In the following, introduction to the key topics in this PhD project will be presented. Knowledge gaps will be illuminated and recaptured in aims and hypotheses.

2.1. Chronic low back pain

Pain in the lower back is a widespread phenomenon and is one of the most common and costly healthcare problems [8]. Due to a high disability burden, sick leave, or permanent severance from the labour market, chronic low back pain (CLBP) has major economic consequences CLBP is described as one of the most onerous diseases globally [9,10], and is ranked highest in terms of disability. In terms of overall burden, CLBP ranked sixth among 291 conditions [11]. Thus, CLBP has a large influence on individual lives and on society as a whole [10]. Women suffer from LBP more often than men, a difference perceived to increase with age [12,13]. Furthermore, the majority of CLBP patients seem to be in the lower socioeconomic groups as 62% of CLBP indicated having primary education or short-term education as their highest educational level, and 50% were outside the labour marked [14].

When conservative treatment in CLBP fails, surgery can be offered to a selected group of patients. The overall rate of back surgery in Europe, the US, and Australia has revealed an exponential increase during the last two decades [15-20]. During the last 15 years, spine fusion has become one of the most common surgical procedure performed when treating various conditions such as deformity, trauma, tumours, or instability caused by infection or in patients with degenerative spinal disorders like stenosis and spondylolisthesis [16]. In a ten-year period from 1998 to 2008, spinal fusion procedures increased by 137% in the US [16]. The rate of lumbar spine fusion (LSF) due to degenerative disorders has increased with a similar trend. Fusion of the lumbar spine is offered to a selected group of patients with chronic back and/or leg pain. In Denmark, the number of patients undergoing LSF in 2008 was 1,400, increasing with 82% to 2,550 in 2013 and has since found a steady rate of approximately 2000 operations per year in 2014-2016 [21].

As a consequence of the increasing number of patients referred to and undergoing surgery, the cost of spine fusion has increased [16]. Spine fusion accounted for 14% of the US spending on back surgery in 1992, and 47% in 2003 [22].

*Lumbar Spine Fusion*

The aim of spine fusion is to prevent motion at one or more adjacent segments of the spine and thereby decrease back and/or leg pain. The surgical procedures target three overall issues: decompression of neural structures,
stabilisation of one or more adjacent segments of the spine, and finally restoring spine balance. Numerous surgical techniques have evolved during the last two decades, focusing on different anatomic approaches, implant devices, and materials, i.e., pedicle screws, rods, cages, and bone graft materials (autograft, allograft, synthetic bone graft substitutes, and growth factors) [23]. The study population included in the clinical study within this dissertation had undergone LSF. The two LSF surgical techniques applied in the current study were instrumented posterolateral fusion (PLF) and transfemoral interbody fusion (TLIF), see Figures 1 & 2.

Today, overall clinical improvement is seen after LSF; however, several patients still experience residual pain and physical impairments. Twenty-two percent of patients undergoing LSF indicate having poor results, and some of “the successes” are found to have persistent problems [24]. Studies find that as many as 15 to 40% cannot expect to improve significantly with regard to pain and physical function [15,25-28]. The success rate is lower than with other orthopaedic surgical procedures [29], adding to the expenses within this group of patients. The increasing demand and resultant costs are a challenge, and at the same time treatment success must be secured and patient satisfaction must be increased. A wider focus has been developed when looking at CLBP and surgical outcomes [30,31], and thus, this lack of improvement in some patients after LSF may be explained by the complexity of CLBP, which will be described to a larger extent in the following chapters.
2.2. Anxiety and depression in chronic back pain patients

Patients with CLBP are commonly found to have symptoms of anxiety and depression [8]. This dissertation addresses both symptoms of anxiety and symptoms of depression. Anxiety and depression are two different medical conditions, the symptoms caused by, the causes leading to, and the treatments used to treat anxiety and depression do, however, often overlap and many people with depression often develop anxiety and vice versa [32]. A survey showed that approximately 60% of those with depression also have anxiety, and 30% of those with anxiety also have depression [33]. Symptoms of both anxiety and depression are found two to three as often in patients with low back pain than in the general population [8]. For the sake of clarity, it is important to mention that in the majority of studies referred to in this dissertation that deal with anxiety and depression in relation to CLBP or spine surgery, the occurrence of anxiety and depression is evaluated with the use of numerous self-assessment scales, and thus in most cases not with diagnosed anxiety or depressive disorders.

Symptoms of anxiety and depression in LSF patients

Preoperative symptoms of anxiety and depression occur among one-third of LSF patients prior to their surgery [34,35], and it has been known for several years that there is a connection between patients’ mental health and surgical outcome [30,31]. During the last decade, increasing attention has been directed towards symptoms of anxiety and depression in connection with spine surgery and findings indicate that preoperative anxiety and depression and their co-occurrence are important outcome predictors of greater pain, disability, and lower health-related quality of life [26,36-39]. A correlation that was found to persist even 10 years after surgery [40]. The prevalence of symptoms of anxiety and depression do decline after surgery and are found to occur in approximately 20% of patients one year after surgery [41]. However, a large Californian study found that patients who underwent spine surgery, especially spine fusion surgery, had a higher risk of new onset depression within five years after surgery compared to patients treated for other surgical (coronary artery bypass grafting, hysterectomy, cholecystectomy) or medical conditions (chronic obstructive pulmonary disease, congestive heart failure exacerbation) [42]. Depression being the single strongest negative predictor of return to work status after lumbar surgery, depression has a correspondingly large influence on rehabilitation, return to work, and on patient-perceived quality of life [43]. Symptoms of anxiety and depression are found to have a large influence on everyday life [44].

It has been shown that health informatics has the potential to decrease the occurrence of symptoms of anxiety and depression in patients undergoing surgery [45-48]. In 2014, a systematic review was published investigating the effect of various information strategies used in order to reduce the occurrence of symptoms of anxiety before surgery. Eight of the included 14 trials found a significant reduction in symptoms of anxiety before surgery.
However due to the heterogenic results, it still remains unclear which mode and specific content could reduce symptoms of anxiety and depression most effectively [49]. Another two trials have been published assessing the effect of an educational intervention on symptoms of anxiety and surgical outcomes in patients undergoing cervical disc herniation surgery [50] and in patients undergoing surgery due to spinal stenosis [51]. In agreement with the review, these studies present findings indicating that additional preoperative information can reduce preoperative symptoms of anxiety. These findings are supported in an additional study, including 175 consecutive patients undergoing lumbar laminectomy or discectomy [52] where findings indicate that patients’ knowledge of the procedure reduces symptoms of anxiety [52].

With regard to using information in order to accommodate symptoms of anxiety and depression in spine surgery patients, uncertainties still remain and need to be addressed: which mode and which content of information have the largest effect and hence accommodate patients’ symptoms of anxiety and depression most efficiently throughout the course of treatment and not solely preoperatively.

This interrelatedness between information and symptoms of anxiety and depression and surgical outcomes confirms that there are other key factors besides diagnosis and surgical technique which seem to some extent to play a role in the lack of positive surgical outcomes, and insight into the complexity of interacting factors, in addition to the important surgical aspects, may potentially point to future action areas that might support a better outcome after spine surgery.

2.3. A biopsychosocial perspective on chronic low back pain

In the following section, a biopsychosocial perspective will be presented in order to illuminate the complexity of interaction factors in patients undergoing LSF. The correlation found between the above-described symptoms of both anxiety and depression and pain, disability, and health-related quality of life may be explained by the theoretical standpoint expressed in the World Health Organisation’s (WHO) International Classification of Functioning, Disability and Health (ICF) and may be illustrated by the ICF model (Figure 3). The ICF model is an international standard, representing a broader view than that of the biomedical paradigm alone. [53,54]. The model was published by WHO in 2001 and the same year endorsed by all 191 WHO member states, including Denmark [55]. The ICF model is divided in three parts (health condition, function, and disability and contextual factors) and has six components (health condition, body function & structures, environmental factors, personal factors, participation, and activity), all equally important and interactive, see Figure 3. The ICF defines a reduced ability to function as a multiaxial model, with arrows pointing in both directions and with all components in the model being able to influence each other in a dynamical, interactive, and a non-linear process, [54,56] Thus,
reduced ability to function according to ICF is seen as a consequence of a complex and dynamical interaction between states of health, functional ability, and contextual factors [57].

Figure 3. ICF model, illustrates the components of the ICF, including their mutual influence on each other and their ability to function in a complex, multifactorial, and dynamical way (World Health Organisation (WHO) International classification of functioning, disability and health. Geneva, World Health Organisation 2001) [54].

The ICF model and LSF patients

In the perspective of the ICF model the solution to achieving better surgical outcomes in LSF patients is not found just by improving biomedical/mechanical investigations or methods of treatment, the obtainment of a wider focus is central [58]. Thus, accommodating symptoms of anxiety and depression could affect other factors of the model and hence improve surgical outcomes such as pain, disability, and health-related quality of life. In line with the biopsychosocial perspective on LSF patients, a few studies have been performed within the last eight years using cognitive behavioural therapy (CBT) in addition to exercises in the rehabilitation of LSF patients. CBT targets negative cognitive beliefs, thoughts, and expectations (ICF: personal factors), which contribute to negative emotions, such as anxiety and depression. The goal of CBT is to induce positive behaviour by creating awareness of negative thoughts, and by modifying these thoughts, and finally by modifying how these thoughts affect behaviour [59]. There is substantial evidence supporting the use of CBT in the overall treatment of anxiety and depression [60], and in addition, CBT used together with exercises in the rehabilitation of LSF patients has been found to have beneficial effect on disability, self-efficacy, outcome expectancy, fear of movement, and quality of life [26,45,61]. In all three studies, patients were asked to attend several face-to-face sessions, and thus the treatment demands ability to move from own home to where the sessions are held, which could be an obstacle in several patients with physical impairments.

Within recent years, the use of the internet has had a large impact on CBT, introducing computerised cognitive behavioural therapy (CCBT). CCBT for depression and anxiety has opened up new ways of supporting patients
both before and after surgery, making treatment more accessible and taking geography out of the equation [60,62]. In the following section, an overview of internet use will be provided and related to the population of LSF patients in order to clarify the applicability of providing web-based support to LSF patients.

2.4. Web-based support

Applying web-based support in healthcare offers unique opportunities, taking geography out of the equation and providing the users with an easily assessable healthcare service and information, enabling citizens to seek and gain information as questions arise. Furthermore, healthcare information technology is looked upon as one of the ways to reduce the escalating healthcare expenses and provide profit by providing patients with time-, place- and environment-independent healthcare service [63,64]. Accordingly, healthcare information technology is a part of the present Danish Government’s political platform November 2016 [3]. The possibility of web-based healthcare service is increasing, as the availability of the internet continues to increase. In January 2017, 96% of all Danish homes had an internet connection, compared to 84% in 2011[65,66]. A similar increase is seen in other European countries [66-68], in the US 88.5% had an internet connection in 2016 [69] and in Australia, 85.1% were connected in 2016 [69]. The largest increase is now seen in mobile usage; mobile browsing currently accounts for just above half of the world’s web-traffic, noting an increase of 30% from January 2016 to January 2017 [66]. Even among the population between 65 and 75, 70% use a mobile device in addition to their computer [70]. The usage of social media is increasing too, with a year-to-year growth of eight percent and a total of 37% of internet users used social media in January of 2017 [66]. A large study from 2013 conducted in the US found that almost one-third of the 3,000 included individuals looked at peers’ experience of health condition when seeking advice [71]. The use of social media in healthcare has increased, which, according to the Pew institute in the US, can be attributed the spread of social media use in general and a growing desire from patients to connect with each other [72]. Introducing peer support to LSF patients could accommodate a well-known feeling amongst these patients of being lonely and not being satisfied with their social lives in the early period after surgery, which emerges due to the physical restrictions, fear avoidance, or fear of movement the first months after surgery [73,74].

The body of literature exploring the use of social media in the form of internet support groups (ISG) in relation to patients with depression, cancer, HIV/AIDS, or other long-term conditions has grown [75-82], finding benefits when looking at patients’ psychological outcomes and quality of life [79-82].

The still growing availability of the internet and the growth of social media usage provides healthcare with the possibility to provide easy and assessable information and peer support. Hence, integrating healthcare and new technologies could revolutionise education and peer support in LSF patients.
Despite the increase of internet use, the access, however, still differs between socioeconomic groups. In a Danish perspective, 17% of the low-income group were without an internet connection in 2016, compared to 100% of the high-income group, and in addition access decreases with age [65]. Thus, patients in the higher age groups and in the lower socioeconomic groups may not benefit from web-based support to the same degree as those of younger age and in the higher socioeconomic group.

Thus, there are several evident benefits providing patients with a web-based support, as illustrated above; however, the group of patients undergoing LSF does not reassemble the groups most prone to using use web-based support, compared to other population groups, and thus it remains uncertain whether a web-based solution is applicable in the LSF population. Most studies exploring the use of ISG use already established forums, and little is known about newly initiated forums [83].

In the upcoming section, key topics will be summarised, and knowledge gaps illuminated and presented again in the following aims and hypotheses.

2.5. Summary of introduction and clarification of knowledge gaps

Despite the development within LSF surgery, a substantial group of patients continues to have pain, disability, and low health-related quality of life. Research finds a correlation between the occurrence of symptoms of anxiety and depression and poorer surgical outcomes, calling for addressing those symptoms in order to hopefully subsequently achieve better surgical outcomes. This interrelatedness between the psychological factors and surgical outcomes has brought forward a biopsychosocial perspective on LSF patients. However, knowledge is lacking in terms of identifying which factors are associated with symptoms of anxiety and of depression, limiting the ability of developing effective and preventive aids.

Within other patient groups, utilisation of the internet and the use of online peer-support in order to accommodate symptoms of anxiety and depression have proved advantageous. However, the applicability of web-based peer-support in the form of a newly established internet support group (ISG) is unknown in LSF patients.

Finally, profound information and CCBT are found to have a potential decreasing effect on the occurrence of anxiety and depression in patients undergoing LSF; however, the content and mode for the most effective accommodation is still unknown.
3. Aims and hypotheses

In the following aims, objectives, and hypotheses will be presented, followed by the three papers.

**Aim I:**
To identify factors associated with symptoms of anxiety and depression throughout the course of treatment in patients with degenerative diseases undergoing spine surgery. The objective was to summarise existing knowledge and to inform policy and practice in order to target these symptoms and hopefully achieve better surgical outcomes after spine surgery. The first aim and objective formed the basis of Paper I:

*Anxiety and depression in spine surgery – a systematic integrative review*

**Aim II:**
To describe the use of an internet support group in Danish patients undergoing instrumented LSF due to degenerative spine disorders. The aim of this mode was to support LSF patients online providing easy and accessible support, and the objective of the study was to create knowledge of the applicability of internet support groups within this patient group. The second aim and objective formed the basis of Paper II:

*To Use or Not to Use – a Descriptive Study of Lumbar Spine Fusion Patients’ Use of an Internet Support Group*

**Aim III:**
To examine the effect of a WP on symptoms of anxiety and depression, pain, disability, and health-related quality of life in patients undergoing LSF surgery. The following hypothesis guided the study objective and design: receiving access to a WP will reduce symptoms of anxiety and depression and subsequently reduce disability, pain, and increase health-related quality of life. Thus, the objective was to better surgical outcomes after LSF. The third aim, hypothesis and objective formed the basis of Paper III:

*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.*

Before moving on to the methods and materials for each paper, the development of the web-based intervention used in both Paper II and Paper III will be presented.
4. Development of the intervention

In the following chapter, the development of the web-based intervention examined in Papers II and III will be presented. The aim was to design and develop an intervention able to accommodate symptoms of anxiety and depression throughout the course of treatment and thus support LSF patients preoperatively, during treatment/admission, and after discharge during the first three months of rehabilitation.

As presented in the background, a version of the WP has been continuously developed during the last ten years. The initial study was a RCT offering a telemedicine support to patients undergoing fast-track hip replacement. This study aimed to optimise fast track procedures without compromising quality, safety, or patient-perceived parameters [4]. The study found that the telemedicine intervention could shorten length of stay, without compromising patient-perceived or clinical parameters [4]. The study was, however, not able to present positive results regarding reduction of patient anxiety. A second study was conducted, using an un-controlled before and after design, testing the psychosocial effect of a different type of WP now containing animated as well as written and instructing information on the fast-track total hip replacement regime [5]. Subsequently, the platform applied in this study was a further development of the telemedicine support first used by Vesterby et al. [4]. However, no additional effect of the WP was found on any of the psychological parameters, and a randomised trial was therefore recommended [5]. Furthermore, a possible reason for the lack of effect on psychological parameters was found to be the relative few psychosocial challenges in patients undergoing fast-track hip replacement. A decision was made to develop the WP aiming to accommodate factors associated with symptoms of anxiety and depression in patients undergoing LSF surgery. This decision was made due to the extensive literature focusing on anxiety and/or depression in the group of patients undergoing spine surgery, and the consequences of these symptoms on surgical outcomes. In the following sections, an overview of the development will be presented.

A clear and concise overview of intervention development is presented by Fraser et al. (2009) [84], and in order to present a transparent process, this framework will be used. Fraser et al. [84] conceptualise intervention research as being comprised of five steps: three steps for development of the intervention, one for assessing effectiveness in a variety of settings and circumstances, and one for disseminating both findings and the material used [84]. Presentation of the development process will be outlined under the first three steps used by Fraser et al. [84]:


1. Specify the problem and develop a programme theory
2. Create and revise programme materials
3. Refine and confirm programme components

Step four is presented in study III, and the evaluation of those results was qualified with the use of results from Papers I & II (for further explanation of how the studies complement each other, see section 5.1. Overall study plan). Step five will partly be accommodated by publishing this manuscript, sharing programme materials, and partly by publishing results from the efficacy studies. The first three steps will be chronologically described as outlined, even though the development of the steps did not consequently follow a linear process, and some of the processes were overlapping.

4.1. Specify the problem and develop a programme theory

This first step is divided in two; first we focus on what is the problem, clarifying factors associated with symptoms of anxiety and depression; second, we hypothesise on the processes within the intervention, i.e. how is it possible to accommodate the problem after it has been clarified. Using the terms from Fraser et al. [84], we first clarify the problem theory and then the programme theory will be presented.

4.1.1. Problem Theory

Firstly, we need to clarify: What is the problem? In this perspective, we needed to clearly specify the mechanisms that both produce and suppress symptoms of anxiety and depression, and we needed to portray those factors that are malleable, as we needed to identify targets for change. Though some parameters may have some influence, we are not able to alter all, e.g. patient income status, marital status, or sex. Designing an intervention involves not only expertise in the problem area, but also in the context and in the population in which the intervention is to be implemented [84].

Obtainment of knowledge of the field and clarifying the problem were divided in three parts: 1) a literature review provided an overview of existing literature concerning symptoms of anxiety and depression in conjunction with admission and surgery, 2) collaboration with surgeons, nurses, occupational therapists, physiotherapists, secretaries, and researchers provided an overview of existing knowledge and experience among healthcare professionals, and 3) a workshop including patients who had gone through LSF, together with their primary support persons, gave insights to their knowledge and experience. Based on these sources of knowledge and experiences, several areas were identified, and the WP was aimed to address as many as these areas as
The largest theme emerging concerned information. We found both in the literature and from patients and support persons that lack of information, too much information, or even not the right information gave rise to symptoms of both anxiety and depression [46,48,85-89]. Furthermore, we found that several factors had influence on patients’ symptoms of anxiety and depression in conjunction with admission, surgery, and discharge an extract of factors will be presented in the following.

Seeing medical devices [90], even the mere presence of medical devices in a room, was found to induce anxiety [90]. Waiting to be collected for surgery [91,92]. Undergoing spine surgery and general anaesthesia, this was pointed out quite clearly in the literature, from staff and from patients, patients experienced a fear of not waking up again or of being left alone in the theatre while sleeping [52,93,94]. Pain was another theme, the expectance of pain and the fear of not being able to manage analgesics was expressed by both patients and their support persons [95-97]. Another theme were unmet expectancies [98,99] or unexpected physical reactions, e.g. a sudden pain or an unexpected sensation created anxiousness that something was wrong [100]. Also, patients expressed an experience of solitude after discharge and a lack of social interaction and a dependency towards their support persons [73,74] and spouses provided the most emotional support [101]. Furthermore, although non-malleable, the occurrence of anxiety was found to decrease with age [48,102,103], and women were found more prone to develop anxiety and depression than males [48,52,104,105]. Finally, patients attending their first-time surgery were found to have a larger occurrence of preoperative anxiety than those who had undergone previous surgery [104-106] (Figure 4).

*Figure 4. overview of uncovered malleable and non-malleable factors.*

Malleable factors – targets of change

- Information
- Seeing medical devices
- Waiting to be collected for surgery
- Undergoing general anaesthesia
- Experiences of pain
- Being able to manage pain
- Unmet expectations
- Unexpected physical reactions
- Lack of social interaction

Non-malleable factors

- Age
- Gender
- First time surgery
4.1.2. Program Theory

The next step was the programme theory [84], hypothesising on the processes within the intervention, i.e. how it was perceived possible to accommodate malleable factors. In the following, the expected processes will be presented using six headings outlining considerations concerning the mode of the intervention: health literacy, narratives, principles from CBT, visual feedback, WP, and target level. The choice of modes will be explicated under each headline as will the hypothesised effect of each mode.

Health literacy

Findings indicate that information had influence on anxiety and depression, and thus we aimed to increase the uptake of information. The intervention focused on accommodating a possible low degree of health literacy. The following is given in order to clarify the concept of health literacy: health literacy has been defined as both the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand, and use information in a way which promotes and maintains good health [107]. Due to an expected positive effect on the level of health literacy, we chose to apply animated videos on the WP [108-110]. This visual approach was designed to reduce the complexity of the information and optimise the acquisition of knowledge [110]. Traditionally patient information is based on written material and pictures; written material, however, often requires high levels of literacy [111,112]. Using animations seems to have a potential as studies find that animations increase the ability to comprehend information notwithstanding the degree of health literacy [110,113]. Studies comparing patient information based on animation and static information like text and pictures find a positive effect of animations, which was further increased when the animations were added a voice-over [108]. Animation with a voice-over is found to be the best way to communicate health information to patients with health literacy [114]. Animation is found to have a positive effect on patients with low health literacy, and although some patients might find written information most appropriate, animation was not found to have a negative effect on patients with high health literacy [114]. Furthermore, animated films using advertising techniques such as light, colour, and music have beneficial effect on the patients’ attentiveness, and therefore knowledge gained from seeing animations using these techniques could be increased [113,115,116].

Narratives

In order to enhance patients’ ability to recall the information they received, storytelling was used. A character was built in the first animation: a former school teacher and her primary support person, her son. The middle-aged woman was first displayed as a younger woman, teaching in a class room, and living an everyday life (i.e.
hanging up laundry and playing on the beach with her son). She then grows older and gets pain in the back, now having problems with executing the mentioned everyday life activities. Meanwhile the voice-over explains how the back is subject to degenerative changes, changing lives. Storytelling is known to have influence on memory, and by creating a story containing the messages in need of being communicated, storytelling is found to increase the ability to recall [117]. A compelling narrative can imprint itself on the mind, leaving an unforgettable impression, and narratives are therefore found to advantageous as a teaching tool, facilitating memory, getting people to remember things [117]. The intent is to strengthen patients and support persons memory using the WP.

**Principles from cognitive behavioural therapy**

Elements of exposure and computer-aided cognitive behavioural therapy (CCBT) was used on the WP as it is found to minimise the occurrence of anxiety and depression [60,62]. One of the main assumptions within cognitive behavioural therapy (CBT) is that patients’ perception is the foundation of thoughts and emotions and consequently the foundation of actions [59]. Thus, the pictures within the animations were developed with the purpose of presenting patients with realistic images, not provoking anxiety. The aim was to make patients able to adopt a more positive attitude and thus initiate a more appropriate behaviour. Subsequently, the aim was to achieve behaviour changes, helping patients to not prioritise thoughts and thereby behaviour related to their anxiety.

With focus on the themes emerging in the literature and the expressed experiences from patients and healthcare professionals, pictures on the WP aimed to decrease symptoms of anxiety and depression in specific situations. The animations presented rooms and devices which the patients would be introduced to (Figure 5). Animation prepared patients for the wait before surgery (Figure 6), emphasised that healthcare professionals would remain at their side throughout the operation (Figure 7), and animations were made supporting management of analgesics (Figure 8) etc.

*Figure 5. The recovery room after surgery is presented in the first picture, and the first time out of bed is presented in the second – the different devices are presented using a male voice-over in the animations. Illustration by Visikon.*
Figure 6. *Animation present a picture of the patient sitting with a book, a male voice-over explaining that there might be a wait before surgery. Illustration by Visikon.*

Figure 7. *Animation presents a nurse holding hands with the patient during surgery, male voice-over explaining that healthcare professionals will stay with the patients while they are sleeping. Illustration by Visikon.*

Figure 8. *Animations, with a male voice-over made in order to support patients’ management of the use of analgesics. Illustration by Visikon.*

**Visual feedback**

In the WP, visual feedback was used. The intention was to display the physical processes and the progress of pain and then to create a supportive feature teaching the patients to self-regulate the processes using the feedback. The aim was to empower patients or their support persons to self-regulate the use of analgesics, to indicate the experiences of pain and physical activities, thereby gaining empowerment and diminishing symptoms of anxiety and of depression.
**Web-based intervention**

By using the internet, the intention was to improve participant's access to health information and hence their capacity to use it effectively. The intention was also to accommodate individual needs regarding information, as some patients need extensive information while others find that less informed suffices [48,93,104]. Some patients need to receive the information repeatedly, and others only need the information once. Using this web-based approach, the patients were able to self-tailor what, when, and how often they accessed information. The information was divided into small sequences, hence the patients could structure their information, suiting their needs.

Using the internet, it was also possible to provide patients with peer-support without patients actually participating in face-to-face meetings and thereby taking geography out of the equation. Using the internet to establish support groups had advantages, as the support, as well as the information, could be delivered in the environment of the patients’ own home and could be used by both patients and their support persons. The support from peers could also be found and reviewed at a pace and time suited to the individual [82]. Furthermore, patients who did not feel comfortable disclosing experiences in a room with others, patients who due to their health status could not be transported, patients who lived in remote areas and therefore could not participate in face-to-face meeting could more easily access peer support online [82,118]. Furthermore, patients with symptoms of anxiety and depression may be instilled with courage by the ability to remain anonymous [119]. The overall intention of the ISG was to accommodate patients’ feeling of solitude, thereby decreasing symptoms of anxiety and depression, and subsequently also every day abilities [25].

**Target level**

Support persons were included in the development process deliberately as they were perceived to be an important resource for patients both before and during admission and after discharge [4,120]. Spouses or support persons are found to provide a high degree of emotional support and concrete help in everyday life [121]. In order to encourage support persons and thereby also patients, the role of a support person was presented in the animations, and the use of animations on a WP makes the information assessable for the support persons together with patients.

**4.2. Create and revise programme materials**

The materials within the platform was created and revised throughout the creative process, incorporating clinicians, researchers, patients, support persons, and developers; within this step the formulating of material was ongoing, see Table 1.
Several meetings were held as well as e-mail correspondence was used with clinicians throughout the development process. Meetings were held in groups or in the case of the training modules with physiotherapists alone, or in the sequence describing the anaesthesia with anaesthetists alone, and so forth. In addition, three workshops were completed to which patients and their support persons were invited.

Table 1. Timeline of the development divided into three steps according to the process presented by Fraser et al. [84].

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4.3. Refine and confirm program components

We finalised the development process with a small-scale pilot test to which six patients together with their support persons were invited and where developers and researchers were present. Patients and their support persons were equipped with a tablet and introduced to the WP and the different features. They were invited to try out all the features and give feedback on content and on how they perceived the use of WP. All feedback received was used to refine features.

In the following section, the content of the final WP will be presented. In accordance with the above, the intent of the WP was to incorporate means to accommodate health literacy, and therefore the use of animations was chosen. In addition to animation, written information was placed on the platform to accommodate those who might prefer written instead of animated information. The use of narratives was incorporated into the animations, aiming to enhance the ability to recall information. Principles from CBT were used with support from narratives and pictures presenting situation found to induce anxiety. Also, visual feedback was incorporated into a diary, providing patients with a visual display of physical development and development of pain. In order to provide peer support for patients and to accommodate questions that might arise, an ISG was developed, and a section for frequently asked questions was placed on the platform. The platform was developed with the use of five overall features: informative animations, ISG, diary, written information, and frequently asked questions.

**Informative animations**

In order to optimise the acquisition of knowledge, animated information was chosen. The WP contains approximately 16-min long and two-dimensional videos, comprising of 17 sequences: 13 sequences explaining the course of treatment (the initial preparation to surgery, animated films of the surgical procedure, post-surgical rehabilitation the first three months at home, animations supporting the use of analgesics), two sequences explaining the most advantageous way of moving during everyday tasks at home after discharge, and two sequences containing animated training instructions to be used the first three months after surgery. The animations were created in light colours, with soft underlying music and a male voice-over in all sequences. The same avatar is used in this study as in the study by Jørgensen et al. [5]. This decision was made based on results from a study testing the avatar identification. This study found potential in using this avatar in animations in health informatics, and, furthermore, the study found that animations using this avatar produce a sense of presence and therefore hold a perspective for learning in the context of health informatics [6] (Figure 9).
Figure 9. The middle-aged female avatar model together with her son, two grandchildren and two healthcare professionals. Illustration by Visikon.

Internet support group

An internet support group was developed, as the aim was to accommodate participants’ feeling of solitude, increase the possibility for peer support, and open up the opportunity for patients to share their experiences, and thus, to accommodate symptoms of anxiety and depression. The ISG consisted of a message board visible for all patients (Figure 10). On this page, patients could post their experiences, their thoughts, or their questions for other patients to answer or to comment on.

On a designated personal page called “my story”, each patient could upload a picture, note date of birth or a date of operation, and it was possible to write a personal or background story (Figure 11). Everything written on the discussion board and on the personal page was visible for all patients. If the patients wished to send a personal message to one of the other patients, then this was possible, using the feature “messages”.
Figure 10. The message board - stock photos, text is based on inspiration from real posts [122]. Illustration by Visikon.

Figure 11. Personal page - stock photo, the text is based on inspiration from a real story [122]. Illustration by Visikon.
**Diary**

The content of the platform also comprises a diary, not in the traditional form with room for extensive writing, instead the patients “click” through the diary. First, they indicate the degree of activity; then they note how long they had been walking; how many abdominal, back, and leg exercises they have done; and finally, how many balance exercises they did. Then the degree of pain is registered. They indicate the mean intensity of pain divided into two, first the mean back and then mean leg pain, both while active and then while resting. When finalising the registrations, a graph appeared displaying the development in activity and pain during the last week. If wanted, it was possible to see the development on all registered dates. This choice was made to provide patients with feedback on the development of both activity and pain, empowering them to manage analgesics, and to regulate their activity accordingly.

**Written information**

All information given the patients through animations was also provided in chronological order in writing, and with static pictures from the animated sequences, see Figures 12 & 13. This option was chosen in order to accommodate those patients preferring written information instead of animated.

**Frequently asked questions and answers**

In addition, the WP contained a section with frequently asked questions and answers, divided into five themes: discharge, medication, transportation, the wound, activity. This section contained answers regarding length of stay, which help could they expect to need the first days after discharge; the expected length of analgesic use; observation of the wound; when could the participant expect to drive their car, or a bike, or swim, or carry the groceries; and when was intimacy with a partner possible. This section was added to accommodate doubts, and was developed based on feedback from patients, support persons, and clinicians.

All together, the development of a Web-based Spine Platform featuring Interaction and Information by Animation (w-SPIINA) took approximately one year and was done in close collaboration with clinicians, patients, support persons, developers, and researchers. All results and considerations were shared with the staff, and the WP was presented in various settings in order to facilitate implementation before start of clinical studies. In the following chapter, the overall study plan will be presented, and the materials and methods used in the three studies will be clarified.
Figure 12. Written information about the operation, with static pictures from the animations. Illustration by Visikon

Stabilizing operation in the lower back

- Patients and support persons
- Why stabilizing operation in the lower back
- The course before admission
- Admission on the day of operation
- The day after the operation
- Home again
- After discharge
- Your diets influence on your operation
- Check list - are you ready for discharge?

Complications may arise in connection with the operation, both during the course of surgery and in the post-surgery period. There may be inflammation of the wound, bleeding, blood accumulation, nerve injury, nerve affection in the legs, and affected function of bladder and rectum. In the long term, the screws can loosen or break and there may be lack of ingrowth in the bones in the back.

The complications are fortunately very rare. Generally, a stabilizing operation in the back is a good surgery where 70-80 % of the patients have good effect of the operation. The outcome of the operation depends on the causes of the problems. Few patients get completely free from pain, but most experience a significant improvement, so they have the opportunity to become more active in everyday life.

Figure 13. Written information on the patient and the role of support person. Illustration by Visikon

Stabilizing operation in the lower back

- Patients and support persons
- Why stabilizing operation in the lower back
- The course before admission
- Admission on the day of operation
- The day after the operation
- Home again
- After discharge
- Your diets influence on your operation
- Check list - are you ready for discharge?

Support person

Many patients find that it is beneficial to have a relative who can support them throughout the course. It may be nice to have a person to talk to about the course, and preferably one who, having been in the hospital, knows what it entails. It is important that it is a person you know well and someone who has time, desire and physical and mental surplus to be a support person.

Orthopedic surgical ward

In the ward several different professional groups work together on care, treatment and rehabilitation. You may use your mobile phone, tablet and laptop in the ward, and there is wireless network access. To use this, you must connect to RegionMidt-Guest, and then log in with "hotspot.m-id.uk". Subsequently you can log in with social security number, NemID or SMS

Visiting hours

There is free visit time at the hospital, except the hours between 12:00 and 14:00, where patients should have the opportunity to rest and eat. It is not possible to follow or visit patients.
5. Materials & methods

The overall aim of this PhD project was to test and evaluate the developed intervention designed to reduce symptoms of anxiety and depression in LSF patients. This section first describes the overall plan of the study and thus how the single studies were expected to supplement each other. In the following, the material and methods of the papers will be presented.

5.1. Overall plan for the study

In Paper I, an integrative review was performed. The aim of this review was to identify factors associated with symptoms of anxiety and depression. The hope was that the review would capture the complexity of findings and inform development of future effective preoperative and postoperative aids. This review also provided the additional insight required in order to evaluate the WP explored in our randomised controlled trial in Paper III. In Paper II, a descriptive study was performed, aiming to describe the use of an ISG in LSF patients. The descriptive study provided insight into LSF patients’ use of an ISG, contributing and informing practice with regard to whether web-based support tools in the form of an ISG can be of utility in a group of patients undergoing LSF. Furthermore, knowledge gained from this descriptive study was intended to further inform the evaluation of the results obtained in Paper III.

Finally, in Paper III a randomised controlled trial was conducted, exploring the effect of the WP. The intention was to contribute to the knowledge of using alternative educative and cognitive methods in order to reduce symptoms of anxiety and depression in patients before and after undergoing LSF.

In the following sections, the aims, study designs, population, outcomes measures and analysis forming the basis for each of the papers will be described. Paper I will as a review be described separately. Papers II and III share design and population and will be described together. Finally, outcome measurements and the statistical data used in Paper II and Paper III are not shared and will be described separately.

5.2. Paper I

I. Anxiety and depression in spine surgery – a systematic integrative review.

5.2.1. Study aim and design

The aim of Paper I was to identify factors associated with symptoms of anxiety and depression in patients with degenerative diseases undergoing spine surgery. An integrative systematic review was performed [123],
incorporating qualitative and quantitative studies. Using this design, the aim was to provide a comprehensive understanding of the phenomenon. The method as described by Whittemore and Knafl (2005) [123] was used and comprised of five stages; 1) problem identification; which contains a clear identification of the problem; 2) literature search; including a well-defined search strategy; 3) data selection and evaluation. Because each research design has different criteria and frames of evaluation, this step requires reviewers within different approaches to be able to evaluate studies conducted within different traditions; 4) data synthesis; requiring that data were unbiasedly ordered, coded, categorised, and summarised into conclusions concerning the identified problem, and , 5) presentation of findings; in this final stage the results ideally capture the depth and the breadth of the problem being investigated. This final step will be partly presented in the results chapter of this dissertation and further discussed in the discussion chapter [123]. A more thorough presentation of the results and discussion can be found in Paper I, Appendix A.

5.2.2. Materials

A three-step search was performed. First, an initial search was performed, with assistance from a medical research librarian, using preliminary subject headings and keywords based on experience and knowledge of the field. Second, in accordance with the findings in the initial search, subject headings and keywords were revised, and a second search was conducted. This search was performed with assistance from a research librarian and a medical research librarian in September 2016. The search was conducted in seven databases: Scopus, Web of Science, PsycINFO, Cochrane, PubMed, CINAHL, and Embase and was performed using main keywords and additional variables as presented in Paper I, Appendix A. Third, a final search was conducted in which reference lists were consulted in order to identify additional articles.

Inclusion & exclusion criteria

Articles were included if they dealt with spine surgery due to degenerative disorders in both the lumbar and cervical spine. This criterion was chosen as several of the articles obtained referred to symptom of depression and anxiety regardless of spine diagnosis, surgical method, and anatomic locations [124-126]. Inclusion criteria comprised the following: articles published from January 1, 1986, because the first articles dealing with mental health in back patients were published in 1986 [127]. Articles reporting, investigating, or including results related to the aim of the review were included. Articles written in English, Danish, Swedish, or Norwegian were included. Moreover, only articles published in peer-reviewed journals were included. Excluded were articles that included a population with mental illness only, or patients with malignant disorders and those that did not provide sufficient information to allow adequate interpretation of the design, measures, or results.
Selection and assessment process of retrieved articles

Then a three-step selection and assessment process was performed. First, I skimmed all titles and abstracts for relevance. Second, a total of 53 articles were read in full text by myself and a co-author. Studies that did not meet the inclusion criteria were excluded. When I doubted whether the criteria were met, a third co-author was consulted. Thirdly, the remaining articles were appraised for methodological validity. In order to minimise inconclusive results of the review, it was agreed that at least 75% of the criteria had to be satisfied. Whittemore and Knafl [123] did not offer a particular strategy for the assessment of research. The Critical Appraisal Skills Programme (CASP) contained various checklists to investigate quantitative and qualitative research for trustworthiness, results, and relevance. However, CASP was found less sensitive to validity compared to tools from the Joanna Briggs Institute, assessed by Hannes et al. [128]. Thus, instruments suitable for appraisal of both qualitative and quantitative studies were found and consisted of the appraisal tools from the Joanna Briggs Institute [129]. All studies were appraised by two independent co-authors depending on research design, i.e. when qualitative studies were presented, qualitative researchers did the appraisal, and when quantitative research was presented, the quantitative researchers did the appraisal. In the case of disagreement, a third co-author was consulted. A final 14 articles were included in the review and summarised in Paper I, Appendix A.

5.2.3. Data synthesis

For the synthesis of data, a convergent qualitative design was applied. This design allows transforming the results from both qualitative and quantitative studies into qualitative findings [130]. This design was applied as it allows for heterogeneous and diverse research to be included into the same review. The qualitative and quantitative data were collected simultaneously and then analysed simultaneously using a qualitative content analysis [131], giving equal weight to qualitative and quantitative data. The analysis was conducted in four stages. 1) Sentences meaningful to the aim of the review were extracted from the articles, as findings. 2) The finding was then coded using one of five components in the ICF, as shown in Figure 3 (body functions and structures, activities, participation, personal factors, and contextual factors). 3) The coded findings were then analysed, and meaningful categories were generated. 4) Then an explanatory synthesis was aggregated from categories to answer the research question.
5.3. Papers II & III

Design and population in Papers II and III.

II. To Use or Not to Use – a Descriptive Study of Lumbar Spine Fusion Patients’ Use of an Internet Support Group.

III. 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.

5.3.1. Study aims and design in Paper II and Paper III

In Paper II, the aim was to describe the use of an ISG in Danish patients undergoing instrumented LSF due to degenerative spine disorders, from baseline (one to five weeks prior to surgery) and until three months after surgery. The design of a prospective cohort study was chosen. Patients in this study were recruited from the larger randomised controlled trial (RCT) presented in Paper III and thus comprised those 48 patients assigned to the intervention group (Figure 15).

In Paper III, the design of a RCT was chosen in order to examine the effectiveness of the web-based intervention primarily on the development in anxiety and depression at three months after surgery and secondarily on anxiety and depression the day before surgery and on anxiety and depression, pain, disability, and health-related quality of life two days, three and six months after surgery. At baseline, patients were allocated one-to-one to either a control or an intervention group. Randomisation was done using random block sizes of four or six patients. Assignments were obtained using a simple “shuffling envelope” procedure.

5.3.2. Population in Paper II and Paper III

From September 2015 to May 2017, eligible patients were consecutive recruited from the Spine Unit, Elective Surgery Center at Silkeborg Regional Hospital in Denmark. All patients included in the study were planned for first-time elective one- to three-level lumbar spine fusion, i.e., instrumented posterolateral fusion (PLF) or transfornaminal interbody fusion (TLIF) due to degenerative disc disease or spondylolisthesis.

Exclusion criteria comprised age below 18, patients with psychotic disease, schizophrenia or other psychotic disorders, inability to communicate in Danish, patients with no internet connection.
Patients were invited to participate in the study when they attended the outpatient clinic and were scheduled for surgery. Upon invitation, the patients received written and verbal information about the study and the conditions of their participation, should they choose to participate.

Patients then received a phone call two days later, where they gave verbal consent or declined. At baseline one to five weeks prior to surgery, they then signed an informed consent form and were randomly assigned to either the intervention group or the control group. Due to the nature of the intervention, the study did not allow blinding of the patients or the allocators.

Patients allocated to the control group received the standard course of treatment, rehabilitation, and information. The standard course included a two-hour joint information meeting, which took place the same day as the baseline visit. At the two-hour joint-session, patients and their support persons received information, verbally, supported by slides and written handouts. These joint sessions were managed by nurses, physiotherapists, and occupational therapists.

Patients randomised to the intervention group also attended the two-hour joint session and furthermore received access to w-SPIINA. All patients went through a 15-minute introduction to w-SPIINA that included all the features on the platform, given by a study nurse. Patients in the intervention group were offered the opportunity to borrow a tablet if they were not in possession of one. This loan ran from baseline until three months after surgery.

Inclusion of patients was performed every other Wednesday when the two-hour joint information meeting was held. In order to avoid one or two patients being alone on the platform the first few weeks, six former patients were invited to participate. They were asked to facilitate activity and provide peer support. These six facilitators were not included in the analysis.

In the following outcome measures and statistical analysis from Papers II and III will be presented separately.

5.4. Paper II

5.4.1. Outcome measures

For each participant, the following data were collected at baseline: gender, age, educational, employment, marital status, and symptoms of anxiety and depression using the Hospital Anxiety and Depression Scale (HADS). The use of HADS is further substantiated in section 5.5.1. outcome measures in Paper III.

In order to describe activity on the WP, user data were gathered and contained activity on the ISG monitored during approximately a four-month period for each patient. Mentoring was initiated at baseline, one to five weeks prior surgery, and finalised when each patient attended three follow-up visits. The monitoring was done by manually tracking the use of the WP with Google Analytics, including location data, browser data, device
type, event type, and event time; with the use of user-generated content data, including all posts, comments, and stories posted by individual users; and finally with the use of personal data, including location, access date, date of operation, and from which device the participant gained access.

Activity was quantified by use of interactions. One interaction often comprised a group of pageviews taking place within the same session. Contributions were presented in posts or comments. A post was defined as starting a tread, with a question, a remark, or a message on the message board. Comments were questions, remarks, or messages written in an already existing tread.

5.4.2. Statistical analysis in Paper II

Demographics were collected and managed using Research Electronic Data Capture (REDCap), which is an electronic data capture tool hosted at Aarhus University, Denmark [132]. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Data were exported to the statistical software program STATA15, where all statistical calculations were done.

All user data were coded to compute the data statistically, and then twice entered into Excel. All data were then transferred into the statistical software program STATA15.

Descriptive statistics were done using frequencies and percentages to describe the sample profile and summarise data. Means and standard deviations were reported for continuous variables. Due to the nonparametric distribution of the data, non-parametric tests were performed, and thus, data were analysed using Spearman’s correlation tests to detect correlation between variables. Kruskal-Wallis ranks tests and Wilcoxon rank-sum test were used to establish differences between unordered groups.

5.5. Paper III

5.5.1. Outcome measures

For each participant, the following baseline characteristics were registered one to five weeks before surgery: gender; age; body mass index (BMI); smoking, educational, employment, and marital status; and primary diagnosis. Furthermore, perioperative complications were registered.

In order to evaluate interaction with w-SPIINA, an overview of activity was assessed, as described in Paper II section 5.4.1. However, user data used in the RCT comprised the total number of interactions on w-SPIINA from the time the first patient entered until the last patient attended six-months follow-up.
Data were collected using self-reported questionnaires at baseline before access to w-SPIINA, the day before surgery, and two days, three and six months after surgery using the following questionnaires:

**Primary outcome**
HADS has been found to be a reliable instrument for detecting caseness and severity of both anxiety and depression in somatically ill patients in a hospital setting [133,134]. A repeated administration of the scale can give reliable information assessing the change in patients’ emotional state both during the course of diseases and in response to psychotherapeutic and psychopharmacological interventions [134,134,135]. HADS is a self-reported and generic questionnaire with a fourteen-item scale; seven items related to anxiety (HADS-A) and seven items related to depression (HADS-D) [134] and with a maximum score of 21 for each subscale. The greater the score, the more severe are the symptoms. Using a score of 8+ on each subscale to identify caseness has been found to provide the optimal balance between sensitivity and specificity [133]. Based on previous studies, the minimum clinically important change (MCID) of HADS is around 1.5 [136]. With the use of HADS, anxiety is seen as a worry about a future event, it is a feeling of fear, worry, and uneasiness [134]. When using HADS, the caseness of depression is based on the symptom: loss of pleasure response, loss of optimism, or cheerfulness [134].

**Secondary Outcome**
The Low Back Pain Rating Scale (LBPRS), a self-reported questionnaire, was used to evaluate back and leg pain [137]. The evaluation was done using a visual analogue scale, 0 indication no pain and 10 the worst possible pain. A change of at least 1.2 for backpain and 1.6 for leg pain must be present for the difference to reach the MCID [138].

Oswestery Disability Index (ODI) was used to obtain and evaluate disability. ODI is a self-reported questionnaire [139,140]. The ODI assesses the impact of lumbar spine disorder on ten different aspects of daily living, demonstrating a good test-retest reliability and good internal consistency [140]. Patients rate on a six-point scale how difficult a given task is to preform: high scores indicate worse disability; the maximum score is 100. A change in ODI of at least 15, must be presented in order to reach the MCID [139,141].

EuroQol-5 Domain (EQ-5D-5L), a self-reported, 5-dimension questionnaire, was used to obtain health-related quality of life. The index score was assigned the health state using crosswalk value sets available for Denmark and ranged between 1, representing the best health, and −0.624, representing the worst health [142]. The change in index score has to reach at least 0.08 in order to reach the MCID [143].
5.5.2. Statistical analysis in Paper III

Study data were collected and managed using Research Electronic Data Capture (REDCap) as described in section 5.4.2. The primary outcome was the change in HADS three months after surgery, and thus, the sample size calculation was based on the evaluation of HADS. The minimal important difference of HADS was set at 1.5 [136], and the standard deviation (SD) on the change in HADS was set at 2.5 [136]. With a significance level at 0.05 and a power of 0.80, the study needed a total of 44 patients in each group, a total of 88 patients. Due to the risk of losing study power if patients withdrew, were excluded, or lost to follow-up, an additional 30% were included, and thus randomisation ended when 114 patients had entered the study.

Due to the nonparametric distribution of parameters, nonparametric statistics were applied, and thus, the difference from baseline to 3- and 6-month follow-up is presented with the use of medians and percentiles, and comparisons of difference between the two groups were done using Mann-Whitney test.

5.6. Ethical considerations

The project did not in any way include changes in the surgery performed or in the medication prescribed, and thus the course of treatment was the same for those who participate as it was for those patients who did not participate.

Patients receiving access to w-SPIINA were not in any way expected to be exposed to any additional risk or to any divergent, harmful, or unpleasant events as a consequence of participation.

For those patients who did not wish to participate, it had no influence on their course of treatment or on their relation to any of the healthcare professionals involved in their treatment.

In line with the Helsinki Declaration, patients were informed about the study both in writing and verbally, and they all had at least 24 hours to consider their participation [144].

The science ethics committee was notified of the study, and it did not find that permission was required. Data security and management were approved by the Danish Data protection agency (J.no. 2014-41-3583) and the trial was registered at Clinical Trials.gov (record NCT02615483).
6. Results

The key results from the papers will be presented in the following; however, a detailed presentation is provided in the publication and the manuscripts in Appendices A, B, and C. First, five interacting factors associated with anxiety and depression within spine surgery, as reported in Paper I, will be presented: pain, information, disability, employment, and mental health. Following that, patient characteristics in Papers II and III and use of w-SPIINA will be presented together, and the key results from the separate Papers II and III will be presented separately. Paper II reports no differences in gender, age, or any sociodemographic data in relation to the use of the ISG except that women were more prone to upload posts than men, and anxious patients tended towards a higher posting frequency. Paper III reports no additional effect of w-SPIINA on the chosen outcome parameters and finds no differences between groups. However, Paper II and III reports a high frequency of use of the w-SPIINA, especially by the ISG.

6.1. Results Paper I

In Paper I, the aim was to identify factors associate with symptoms of anxiety and depression in patients undergoing spine surgery. The review included a total of 14 studies. Of these, three were qualitative studies and 11 quantitative. Based on these 14 studies and a total of 4,833 participants, 75 individual findings were uncovered. Five factors associated with symptoms of anxiety and depression throughout the course of treatment in patients undergoing spine surgery emerged from those 75 findings: pain, information, disability, employment, and mental health (Figure 14). In the following, the five factors will be briefly explicated.

Figure 14. Factors associated with symptoms of anxiety and depression in patients undergoing spine surgery.
The experience of pain and its association with anxiety and depression

Studies report a correlation between the experience of pain and the presence of anxiety or depression. Quantitative studies report a correlation between chronic pain and preoperative symptoms of anxiety and depression [28,126,145] and furthermore between pain and symptoms of anxiety and depression six and 12 months after surgery [126,145]. In the qualitative studies, patients perceive that intense pain reduces their ability to cope with pain, inducing symptoms of anxiety and depression [146], and furthermore express the opposite experience that pain-free periods created relief [146]. A temporal variation was found in the association between pain and symptoms of anxiety and depression. In the first and second day after surgery, pain is found only to be moderately related to symptoms of anxiety and depression [147,148] and one month before surgery no correlation was found [149]. In contrast, a prospective cohort study finds that the presence of both symptoms of anxiety and of depression was a natural response to pain one year after surgery [28]. This connection is supported by a qualitative study, where patients express that pain made their personality change, made them feel less joyful, and caused a large amount of distress [146].

Need for information and associations with anxiety and depression

Primarily the qualitative studies have shown that patients have a need for individualised information and that there is connection between the lack information and symptoms of anxiety and depression. Patients reported experiencing anxiety when not knowing what to expect, both before surgery and years after [146,150,151]. Especially discharge was expressed to induce high levels of anxiety [151]. There was an agreement across studies that information was of great importance and should be presented in an individual, timely, and appropriate manner [146,150,151].

Disability and the associations with anxiety and depression

In several of the quantitative studies, a strong correlation between self-reported disability and symptoms of anxiety and depression was presented [28,43,124-126], and those patients with symptoms of anxiety and depression experienced worse disability [28,43,124-126]. As the disability declined so did the occurrence of symptoms of anxiety and depression [126,145]. Finally, inducing a more positive attitude in patients with the use of CBT resulted in an increase in physical performance [45].

Employment and its association with anxiety and depression

Being employed, using one’s education, and thereby maintaining a feeling of contributing to society were found to have a positive influence on depression [146,149]. Quantitative studies have shown that depression lowers the rate of patients returning to and sustaining employment [43,145,146,150,152]. According to quantitative studies,
depressed patients were less likely to be working, both within the first weeks after surgery and within three years after surgery [43,145], and if employed, patients with depression had more sick leave than those without depression [43].

**Mental health and its association with anxiety and depression**

Studies have found associations between anxiety, depression, and other psychological disturbances like post-traumatic stress disorder, catastrophising, worsened mental health scores, and stress and have reported associations between symptoms of anxiety and depression, both before and after surgery [43,125,147,148].

**Information as a mediator**

Emerging from the discussion in Paper I is the notion that the cognitive element of anxiety and depression in relation to the four factors, pain, disability, mental health, and employment status, is found to be mediated via the use of information. Learning to modify “mistaken fears” or learning to adopt a new life trajectory induces a positive attitude and more appropriate behaviour.

**6.2. Patient characteristics in Paper II and Paper III**

As shown in Figure 15, 212 consecutive patients were assessed for eligibility. Of these, 98 did not enter the study: 3 (1%) changed residence; 45 (21%) declined participation mainly because of severe pain, perceived the study to be “too much”, or because of lack of interest in the study; 22 (10%) did not meet the inclusion criteria because they had severe post-traumatic stress disorder, previously undergone spine fusion, lacked language proficiency in Danish; and finally two had no access to the internet. In addition, 28 (13 %) were excluded because their surgery was scheduled before or after the time frame criteria of the baseline visit, one to five weeks before surgery. Thus, a total of 114 patients fulfilled the in- and exclusion criteria. However, 15 (7%) additional patients were excluded, as shown in Figure 15. A total of 99 patients comprised the study population and were included in the analyses. In the RCT, the control group comprised of 51 patients, and the intervention group comprised of 48 patients. The same 48 patients comprised the population of the cohort study (Figure 15).

Patients in the two groups were comparable at baseline; however, by chance, the intervention group included 54% female patients, whereas the control group included 75% female patients, see Table 2. Both groups were comparable regarding length of stay, surgical procedure and complication, see Table 3.
Figure 15. *Patient flow in Papers II and Paper III [153]*.
Table 2. Baseline characteristics of study population [122,153].

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Total (n=99)</th>
<th>Intervention group/Cohort study population (n=48)</th>
<th>Control group (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>64 (65)</td>
<td>26 (54)</td>
<td>38 (75)</td>
</tr>
<tr>
<td>Age, mean. (range)</td>
<td>54 (29-79)</td>
<td>53 (29-77)</td>
<td>55 (30-79)</td>
</tr>
<tr>
<td>BMI &gt; 30, n (%)</td>
<td>26 (26)</td>
<td>15 (31)</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Smoking, n (%)</td>
<td>19 (19)</td>
<td>7 (15)</td>
<td>12 (24)</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/cohabitating</td>
<td>81 (82)</td>
<td>41 (85)</td>
<td>40 (78)</td>
</tr>
<tr>
<td>Living alone&lt;sup&gt;1&lt;/sup&gt;</td>
<td>18 (18)</td>
<td>7 (15)</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic education&lt;sup&gt;2&lt;/sup&gt;</td>
<td>22 (22)</td>
<td>12 (25)</td>
<td>10 (20)</td>
</tr>
<tr>
<td>Secondary education&lt;sup&gt;3&lt;/sup&gt;</td>
<td>73 (74)</td>
<td>33 (69)</td>
<td>40 (78)</td>
</tr>
<tr>
<td>Higher education&lt;sup&gt;4&lt;/sup&gt;</td>
<td>4 (4)</td>
<td>3 (6)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Employment status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>33 (33)</td>
<td>15 (31)</td>
<td>18 (35)</td>
</tr>
<tr>
<td>Sick leave/disability pension/unemployed&lt;sup&gt;5&lt;/sup&gt;</td>
<td>39 (39)</td>
<td>23 (48)</td>
<td>16 (31)</td>
</tr>
<tr>
<td>Retirement/student</td>
<td>27 (27)</td>
<td>10 (21)</td>
<td>17 (33)</td>
</tr>
<tr>
<td>Indication for fusion, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>35 (35)</td>
<td>16 (33)</td>
<td>19 (37)</td>
</tr>
<tr>
<td>Degenerative disease</td>
<td>64 (65)</td>
<td>32 (66)</td>
<td>32 (63)</td>
</tr>
<tr>
<td>Anxiety (HADS-A) (&gt;8), n (%)</td>
<td>36 (36)</td>
<td>16 (33)</td>
<td>20 (39)</td>
</tr>
<tr>
<td>Depression (HADS-D) (&gt;8), n (%)</td>
<td>26 (27)</td>
<td>17 (35)</td>
<td>13 (25)</td>
</tr>
<tr>
<td>HADS-A score, median (IQR)&lt;sup&gt;6&lt;/sup&gt;</td>
<td>6 [4 to 9]</td>
<td>6 [4 to 8]</td>
<td>6 [4 to 9]</td>
</tr>
<tr>
<td>HADS-D score, median (IQR)</td>
<td>5 [3 to 8]</td>
<td>5.5 [3 to 8.5]</td>
<td>5 [2 to 7]</td>
</tr>
<tr>
<td>Disability (ODI), median (IQR)</td>
<td>47 [32 to 56]</td>
<td>48 [30 to 54]</td>
<td>49 [32 to 60]</td>
</tr>
<tr>
<td>Pain – median (IQR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain right now</td>
<td>6 [4 to 7]</td>
<td>6 [4 to 7]</td>
<td>6 [4 to 7]</td>
</tr>
<tr>
<td>Leg pain right now</td>
<td>5 [3 to 7]</td>
<td>5 [3 to 7]</td>
<td>5.5 [3 to 8]</td>
</tr>
<tr>
<td>Worst back pain within the last 14 days</td>
<td>8 [7 to 9]</td>
<td>8 [7 to 9]</td>
<td>8 [7 to 9]</td>
</tr>
<tr>
<td>Worst leg pain within the last 14 days</td>
<td>8 [5 to 9]</td>
<td>8 [6 to 9]</td>
<td>8 [5 to 9]</td>
</tr>
<tr>
<td>Mean back pain within the last 14 days</td>
<td>6 [5 to 7]</td>
<td>6 [5 to 7]</td>
<td>7 [5 to 7]</td>
</tr>
<tr>
<td>Mean leg pain within the last 14 days</td>
<td>6 [4 to 8]</td>
<td>5.5 [4.5 to 7]</td>
<td>6 [3 to 8]</td>
</tr>
<tr>
<td>Quality of life (EQ-5D 5L), index score median (IQR)</td>
<td>.56 [.46 to .68]</td>
<td>.59 [.42 to .68]</td>
<td>.56 [.48 to .64]</td>
</tr>
</tbody>
</table>

<sup>1</sup>Includes widowed, single or divorced, <sup>2</sup>Basic education level comprised ISCED levels 0-2 (early childhood education, primary education and lower secondary education) <sup>3</sup>Secondary education comprised ISCED levels 3 (upper secondary education), <sup>4</sup>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) [154], <sup>5</sup>Includes patients not employed for other reasons than illness or unemployment, such as housewife, on leave, or student. <sup>6</sup>IQR indicates interquartile range (25th and 75th percentile).
Table 3. Length of stay, surgical procedures and complications [153].

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Total (n=99)</th>
<th>Intervention group/Cohort study population (n=48)</th>
<th>Control group (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay, mean (range)</td>
<td>5.1 (2-18)</td>
<td>4.9 (2-18)</td>
<td>5.3 (2-13)</td>
</tr>
<tr>
<td>Surgical procedure, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterolateral fusion (PLF)</td>
<td>94 (95)</td>
<td>46 (96)</td>
<td>48 (94)</td>
</tr>
<tr>
<td>Transforminal interbody fusion (TLIF)</td>
<td>5 (5)</td>
<td>2 (4)</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Complications, n (%)</td>
<td>10 (10)</td>
<td>5 (10)</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Dural lesion, n (%)</td>
<td>5 (5)</td>
<td>3 (6)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Length of stay within this group, mean (range)</td>
<td>8.2 (4-18)</td>
<td></td>
<td>9.8 (3-13)</td>
</tr>
</tbody>
</table>

6.3. Interaction with w-SPIINA Paper II and Paper III

All patients in the intervention group/cohort study interacted with w-SPIINA. The total number of interactions registered on w-SPIINA amounts to 4306 interactions. The number of interactions can be divided into three different features on w-SPIINA: animations/information, diary and ISG. Animations/information accounted for 656 interactions, which most often occurred just before or after surgery. The diary accounted for 293 interactions, being the least used feature, and the ISG accounted for 3357 events, being the most frequently used feature. A total of 43 (90%) patients accessed the ISG on w-SPIINA, and 23 (48%) were active users in the ISG by contributing with comments or posts.

6.4. Results Paper II

In Paper II, the aim was to describe the use of an ISG in patients undergoing LSF from baseline until three months after surgery. The 48 included patients had a total of 933 interactions on the ISG, comprising activities on the message board and the personal page.

Of these, 48 patients, 90% (n=43) were users of the ISG, accessing the ISG at least twice since its introduction at baseline until three months after surgery. The mean number of interactions for the 48 participants was 19 (range 0-90, SD19.28), the mean number of page views was 42.7 (range 0-312, SD 62.84), and the mean number of comments or posts was six (range 0-61, SD 13). The three most active users posted a total of 25% (238) of all interactions. A total of 59% patients (n=29) borrowed a tablet. No correlations were found between gender, age, or sociodemographic data or between any of the valuables of use in relation to whether the participant chose to borrow a tablet or not (P>0.45).

No correlations were found between gender, age, or any sociodemographic data and the use of the ISG (P>0.24). No correlations were found except for gender, indicating that contributing posts was more common in women (P=0.04) (Table 4).
Table 4. Correlation between activity on the ISG and marital status and gender [122].

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Rank Sum</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>475.5</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>849.4</td>
<td>0.31</td>
</tr>
<tr>
<td>Married/cohabitation</td>
<td>41</td>
<td>1032</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>193</td>
<td>0.85</td>
</tr>
<tr>
<td>Pageviews</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>478.5</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>746.5</td>
<td>0.35</td>
</tr>
<tr>
<td>Married/cohabitation</td>
<td>41</td>
<td>1030</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>194</td>
<td>0.87</td>
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<tr>
<td>Posts</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>442.5</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>782.5</td>
<td>0.04*</td>
</tr>
<tr>
<td>Married/cohabitation</td>
<td>41</td>
<td>1036.5</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>188.5</td>
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<td>Comments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>451</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>774</td>
<td>0.10</td>
</tr>
<tr>
<td>Married/cohabitation</td>
<td>41</td>
<td>1062.5</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>162.5</td>
<td>0.26</td>
</tr>
</tbody>
</table>

*Significant correlation was found between female gender and the contribution of posts on the ISG (Wilcoxon rank-sum test).

No significant differences were found between groups regarding the use of the ISG and the presence or absence of symptoms of anxiety and depression (P>0.07). However, participants with symptoms of anxiety tended to be more prone to contribute with posts or comments on the ISG than those without anxiety (P=0.07). Analysis of user variables of the ISG, comparing passive users (comprising those patients who accessed the ISG without making posts or comments) with active users (comprising those patients who contributed with posts or comments) revealed that the patients with most interactions were passive and patients with the most pageviews were active (P<0.001) (Table 5).

Table 5. Interactions and pageviews in groups who are passive users or active users [122].

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Rank Sum</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Passive users</td>
<td>25</td>
<td>485.00</td>
<td></td>
</tr>
<tr>
<td>Active users</td>
<td>23</td>
<td>374.00</td>
<td>0.0009*</td>
</tr>
<tr>
<td>Pageviews</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Passive users</td>
<td>24</td>
<td>463.50</td>
<td></td>
</tr>
<tr>
<td>Active users</td>
<td>23</td>
<td>761.50</td>
<td>0.0002*</td>
</tr>
</tbody>
</table>

b & c: P<.001

40
6.5. Results Paper III

The aim of Paper III was to examine the effect of a WP primarily on symptoms of anxiety and depression, and secondly on pain, disability, and health-related quality of life in patients undergoing LSF surgery.

For the primary outcome, HADS, no significant differences were found between groups at any of the predefined time points (P>0.12) (Table 6). The primary outcome was the change in HADS three months after surgery. At this time point, the w-SPIINA group reported a median change of $-1(1$ to $3$) in the anxiety subscale and $-1(2$ to $3$) in the depression subscale. The control group reported a median change of $-1.5(0$ to $-3$) in the anxiety subscale and $-1(0$ to $-3$) in the depression sub-scale (Table 6). Thus, the MCID was reached in the control group at three months, with a median decrease on the anxiety subscale of $-1.5$ (0 to $-3$). However, scores declining at six months to a change below the MCID. A positive MCID of HADS was not reached at any other time point. The caseness of anxiety and depression are shown in Table 7.

Regarding the earlier time points, one day prior to surgery and two days after surgery, MCID was reached in the w-SPIINA group with a median increase on the depression subscale of 2 (4 to 1) two days after surgery (Table 6).

Table 6. Median changes in symptoms of anxiety and depression, and median scores at follow-up [153].

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Score at follow-up</th>
<th>N</th>
<th>Control group</th>
<th>Score at follow-up</th>
<th>N</th>
<th>Between-group diff.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change from baseline</td>
<td>Median [IQR*]</td>
<td></td>
<td>Change from baseline</td>
<td>Median [IQR]</td>
<td></td>
<td>P</td>
</tr>
<tr>
<td>HADS-A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 day before surgery</td>
<td>1 [3.5 to 2]</td>
<td>7 [4 to 10]</td>
<td>48</td>
<td>0 [1 to -1]</td>
<td>6 [4 to 8]</td>
<td>48</td>
<td>0.12</td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>1 [3 to -1]</td>
<td>7 [4 to 10]</td>
<td>47</td>
<td>0 [2 to -2]</td>
<td>6 [3 to 9]</td>
<td>42</td>
<td>0.18</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-1 [1 to -3]</td>
<td>5 [3 to 7]</td>
<td>45</td>
<td>-1.5 [0 to -3]</td>
<td>4 [1.5 to 7]</td>
<td>46</td>
<td>0.37</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-1 [1 to -3]</td>
<td>5 [2 to 8]</td>
<td>43</td>
<td>-1 [1 to -3]</td>
<td>4 [1 to 8]</td>
<td>45</td>
<td>0.78</td>
</tr>
<tr>
<td>HADS-D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 day before surgery</td>
<td>0 [2 to -1]</td>
<td>6 [3 to 9]</td>
<td>47</td>
<td>1 [2 to -1]</td>
<td>6 [3 to 8]</td>
<td>48</td>
<td>0.67</td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>2 [4 to 1]</td>
<td>8 [5 to 12]</td>
<td>47</td>
<td>1 [3 to 0]</td>
<td>6 [3 to 9]</td>
<td>41</td>
<td>0.15</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-1 [2 to -3]</td>
<td>3 [1 to 6]</td>
<td>45</td>
<td>-1 [0 to -3]</td>
<td>3 [1 to 5]</td>
<td>46</td>
<td>0.78</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>0 [1 to -2]</td>
<td>5 [2 to 8]</td>
<td>43</td>
<td>0 [2 to -2]</td>
<td>3 [1 to 8]</td>
<td>45</td>
<td>0.97</td>
</tr>
</tbody>
</table>

*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
Table 7. Caseness of anxiety and depression at baseline and at 3- and 6-month follow-up [153].

<table>
<thead>
<tr>
<th></th>
<th>HADS-A (&gt;8) n (%)</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>14 (29%)</td>
<td>18 (37%)</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>11 (24%)</td>
<td>11 (22%)</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>12 (28%)</td>
<td>13 (28%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>HADS-D (&gt;8) n (%)</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>17 (35%)</td>
<td>11 (22%)</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>8 (18%)</td>
<td>8 (17%)</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>11 (26%)</td>
<td>12 (26%)</td>
<td></td>
</tr>
</tbody>
</table>

Both groups reached the MICD and comparable reductions in pain and health-related quality of life after both three and six months after surgery (Table 8 & 9). Both groups achieved a median reduction of two or more than two points in both leg and back pain, except regarding “worst leg pain within the last 14 days” in the w-SPIINA group, where the median decline reached 1.5 (−4 to 0). Both groups reported a median increase in health-related quality of life of at least 0.08 at all time points. The MICD was reached on ODI in the control group, with a median change of 15.5 (0 to 27.5). Both groups achieve a median decline in the ODI of at least 9 in the remaining time points at three and six months, but the values did not reach the MICD.

For most part, the parameters increased at the earlier time point of two days after surgery (Table 8 & 9); only pain in the back or leg within the last 14 days remained the same, as did back pain right now in the control group. There were no significant differences in the chances between groups.
<table>
<thead>
<tr>
<th>Intervention group</th>
<th>Score at follow-up Median [IQR]</th>
<th>N</th>
<th>Control group</th>
<th>Score at follow-up Median [IQR]</th>
<th>N</th>
<th>Between-group diff. P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Back pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>– back pain right now</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>1 [2 to -2]</td>
<td>47</td>
<td>0 [-2 to 2]</td>
<td>5 [3.5 to 7]</td>
<td>44</td>
<td>0.42</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-2 [-1 to -4]</td>
<td>45</td>
<td>-3 [-1 to -4]</td>
<td>3 [1 to 4]</td>
<td>49</td>
<td>0.38</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-3 [-1 to -4]</td>
<td>43</td>
<td>-2 [-1 to -4]</td>
<td>3 [1 to 5]</td>
<td>47</td>
<td>0.51</td>
</tr>
<tr>
<td><strong>– the worst back pain within the last 14 days</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>1 [2 to 0]</td>
<td>46</td>
<td>1 [2 to 0]</td>
<td>9 [8 to 10]</td>
<td>43</td>
<td>0.78</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-2 [-4 to 0]</td>
<td>44</td>
<td>-3 [-5 to 0]</td>
<td>5 [2 to 8]</td>
<td>48</td>
<td>0.24</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-3 [-4 to 0]</td>
<td>42</td>
<td>-3 [-5 to 0]</td>
<td>5 [2 to 7]</td>
<td>47</td>
<td>0.59</td>
</tr>
<tr>
<td><strong>– median back pain within the last 14 days</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>0 [1 to -1]</td>
<td>45</td>
<td>0 [1 to -1]</td>
<td>8 [5 to 8]</td>
<td>42</td>
<td>0.79</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-2 [-0.5 to -3.5]</td>
<td>44</td>
<td>-3 [-1 to -4]</td>
<td>3 [1.5 to 5]</td>
<td>48</td>
<td>0.26</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-2 [-1 to -4]</td>
<td>42</td>
<td>-2 [-1 to -4]</td>
<td>4 [2 to 5]</td>
<td>47</td>
<td>0.98</td>
</tr>
<tr>
<td><strong>Leg pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>– leg pain right now</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>1 [3 to 2]</td>
<td>46</td>
<td>3 [5 to 0]</td>
<td>2 [0 to 4]</td>
<td>43</td>
<td>0.01</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-5 [-5 to 0]</td>
<td>44</td>
<td>-3 [-5 to -1]</td>
<td>1 [0 to 3]</td>
<td>48</td>
<td>0.17</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-2.5 [-5 to 0]</td>
<td>42</td>
<td>-3 [-5 to -1]</td>
<td>1 [0 to 4]</td>
<td>46</td>
<td>0.38</td>
</tr>
<tr>
<td><strong>– the worst leg pain within the last 14 days</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>1 [0 to 3]</td>
<td>46</td>
<td>1.5 [0 to 4]</td>
<td>7.5 [5.5 to 9]</td>
<td>42</td>
<td>0.40</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-1.5 [-4 to 0]</td>
<td>44</td>
<td>-2 [-4 to 0]</td>
<td>1 [0 to 5]</td>
<td>47</td>
<td>0.73</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-2 [-4 to -1]</td>
<td>42</td>
<td>-2 [-4 to 0]</td>
<td>2 [0 to 6]</td>
<td>46</td>
<td>0.62</td>
</tr>
<tr>
<td><strong>Leg pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>– median leg pain within the last 14 days</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>0 [-2 to 0]</td>
<td>46</td>
<td>0 [1 to -2]</td>
<td>5 [3 to 7]</td>
<td>43</td>
<td>0.20</td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-3 [-5 to -1]</td>
<td>45</td>
<td>-3 [-5 to -1]</td>
<td>1 [0 to 3]</td>
<td>49</td>
<td>0.55</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-2 [-5 to -1]</td>
<td>43</td>
<td>-3 [-5 to 0]</td>
<td>1 [0 to 5]</td>
<td>47</td>
<td>0.51</td>
</tr>
</tbody>
</table>

*IQR indicates the interquartile range (25th and 75th percentile); Back and Leg pain; Low Back Pain Rating Scale (LBPRS)*
Table 9. Median changes in disability and health-related quality of life and median score at follow-up [153].

<table>
<thead>
<tr>
<th></th>
<th>Intervention group Change from baseline Median [IQR]</th>
<th>Score at follow-up Median [IQR]</th>
<th>N</th>
<th>Control group Change from baseline Median [IQR]</th>
<th>Score at follow-up Median [IQR]</th>
<th>N</th>
<th>Between-group diff.</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ODI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>34 [17 to 43]</td>
<td>80 [63 to 87]</td>
<td>47</td>
<td>26 [11-40]</td>
<td>76 [59 to 87]</td>
<td>43</td>
<td>0.25</td>
<td></td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>-10 [0 to -23]</td>
<td>32 [16 to 47]</td>
<td>45</td>
<td>-15.5 [0 to -27.5]</td>
<td>30 [15.5 to 47.5]</td>
<td>48</td>
<td>0.42</td>
<td></td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>-11 [0 to -30]</td>
<td>26 [11 to 46]</td>
<td>43</td>
<td>-9 [5 to -29]</td>
<td>39 [12 to 58]</td>
<td>47</td>
<td>0.58</td>
<td></td>
</tr>
<tr>
<td><strong>EQ-5D-5L</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 days after surgery</td>
<td>-.11 [0 to .22]</td>
<td>.5 [.37 to .58]</td>
<td>45</td>
<td>-.09 [-.03 to -.17]</td>
<td>.5 [.37 to .62]</td>
<td>42</td>
<td>0.52</td>
<td></td>
</tr>
<tr>
<td>3 months after surgery</td>
<td>.12 [.20 to .02]</td>
<td>.69 [.59 to .78]</td>
<td>44</td>
<td>.13 [.06 to .23]</td>
<td>.7 [.64 to .79]</td>
<td>48</td>
<td>0.49</td>
<td></td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>.08 [.24 to .01]</td>
<td>.68 [.59 to .75]</td>
<td>41</td>
<td>.16 [.24 to .06]</td>
<td>.72 [.63 to .8]</td>
<td>45</td>
<td>0.25</td>
<td></td>
</tr>
</tbody>
</table>

*IQR indicates the interquartile range (25th and 75th percentile); ODI, Oswestry Disability Index; EQ-5D-5L, Health-related quality of life questionnaire.

6.6. Summary of results

In the following section, results from the three papers will be summarised.

Paper I revealed five interacting factors associated with symptoms of anxiety and depression in patients with degenerative disease undergoing spine surgery. Pain, disability, mental health, return to work, and information were found to be interacting factors associated with symptoms of anxiety and depression and information was found to have a mediation role in the association between anxiety and depression and the other four factors.

In Paper II, the descriptive analysis of the use of the ISG reviled that the vast majority of patients accessed the ISG feature of the WP. There was no correlation between use of the ISG and gender, age, or any sociodemographic data. Female patients made more posts than male patients, and those with anxiety tended to have a higher activity level in regard to uploading posts and comments than those without anxiety. Finally, those patients who accessed the ISG most frequently were passive and active were the ones with the most pageviews.

In Paper III, patients in the intervention group all accessed w-SPIINA; however, they did not seem to benefit compared to those in the control group. In terms of reducing symptoms of anxiety and depression, a MICD was only reached in the control group at three-month follow-up. All patients achieved a comparable and minimal clinically important reduction in pain and achieved comparable clinically important increase in health-related quality of life. All patients achieved comparable reductions in disability, the control group achieved a clinically important reduction in disability at three months. However, no significant differences were found between groups in any of the chosen outcome parameters at any of the predefined timepoints.
7. Discussion

This dissertation responds to the current interest on symptoms of anxiety and depression within spine surgery. The first paper an integrative review summarises the existing knowledge and identifies factors associated with symptoms of anxiety and depression in spine surgery. The first clinical paper (Paper II) examines the use of an ISG in patients undergoing LSF and adds to our knowledge concerning the applicability of internet support groups in this group of patients. The second clinical paper (Paper III) explores the effect of a WP primarily on symptoms of anxiety and depression and secondly on pain, disability, and health-related quality of life. Paper III adds to our knowledge regarding the effect of a WP on the chosen outcome parameters.

A more extensive discussion of the results in the separate papers and a comparison with other studies is given in the individual papers, which are available in the three Papers I, II and III in Appendices A, B, and C. In the following, the strengths and limitations of the studies will be discussed. Then the feasibility of the intervention and the possible explanations that challenge the effect of our intervention will be discussed and will include all three papers. Finalising the discussion, the external validity will be presented.

7.1. Methodology – strengths and limitations

7.1.1. Strengths and limitations in Paper I

The overall strength of the presented integrative review is the systematic and critical approach, conducted with the use of validated appraisal tools and in collaboration with researchers, who contributed within different methodological approaches in accordance with their experiences and skills. In order to strengthen the validity of the review, a cut point of 75% with regard to the methodological appraisal tool was decided beforehand, and the sensitivity of findings was tested by raising and lowering the cut point while still pinpointing the same categories of findings.

The strength of an integrative review depends on the reviewers’ ability to conduct a relevant search, extract and interpret data, and their skills with regard to analysing findings from diverse methodological approaches into a coherent review [130]. In the review, the search was discussed with collaborating researchers and conducted in close corporation with research and medical librarians, limiting the risk of omitting relevant literature. The time frame was set from 1986 and forward, potentially omitting relevant studies published prior to 1986; however, a hand search of the reference lists did not reveal any additional studies.

The first selection process of the studies was performed by reading titles and abstracts, by one researcher only, which might have influenced the quality of the review [130]; the second selection was performed by two researchers, and if in doubt, they consulted a third researcher.
To extract and analyse data a convergent qualitative design was used, representing the most common data transformation technique used within integrative reviews [130]. No description was, however, presented of how a content analysis including various methodological designs should be performed in order to ensure quality in the integrative review. A qualitative content analysis was performed [131,155] of both qualitative and quantitative studies as described by Schreier and Berg [131,155] First, findings meaningful to the review aim were extracted, and then the findings were categorised or coded using the components of the ICF [55]. The coded data were then analysed, generating five factors with association with symptoms of anxiety and depression. Consistency of categories is a quality criterion of the content analysis, according to Schreier [131], and as the categories within the ICF are well described, they were perceived to be a reliable coding frame. The coding of findings was, however, only performed once and was randomly supervised by two supervisors; thus, the coding was not repeated, and the consistency of categorisation process may have affected the quality of this review.

The included quantitative studies include a wide range of questionnaires. Both the quantitative and the qualitative studies use a wide range of terms related to patients’ symptoms of anxiety and depression, and several studies lack a clarity regarding the definition of the terms used. Thus, with a clear influence on the quality of this review, no clear definition of anxiety nor depression is available.

The review in Paper I includes studies in patients with degenerative disorders at a wide range of anatomic locations and treated with several different surgical methods. This heterogeneity might influence the generalisability of the results and thus the quality of the review.

7.1.2. Strengths and limitations in Paper II

A strength of the cohort study was the random design and the high implementation rate of the ISG. Activity on the ISG was, however, tracked manually, which might have influenced the quality of the study. Adding a unique identifier to the individual patient might have provided a more accurate picture of the activity on the ISG and thereby a more reliable outcome measure.

The aim was to describe the use of an ISG in LSF patients, and in order to support the use of the ISG, all allocated to the cohort and not having a tablet were offered the opportunity to borrow such a device. Even though there were no differences between the activity of those who borrowed a tablet and those who did not, it is not possible to reach any conclusion on the usage of an ISG in homes without a tablet. This clearly had an influence on the quality of the study.

The number of patients in the study is low, compromising the quality and strength of all statistical analysis and compromising the ability to draw sound conclusions. In retrospect, a larger number of patients should have been
included in order to enhance the validity of the study. The recruitment process was consecutive and in periods slow; this might have influenced the quality of our study as the growth of a newly established ISG has been found to play a crucial role in the success or failure of ISGs [83]. In order for a ISG to play a supportive role for patients, it needs members who interact with each other and members who can produce posts and comments diverse enough to engage other members of the group. [83]. Thus, six former patients were invited to help ensure the “critical mass” needed in order to ensure that the group was able to engage with each other. These six patients uploaded posts and commented posts but were not included in the analysis, which might influence the validity of the study.

The lengthy enrolment process of approximately one and a half years resulted in patients on the ISG being in different places during the course of treatment. This diversity is seen in the vast majority of ISG studies, adding to the diversity of comments, addressing a wide variety of concerns, and enabling participants to benefit from their peers’ experiences [83,156]. It is not possible to indicate what influence the enrolment process of this study might have had on the use of the WP; however, the uneven enrolment resembles that seen in other studies and is labelled “burst growth”: in some months many new members are included and, in some months, only a few [83]. Furthermore, and possibly limiting the interaction on the WP, the purpose of this WP was research, and some of the patients included in the intervention group may have been reluctant to join the ISG because their interactions were being studied, compromising interactions on the WP and, thus, the quality of the study.

7.1.3. Strengths and limitations in Paper III

A strength of Paper III was the choice of a randomised design, providing comparable groups at entry, minimising the risk of confounding and selection bias. Furthermore, the high degree of interaction with w-SPIINA and the use of validated outcome measures are strengths, enhancing the validity of our results.

A potential weakness of our study is the uneven distribution of female patients between the two groups, as women in some studies are found with a higher prevalence of symptoms of anxiety and depression than men [48,52,104,105]. However, when looking at the occurrence of both symptoms of anxiety and depression within this study, there were no differences between genders.

Blinding of patients and researchers was not an option. This was an unavoidable limitation, and a possible positive expectation among patients and /or researchers may have influenced the outcomes in a positive direction, as well as a negative expectation in the control group could have influenced the outcomes in a negative direction. However, other than the 15-minute introduction to the w-SPIINA at baseline, there were no differences between attention in the two groups. Furthermore, the lack of between-group differences indicates that patients’ expectations might not have had any influence on results.
Our primary outcome parameter was the change in symptoms of anxiety and depression three months after surgery. However, two-thirds of patients do not score 8+ on the HADS A subscale or on the HADS D subscale. Thus, the possible visible effect of w-SPIINA on those patients with a caseness of either anxiety or depression will be reduced. In retrospect, it would have made sense to include only patients with the caseness of anxiety or depression at baseline or to include a larger number of patients, making it possible to do subgroup analysis on those presenting a caseness of anxiety or depression.

The analysis of HADS at six months in the intervention group lacks one patient according to the power calculation. However, the results on HADS found in this study did come close to statistical significance, and it is not perceived likely that one additional patient would have changed the results.

Our primary outcome was the change in symptoms of anxiety and depression the first three months after surgery, and the time frame of the RCT was, based on a pragmatic choice, set to be 6 months. This decision can be questioned because this limited follow-up period entails the risk that possible relevant changes in clinical outcomes might have been missed. Some studies still find changes in surgical outcomes after LSF one [26,157,158]and two years after surgery [26,159]. Thus, the positive outcome on pain, disability, and health-related quality of life in this study cannot be perceived as the final surgical outcome.

**Outcome measures**

The Hospital Anxiety and Depression Scale (HADS) was used as a baseline measure in Paper II and the primary outcome measure in Paper III. This decision was made as HADS was developed and found reliable for detecting caseness and severity of both anxiety and depression in somatically ill patients in a hospital setting and because repeated administration has been found to give reliable information assessing changes [133-135]. All symptoms of anxiety or depression likely to be present in patients with physical illness were excluded from the scale, thus minimising the interference of physical illness on the evaluation of anxiety and depression [134]. In our study the severity scale was not used, as it was not within the scope of the study. Furthermore, the number of patients with caseness of anxiety or depression is too low for subgroup analysis to be done. In retrospect, it would have made sense to include more patients in order to have enough statistical strength for subgroup analysis.

The accuracy of the depression subscale has been evaluated in relation to the Beck Depression Inventory (BDI), when applied preoperatively in spinal surgery. This evaluation found a strong correlation and a good reliability and found that HADS D could be used to screen for depression [160]. The HADS has been validated in patients with acute low back pain and found to be a valid instrument, showing good psychometric properties, high internal consistency and good convergent validity, and as well as being highly sensitive to changes [161].
A clear limitation in this study is, however, that the power calculation was preformed using a MICD in HADS calculated in a population of patients with chronic obstructive lung disease [136]; however, as HADS is a generic tool, it was decided that the conditions and requirements of the MICD were acceptable.

The Low Back Pain Rating Scale (LBPRS) was used to evaluate the development in leg and back pain, which has been shown to be a valid and reliable instrument in the assessment of low back pain [137].

In order to evaluate patient disability, the Oswestry Disability Index was used [139]. This tool is validated and frequently used in low back pain patients (also known as the Oswestry Low Back Pain Disability Questionnaire) and the test is perceived as the international gold standard for a low back pain functional outcome tool [139]. Furthermore, data concerning approximately 70% of all Danish spine operations are reported and maintained in a Danish database in the possession of by the Danish spine surgery society, called “DaneSpine” [162]. DaneSpine includes patients’ rating on the ODI as a part of normal practice both before and after surgery. Thus, inclusion of the ODI makes it possible to compare our study population with other studies, and to a large Danish population from this database. A change in ODI of at least 15 must be presented in order to reach the MCID [139,141].

In order to evaluate health-related quality of life, the EQ-5D-5L (the 5-level EQ-5D version) was used, and the index score was calculated using Danish preference weights [142]. Initially, EQ-5D-5L was chosen because an additional aim is to do a future economic evaluation of the WP, and the EQ-5D-5L is one of the most frequently used measurements to calculate the spine surgery patients’ quality-adjusted life years [163].

7.2. Feasibility of the intervention

Supporting the feasibility of w-SPIINA was that the implementation rate was high, and patients returned to the w-SPIINA on several occasions. In order to promote implementation, w-SPIINA was developed in order to provide flexible access to information and support, available any time of the day, making it possible to accommodate patients’ needs whenever they occur. However due to the current design and thus the distribution of tablets, it is not possible to evaluate the use of w-SPIINA in a home without a tablet, which might have limited the ability to indicate the feasibility based on w-SPIINA usage in the current study.

In addition, and supporting a high feasibility is that the use of the internet is in general increasing, also among the older population, where the majority in addition to their computer also use mobile devices [70], providing an even more easy access to web-based support. Furthermore, also supporting the feasibility of use of w-SPIINA is the increasing usage of social media and peers increasingly look to each other when seeking health advice [71].
Substantiating this observation of availability, only two patients in the current study were excluded due to lack of an internet connection. A total of 45 patients (of 212) declined participation due to low motivation, and it is not possible to determine whether this was due to the nature of the web-based intervention. However, this number of patients declining was not higher than in other studies recruiting LSF patients from a similar population to non-web-based interventions [157,164], and the nature of the intervention cannot be perceived the overriding reason that patients declined participation.

7.3. Possible explanations that challenge the effect of w-SPIINA

7.3.1. Black box dilemma

A substantial limitation of this study, in terms of evaluation of w-SPIINA, is that it has fallen in to a “black box” category, meaning that the processes within w-SPIINA were not evaluated [165,166]. Focus was aimed at the effect of the hypothesised processes on our chosen outcome parameters: anxiety, depression, pain, disability, and health related-quality of life.

W-SPIINA was constructed using a number of separate components: an ISG, animations, a diary, written information, and frequently asked questions. These components might act independently but also interdependently, and thus w-SPIINA can be considered a complex intervention [165,166]. Exploring the effect of a complex intervention, there is a risk that the actual processes cannot be untangled. In order to accommodate that risk and furthermore make readers able to compare or even apply our results, a through description of the design, the rationale, and the theory underpinning the choices was presented in Chapter four. And in section 4.1.2, the program theory was presented, including hypotheses regarding the processes within w-SPIINA, i.e. that animations would increase knowledge, which would decrease symptoms of anxiety and depression, or that feedback of pain and activity would empower patients, which again would decrease symptoms of anxiety and depression and so forth.

However, as w-SPIINA failed to provide us with positive results on the chosen outcome parameters in the intervention group compared to those in the control group, questions remain unanswered: Is the intervention inherently ineffective?, Was it applied inadequately?, Was it applied in the wrong context or in the wrong population?, Was a RCT the right choice of design?, and Were the chosen outcome parameters the right choices made in order to evaluate the intervention? A few perspectives will be given under the following subheadings: w-SPIINA aimed accommodating symptoms of anxiety and depression, the development in pain, disability and health related quality of life, Pros and cons of a social arena, and implementation of the biopsychosocial perspective.
7.3.2. W-SPIINA aimed accommodating symptoms of anxiety and depression

Developing w-SPIINA, a primary aim was to accommodate well-known symptoms of anxiety and depression in LSF patients [34,35] and hopefully thereby better surgical outcome. However, even though w-SPIINA was diligently used, the results in Paper III did not indicate an additional reduction in symptoms of anxiety or depression.

A possible explanation for the lack of effect of w-SPIINA could be that the amount of information and features on w-SPIINA resulted in an information overload. Too much information has been found to decrease the accessibility of the information [167]. When extensive information is at patients’ disposal, it can affect patients’ ability to select and use the right information. The amount of information simply surpasses the ability to select the right information at the appropriate time. This can result in patients feeling even more insecure [167]. As reported in the background section of this dissertation, studies support the use of surgery-related information in order to decrease anxiety prior to surgery [49-51]; however w-SPIINA presented extensive information that was related not only to surgery but also information that incorporated elements related to the period both before and until three months after surgery. Thus, even though animations are found to increase uptake of information and thus optimise patients’ acquisition of knowledge [108,109,113,115,116], the amount of information on w-SPIINA may have hindered uptake because it was too large.

Furthermore, another influence on information uptake is the presence of both anxiety and depression. Anxiety and depression have been found to influence cognitive abilities and predict poorer ability to adopt new information. Studies point out the advantages of information being provided when patients’ anxiety and depression levels are low [168,169]. However, seeking information when one is the most prone to accommodate, thus having low levels of anxiety and depression, may not come naturally. According to the Comprehensive Model of Information Seeking, it seems that anxiety induces an information seeking behaviour [170]. This is in accordance with a study that found that anxious and depressed patients are more prone to take part in an ISG and seek information [171]. Paper II was not able to reproduce similar results, indicating that the implementation of an ISG appealed more to those having symptoms of anxiety or depression than to those who did not have these symptoms; however, a tendency was found that pointed towards anxious patients being more prone to upload posts. Thus, the extensive information, the presence of anxiety and depression and the accessibility might not have added to increased information uptake and thus, reduction of anxiety and depression but rather hindered information uptake.
7.3.3. The development in pain, disability, and health-related quality of life

Pointed out and elaborated within Paper I, the lack of effect on patients’ symptoms of anxiety and depression might have a negative influence on the patients’ perceived development of the other outcome parameters. The occurrence of anxiety and depression has been found to affect patients self-reported pain, disability, and quality of life [38,172]. Anxiety and depression have been found to account for 12-14% of the variance in pain and 20% of the variance in disability and general well-being among patients with back pain [38]. Six months after surgery approximately one of every four patients report a caseness of anxiety or depression, which could be considered a bias when evaluating surgical results based only on self-reported questionnaires. And thus, the increase of caseness of anxiety and depression from three to six months may explain the lack of progression in pain, disability, and health-related quality of life from the three-month follow-up to the six-month follow-up. However, this increase in the caseness of anxiety and depression could also indicate that the patients were not prepared for the temporary increase in pain, which is often experienced because the active rehabilitation begins three months after surgery.

A positive development of pain, disability, and health-related quality of life was found in both groups after surgery at three and six months, with no additional effect being provided by w-SPIINA. The lack of an effect of w-SPIINA may be attributed the already existing two-hour joint information session, which has been developed over several years, however in a more informal setting. The clinic in which w-SPIINA was implemented has had years of experience working with health education [4-6], which might have induced a general focus on information and thus influenced the effect of w-SPIINA.

In the following, attention will be given to the social arena of the ISG, as 78% of the interactions took place here. Furthermore, an attempt will be made to clarify possible benefits patients might have achieved that were not evaluated in Paper II or Paper III, and in addition to explore possible explanations in the use of the ISGs that could challenge the effect of the w-SPIINA.

7.3.4. Pros and cons of a social arena

Even though w-SPIINA did not add to the positive development in any of the chosen outcome parameters, the frequent use of w-SPIINA, as reported in Papers II and III, could still indicate a perceived usefulness and an inherent value for patients.

In a two-year period (from first patient entered until the last patient attended six-month follow-up), the total number of interactions on w-SPIINA amounted to 4306, with 3357 interactions in the ISG alone. Thus, patients returned to w-SPIINA and especially to the ISG. The data collected in Paper II or III cannot explain the mechanisms that produced this frequent use, and a clarification of this presumed inherent value is not within the
scope of the present dissertation. However, focusing on the social arena of the ISG and looking into the literature, it is possible to extract some explanations pointing towards user-perceived values of an ISG and even towards explanations which might explain why a positive development of anxiety and depression was lacking. Qualitative studies seeking to explore the experiences of users of ISGs find that ISGs may have a value for patients, as they are found to provide useful information and aid in gaining social and emotional support and connecting with others [173,174]. Studies exploring the content of ISG posts and comments present similar results and suggest that the primary gain for patients is the exchange of information, the connection with patients in the same situation and with the same condition, and the emotional support they gain from their peers [76,175]. It has furthermore been suggested that connecting with others on an ISG reduces the sense of isolation [77,176]. Collectively, it has been argued that participation in an ISG can foster patient empowerment through gaining social and emotional support, through receiving useful information, finding positive meaning, and through helping others [75] and also that this empowerment has a positive impact on self-care and promotes adaptive coping [75]. It is not possible to confirm or reject that the ISG had a positive impact on patients’ self-care or coping abilities; however, it seems fair to assume that patients find some value when using w-SPIINA, or they would not likely have returned.

In the literature, expressed limitations of ISG use can also be found and might explain some of the reasons why w-SPIINA lacks effect regarding the reduction of anxiety and depression. Reduction of isolation was one of the expected effects when adding the ISG to w-SPIINA. This connection online also presents a disadvantage, because even though it is acknowledged that the key reason for patients to participate in an ISG is the connection with others, an online survey suggests that the lack of actual physical proximity makes relationships developed within an ISG less meaningful and actually makes patients feel even more isolated outside of the ISG [78]. This increased feeling of isolation outside of the ISG could have a negative influence on anxiety and depression in LSF patients, who are already known to experience isolation the first weeks after surgery [73,74].

Another disadvantage of ISG use is the nature of posts and comments, as they are found to be overloaded with negativity. While there is a tendency to acknowledge interactions as a positive contribution to the ISG community, it is however found that patients tend to post more when their symptoms of illness flare up and their condition has an increasingly negative influence on their lives [78]. This has been found to create a sense of anxiety of future events in other uses [78].

Finally, there is a distrust towards the information gained in ISGs, which can induce uncertainty. In general, seeking information online has been shown to be associated with some disadvantages. A cross-sectional survey evaluated the quality of 60 web sites containing information on low back pain. The quality of 97% of sites was found to be poor, to the extent that patients were discouraged from using the internet as a source of information [177]. Using ISGs, patients are found to be concerned about the quality of information being shared, and on
occasion they encounter contradictive information [78], adding to a sense of distress. Hopefully w-SPIINA has accommodated this, as information is given right next to the ISG feature. An exploration of posts and comments might uncover this. These challenges in the social arena of w-SPIINA may have had a negative influence on both anxiety and depression.

7.3.5. Implementation of the biopsychosocial perspective

With the intention to accommodate symptoms of anxiety and depression in LSF patients both in the period before and after surgery, a wider focus on w-SPIINA might have been advantageous.

In the introduction to this dissertation, the ICF [54,56] was presented and a commitment was made to a biopsychosocial perspective on LSF patients’ health status. A perspective illustrated by the ICF model, representing a wider view on health status than that of the biomedical paradigm alone [56]. In the development process of w-SPIINA, an effort was made to incorporate knowledge from previous research [4-6] together with the literature and a wide range of stakeholders, e.g. healthcare professionals, researchers, developers of w- SPIINA, patients, and support persons, all contributing with different perspectives in order to accommodate a wide perspective. However, in the light of the results in Paper I, it seems that w-SPIINA did not succeed in being wide enough and lacks central elements to be able to accommodate symptoms of anxiety and depression in LSF patients throughout the course of treatment.

In order to accommodate symptoms of anxiety and depression, the findings in Paper I report five factors: a need to address patients’ ability to cope with and understand pain; a need for individual information; a need to address every day activities and support patients to be active to the limit of their abilities; in some cases a need to inform patients in the direction of a new life trajectory or realistic expectations regarding returning to work; and finally it seems that addressing these issues will also decrease the risk of other mental health issues [178]. W-SPIINA does contain a large amount of information and the aim of the content of both features and information was to decrease symptoms of anxiety and depression. However, w-SPIINA could have address the cognitive-behavioural aspects of both pain and disability to a larger extent, improving the understanding of pain and disability and inducing adaptive coping. W-SPIINA does not focus on illness behaviours; on how to react to frightening thoughts or how to transfer attention away from frightening thoughts, which are incorporated into CBT. Substantiating the benefits of addressing those behaviours, the use of CBT has been shown to be beneficial in LSF patients [26,45,61]. Principles from CBT on w-SPIINA are limited to pictures showing realistic images of different situations as in the examples shown in Figures 5-8. This was done to induce positive attitudes and initiate appropriate behaviours [60,62]. Thus, some elements are incorporated into W-SPIINA; however, these may lack central elements of adaptive coping behaviour.
Considerations regarding return to work or a returning to habitual life were not incorporated, although as shown in Papers II and III, one-third of the included patients were employed. It is known that work disability in general is socio-economically costly and has negative influence on the individual, and one of the reasons for this is that employment is the most important means to obtain economic resources and because employment creates a sense of meaning to life by being able to contribute to society [146,179,180]. This associations between employment and anxiety and especially depression was clearly presented in the review [43,145,146,150,152]. The lack of this quite substantial contextual element in patients’ everyday lives might influence the effect w-SPIINA on the chosen parameters.

Exploring the content of w-SPIINA, it does unfortunately seem that the biomedical paradigm still plays a predominant role. The animations and the written information refer to the upcoming admission, operation, and the following rehabilitation with focus on managing analgesics, physical activity, and training. The diary leaves room for registration of pain and activity, with feedback on both. The ISG, however, is the feature with the largest liberty for patients to focus on what is important in their lives and is the feature with the highest number of events (3357). The results from Paper I could have induced a larger focus on coping behaviour in relation to both pain and disability and on return to work issues, and might even have facilitated inviting psychologists, caseworkers, or even members of rehabilitation teams from the primary sector into the development process. In retrospect, the extensive work of Paper I could have informed the development of w-SPIINA had it been conducted prior to the development process.

7.4. External validity

All patients were recruited from a general hospital, and the population includes patients undergoing first-time elective one- to three-level instrumented LSF. Patients with degeneration and spondylolisthesis were included as these patients were believed to represent general instrumented LSF candidates, and thus increasing the external validity of our results.

An often-seen selection bias in intervention studies is the fact that not all patients are motivated for participation, and often those who are more disabled are those who decline participation. A total of 212 consecutive patients were assessed for eligibility, and 21% of these declined participation, limiting the generalisability of our results by not including those patients less motivated and presumably more disabled. However, the study population does not deviate markedly from the Danish population with spine conditions in relation to gender, age, educational level, and employment status [181], increasing the external validity.

Furthermore, a choice was made to provide patients with a tablet, and thus all patients included in the intervention group and in the cohort were in possession of such device, limiting the generalisability of our results.
8. Conclusion

A considerable share (15-40%) of patients undergoing spine fusion continues to have pain, disability, and low health-related quality of life. Studies have found that the often-occurring preoperative symptoms of anxiety and depression are predictors of greater pain, disability, and lower health-related quality of life after surgery. Therefore, a more biopsychosocial perspective has been adopted in relation to spine fusion patients. Based on the developed WP and the above-described studies, the following conclusions are made.

Findings from the integrative review indicate that pain, the need for information, disability, return to work, and mental health were all factors associated with symptoms of anxiety and depression in a group of patients with degenerative conditions undergoing spine surgery. In addition, information was found to have a mediating effect on the association between anxiety, depression, and the remaining four factors.

The descriptive study, describing patients’ use of the ISG, reported a high implementation rate and a high frequency of use. The accessibility, perceived usefulness, and motivation seemed to be important facilitators supporting this ISG usage. No socioeconomic determinants were found for the use of ISG among patients undergoing LSF. However, women were found to be more prone to contribute with posts, and the perceived risk of spinal surgery experienced by those patients with anxiety may likewise make them more prone to ask questions and to contribute actively.

Finally, the RCT reported a high degree of implementation and a high frequency of use of w-SPIINA. Results reported found no additional effect of the w-SPIINA when provided in addition to a standard two-hour joint information meeting on symptoms of anxiety and depression or on pain, disability, and health-related quality of life the day before LSF surgery or two days, three months, and six months after LSF surgery.

The high usability and the lack of sociodemographic barriers indicate that this type of web-based aid could be applied in LSF patients. It also may indicate that LSF patients find some value in the WP, which is not found within this dissertation, however may have been uncovered had other outcome measures been chosen.

With regard to further development of educational and cognitive aids aimed at reducing symptoms of anxiety and depression and subsequently improving surgical results, consideration could be given to incorporating an even broader and more biopsychosocial perspective with more focus on patients’ understanding and ability to cope with pain and disability. More focus could be given educating patients to be active according to their abilities; and on providing patients with a realistic life trajectory or a realistic adaption of work-life after surgery. Furthermore, considerations could be given to the amount of information presented, or the pace at which this is presented, as too much information might reduce information uptake. Furthermore, using an ISG considerations could be given to the possibilities of decreasing negative posts and finally considerations could be given to the effect of an ISG on patients’ satisfaction with their social life.
9. Perspectives and future research

As of now, no research has been conducted using a WP in LSF patients resembling the one studied and evaluated in this dissertation. Providing patients undergoing LSF with access to w-SPIINA resulted in a high implementation rate and a high frequency of use, which may indicate a perceived value of use. However, based on the current dissertation, it is not possible to conclude what caused the high implementation and use, and thus, further research is needed in order to uncover the potential value of w-SPIINA. Furthermore, in order to evaluate w-SPIINA research in needed in order to untangle the processes within the intervention, accommodating the current “black-box” category. The development was, as previously described, based on a number of hypotheses however none of these are tested. Understanding of w-SPIINA could benefit from research done exploring the processes within the intervention. And as w-SPIINA was developed with focus on involvement of support persons, further research could explore support persons’ experience with w-SPIINA. Considerations should be made regarding the identification of subgroups of patients who could stand to gain the most from w-SPIINA. As the intervention is aimed at accommodating anxiety and depression, research is needed to clarify whether the lack of effect of the interventions used in this study was partly due to the fact that the vast majority of patients did not present caseness of anxiety or depression. Thus, it may be relevant to investigate the use of w-SPIINA on the subgroup of patients presenting the caseness of anxiety or depression. To our knowledge no research has been done using ISG in LSF patients and in general not much research is done in newly established ISGs. Thus, knowledge is lacking with regard to at what pace LSF patients should be recruited to take part in a newly established ISG in order for them to be able to engage each other’s. Thus, implementation should be monitored in relation to activity on an ISG in order to gain knowledge as to when the “critical mass” had been achieved.

In order to accommodate the inherent economic premise an economic evaluation should be undertaken. Healthcare information technology is looked at as one of the ways to reduce escalating healthcare expenses, and further research is needed exploring the cost-effectiveness and the cost utility of w-SPIINA. The economic evaluation of w-SPIINA has been initiated.

There are no standardised preoperative or postoperative curricula for patients scheduled for LSF, and future patient education programmes could benefit from interdisciplinary research done in order to evaluate and further develop educational content and mode of intervening in this and other patient groups, while taking into account the educational, social, or contextual support needed. Furthermore, the way in which information is distributed and the possible lack of coherent information across sectors might be a challenge in patients’ uptake of information because we lack knowledge regarding how information can create coherent treatment and rehabilitation across sectors.
10. References


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11. English summary

Over the last couple of decades, the number of spinal fusion procedures has significantly increased, and a considerable number of these patients undergoing this surgery continue to be challenged by pain, disability, and low health-related quality of life. Several studies have established that the often-occurring preoperative symptoms of anxiety and depression are important outcome predictors of greater pain, disability, and lower health-related quality of life. This interrelatedness between the psychological factors and surgical outcome has brought forward a biopsychosocial perspective on lumbar spine fusion (LSF) patients.

A web-based platform was developed based on the assumption that it was possible with the use of animated information and social interaction to reduce symptoms of anxiety and depression and thus better LSF outcome. A randomised controlled trial was initiated aiming to examine the effect of the platform on symptoms of anxiety and depression and on surgical outcome. Over a period of 18 months, 114 patients were included.

During the inclusion period the following studies were conducted. Firstly, in order to inform policy, practice, and the future development of effective aids accommodating anxiety and depression within spine surgery and finally in order to provide the needed insights to evaluate the effect of the developed web-based platform in the ongoing RCT, an integrative review was performed. This review aimed to identify factors associated with symptoms of anxiety and depression in patients with degenerative disorders undergoing spine surgery. Findings from this review indicated that pain, the need for information, disability, return to work, and mental health were factors associated with symptoms of anxiety and depression in this group of patients. In addition, information was found to have a mediating effect on the association between anxiety, depression, and the remaining four factors: pain, disability, return to work, and mental health.

Secondly, in order to create knowledge about the applicability of an internet support group (ISG) in LSF patients, and furthermore to provide additional insights in order to evaluate the effect of the WP in the ongoing RCT, a descriptive study was performed, aiming to describe LSF patients use of an ISG. Findings from this study report a high implementation rate and usage. Accessibility, perceived usefulness, and motivation seemed to be important facilitators for implementation. Sociodemographic factors were not found to be barriers for implementation. However, the degree of contribution in the social arena of the ISG seemed to be gender dependent and possibly related to mental health.

Thirdly, the RCT was performed. Providing patients with access to WP in addition to a standard two-hour joint information meeting had no additional effect on symptoms of anxiety and depression and patient-reported outcome the day before and two days and three or six months after LSF surgery. However, the high frequency of use was substantiated when looking at the total WP use.
In perspective, the possible perceived value found by patients supporting the implementation rate and frequent use was not identified. However, focus on other outcomes such as patients’ experience of social or emotional support, uptake of information, or even increased empowerment may have brought forward positive findings. In order to accommodate symptoms of anxiety and depression, a wider and more biopsychosocial focus on patient support seems needed.
12. Danish summary

I løbet af de sidste par årtier er antallet af patienter, der gennemgår fusionskirurgi i ryggen øget signifikant. En væsentlig andel af disse patienter har fortsat udfordringer med smerte, nedsat funktionsevne og reduceret livskvalitet efter operationen. Studier har fundet, at de kendte og ofte forekommende præoperative symptomer på angst og depressioner prædikterer for et dårligere operationsresultat. Denne interaktion mellem patienternes mentale tilstande og det fysiske udkom efter operationen, har bragt en mere bipsykosocial anskuelse af fusionspatienter frem i lyset.

En web-baseret platform blev udviklet, baseret på en formodning om at det, ved hjælp af animeret information og social interaktion, ville være muligt at reducere symptomer på angst og depression og derigennem også bedre operationsresultatet, hos patienter der gennemgår lumbal fusion. Et randomiseret kontrolleret studie blev i gangsat med henblik på at undersøge effekten af den udviklede platform.

I inklusionsperioden på havlandet år, gennemførtes en systematisk integrativ litteraturgennemgang. Formålet med denne var at identificere faktorer associeret med symptomer på angst og depression hos ryg opererede patienter. Forhåbningen var at resultaterne vil kunne informere fremtidige udvikling af støtte til disse patienter.

Litteraturgennemgangen identificerede smerte, behov for information, funktionsevne, tilbagevendelse til arbejde og mental sundhed, som faktorer associeret med angst og depression. Desuden fandtes information at have en medierende rolle i interaktionen mellem symptomer på angst og depression og de øvrige fire faktorer.

Dernæst, for at få viden om anvendeligheden af en internetstøttegruppe hos patienter, der gennemgår lumbal fusions kirurgi, samt for at få yderligere viden til at kvalificere vurderingen af resultaterne i det randomiserede studie, blev et deskriptivt studie gennemført. Dette deskriptivt studie havde til formål at analysere og beskrive patienternes brug af støttegruppen. Sociodemografiske faktorer fandtes ikke at være barrierer for implementering, men frekvensen for aktivt at bidrage ind i et sociale forum fandtes at være afhængig af køn og muligvis påvirket af mental sundhed. Implementeringsraten og brugen af gruppen var høj. Tilgængeligheden, en opleved brugbarhed og motivation så ud til at være vigtige facilitatorer for implementering og brugen af gruppen.


En mulig oplevet værdi hos patienterne, som kunne forklare den høje implementering og ofte brug, blev ikke identificeret i dette studie. Havde fokus været rettet mod patienternes oplevelse af social og følelsesmæssige
støtte, mod optaget af information eller mod patienternes evne til at få kontrol og tage ansvar for eget sygdomsforløb, da kunne resultaterne muligvis have været mere positive.

For at kunne imødekomme patienternes symptomer på angst og depression, ser det ud til at platformen kunne have draget fordel af at have haft et bredere og stadigt mere boipsykosocialt fokus på patient støtte.
Appendices

Appendix A
Janni Strøm, RN, MHSn, Merete Bender Bjerrum, MA, PhD, Claus Vinther Nielsen, MD, PhD, Cecilie Nørby Thisted, RN, MScPH, Tove Lise Nielsen, OT, HSC, Malene Laursen, MD, PhD, Lene Bastrup Jørgensen, RN, MScN, PhD, Anxiety and depression in spine surgery – a systematic integrative review, The Spine Journal (2018) 18: 1272-1285.

Appendix B
Janni Strøm, RN, MHSn, Mette Terp Høybye, MSc, PhD, Malene Laursen, MD, PhD, Lene Bastrup Jørgensen, RN, MScN, PhD, Claus Vinther Nielsen, MD, PhD To Use or Not to Use – a Descriptive Study of Lumbar Spine Fusion Patients’ Use of an Internet Support Group - Jan 2018 submitted for publication in Journal of Medical Internet Research – under revision.

Appendix C
Janni Strøm, RN, MHSn, Claus Vinther Nielsen, MD, PhD, Lene Bastrup Jørgensen RN, MScN, PhD, Malene Laursen, MD, PhD, 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 – June 2018 submitted for publication in The Spine journal - in review.
Appendix A

Paper I
Anxiety and depression in spine surgery—a systematic integrative review

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\textsuperscript{f}Department of Clinical Medicine, Aarhus University, Palle Juul Jønsson Boulevard 82, Aarhus N, 8200, Denmark
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Abstract

BACKGROUND: Symptoms of preoperative anxiety and depression occur in approximately one-third of patients with chronic back pain undergoing surgery. In the last 2 decades, several studies have established that preoperative anxiety and depression are important outcome predictors of greater pain and physical impairments, and lower health-related quality of life in patients undergoing spine surgery. To accommodate symptoms of anxiety and depression and thereby better surgical outcomes, we need to identify factors associated with these symptoms.

PURPOSE: We aimed to identify factors associated with symptoms of anxiety and depression in adults both before and after undergoing spinal surgery.

STUDY DESIGN: An integrative literature review was carried out.

METHODS: The independent charity Helsefonden supported this literature review by contributing $45,000 to remunerate a dedicated investigator. A systematic literature search was conducted in PubMed, CINAHL, PsycINFO, Embase, Scopus, Cochrane, and Web of Science. A three-step selection and assessment process was conducted; titles and abstracts of 1,124 articles were skimmed for relevance and of these, 53 articles were found to be of relevance and were read in full. Articles not meeting the inclusion criteria (n=26) were excluded. The 31 articles were critically appraised for methodological validity; 14 of these were synthesized and analyzed using a convergent qualitative design to transform both qualitative and quantitative articles into qualitative findings.

RESULTS: Fourteen studies were included, reporting results based on 4,833 participants, 3,017 men and 1,816 women, whose mean age was approximately 49 years. From these results, we extracted 75 individual findings, which we then divided into five categories of factors associated with anxiety and depression both before and after undergoing spine surgery: pain, information, disability, employment, and mental health.

FDA device/drug status: Not applicable.

Author disclosures: JS: Grant: Independent charity Helsefonden (E, Paid directly to institution), pertaining to the submitted work. MBB: Nothing to disclose. CVN: Nothing to disclose. CNT: Nothing to disclose. TLN: Nothing to disclose. ML: Nothing to disclose. LBJ: Nothing to disclose.

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.
CONCLUSIONS: Five categories of interacting factors that influenced symptoms of anxiety and depression both before and after surgery were identified: pain, lack of information, disability, return to work, and mental health. Information appears to have a regulating effect on anxiety and depression. © 2018 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Keywords: Anxiety; Convergent qualitative design; Depression; Information; Integrative review; Spine surgery

Introduction

This is an integrative review, a method that allows for the inclusion of diverse methodologies. The review aims to identify factors associated with symptoms of anxiety and depression throughout the course of treatment of adults undergoing spine surgery. These factors can be used to develop preoperative and postoperative educational initiatives and aids to reduce anxiety and depression within this patient group. Symptoms of preoperative anxiety and depression occur in approximately one-third of patients with chronic back pain who undergo surgery [1,2] and found to be common in patients with chronic back pain in general [3,4], with an estimated prevalence of depression to be two to three times greater in patients with back pain than in the general population [3]. The last decade, several studies have established that preoperative anxiety and depression are important outcome predictors of greater pain, physical impairments, and lower health-related quality of life in patients undergoing spine surgery [5–9]. Thus, both anxiety and depression can be associated with poor surgical results, leading to poorer rehabilitation.

It has been shown that educating patients about surgical procedures has the potential to decrease the occurrence of anxiety in patients undergoing cervical disc herniation surgery [10]. However, the question is how the identification of the overall factors associated with anxiety and depression in spine surgery is addressed in the literature. The aim of this review is to identify factors associated with anxiety and depression in adult patients, both before and after undergoing spine surgery.

Methods

The International Classification of Functioning, Disability, and Health (ICF) defines the ability to function in a multiaxial model in which interrelated factors influence each other in a dynamic, interactive, and non-linear process [11]. In the present review, this model is used to explain the relationship between anxiety and depression as outcome predictors of greater pain and functional disability, and lower health-related quality of life, and thereby clarify components that are important for the development of educational aids.

An integrative systematic review was undertaken [12]. This specific scientific and validated approach strives to provide a more comprehensive understanding of a challenge or a phenomenon; the method summarizes past empirical or theoretical literature, including qualitative, quantitative, and mixed methods articles. The integrative method supports the ability of grasping the complexity of existing findings and strengthens their ability to inform policy and practice [12]. The integrative review is by Whittemore and Knafl (2005) described in five stages: (1) problem identification, containing a clear identification of the problem, the review purpose and valuably of interest, being the concepts, population and the focus of interest; (2) literature search, with a well-defined search strategy and search being the basis for accurate results; (3) data selection and evaluation, where each research design has different criteria and frame of evaluation; (4) data analysis requiring that the data are unbiased, ordered, coded, and categorized and summarized into conclusions about the identified problem; and finally, (5) presentation, where the results ideally capture the depth and the breadth of the problem being investigated. Explicit details from sources should be presented to demonstrate the chain of evidence [12].

Search strategy

A three-step search was used [13]. First, an initial search was conducted using preliminary subject headings and keywords based on knowledge of the field. Second, subject headings and keywords were revised in accordance with the findings obtained in step one, and a second search was conducted in September 2016 in seven databases: Scopus, Web of Science, PsycINFO, Cochrane, PubMed, CINAHL, and Embase. The search was divided into blocks consisting of main keywords and additional variables (see search string in Table 1).

Third, a final search was conducted in which reference lists were manually consulted to identify additional studies.

Study selection and data evaluation

We aimed initially to include studies in adults undergoing lumbar spine fusion only; however, these studies were scarce, and after a thorough reading of our search results, we found that several of the studies obtained referred to depression and anxiety regardless of spine diagnosis, surgical method, and anatomical locations [14–16]. We therefore decided to include studies dealing with spine surgery caused by degenerative disorders in both the lumbar and cervical spines, and not exclusively spine fusion. The inclusion criteria were the following: articles published after January 1, 1986, as the first studies treating mental health in back patients were published in 1986 [17]; articles reporting, investigating, or
including results related to the aim of the review; articles written in English, Danish, Swedish, or Norwegian; and articles published in peer-reviewed journals. Articles were excluded if they dealt with a population with mental illness only; or patients with malignant disorders; or provided insufficient information to allow adequate interpretation of the design, measures, or results.

A three-step selection and assessment process was conducted (Fig. 1). First, all titles and abstracts (N=1,124) were skimmed for relevance by JS. Fifty-three of these were read in full text by JS and LBJ, and studies that did not meet the inclusion criteria were excluded (n=26); if in doubt, issues were discussed with CVN. Third, the remaining articles (n=31) were critically appraised for methodological validity; before appraisal, it was agreed that at least 75% of the criteria had to be satisfied. The 75% criterion was incorporated to minimize the risk of an inconclusive review as a result of excessive variation in the quality of studies [13]. To accommodate considerations regarding the sensitivity of review findings, the cut point of 75% was both lowered and raised, which gave no reason to alter the review findings. Methodological validity was appraised using the standardized critical appraisal instruments Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MASrAI) and Joanna Briggs Institute Critical Appraisal Checklist for Interpretive & Critical Research (JBI-QARI) [13,18] by two independent reviewers (JS and TLN or JS and CNT) depending on the study design. In case of disagreement, MBB or CVN was consulted. There were no disagreements regarding methodological validity in the three qualitative studies; however, eight quantitative references were consulted with CVN [16,19–25]. Owing to lack of methodological validity, 17 articles were excluded. Of these, seven articles were based on the same study [21,22,26–30]. The articles were excluded because of uncertainty as to whether the sample was representative of the population as a whole, lack of clarity as to whether all questionnaires were validated, and lack of a description of or inclusion in the analysis of the outcomes of participants who withdrew. Three articles also based on the same study [19,31,32] were excluded because the instruments used lacked validation, the use of instruments varied, and missing data were not consistently dealt with. The remaining seven articles [24,33–38] were excluded for a number of different reasons: it was not clear whether the sample was representative of the population, or whether it was based on a random sample, whether the outcomes of participants who withdrew were not described or included in the analysis, and in five of these studies it was questionable whether appropriate statistical analyses had been used. Assessment criteria and process are presented in Tables 5–7.

Data synthesis

A convergent qualitative design was used transforming qualitative and quantitative results into qualitative findings [47]. This approach was applied as it allows diverse and heterogeneous research to be incorporated into the same review, thereby striving to overcome the limitations of qualitative reviews (addressing only qualitative questions) and quantitative reviews (addressing only quantitative questions) [47].

The included articles were analyzed using qualitative content analysis [48,49]. The analysis was conducted in four stages by JS and thoroughly discussed with LBJ and MB. First, each sentence meaningful to the aim of the review was extracted from the articles, as a finding. Second, the extracted findings were coded using one of the five components in the ICF: body functions and structures, activities, participation, personal factors, and contextual factors (Fig. 2). Third, the coded data were analyzed, and five meaningful categories were generated. Fourth, an explanatory synthesis was aggregated from categories explaining the aim of the review.

A wide range of terms describing the occurrence of anxiety and depression was applied interchangeably in the included
studies, and multiple questionnaires were used. Findings were extracted when anxiety and depression were incorporated into the questionnaires or terms used. An overview of data collection tools, terms contained, and terms extracted is given in Table 2. Owing to the use of several questionnaires and terms, the associations were often ambiguous, but became less so when the outcomes were incorporated into categories. In this review, the terms anxiety and depression are used.

Results

The 14 included studies, 3 qualitative and 11 quantitative, reported 75 individual findings based on 4,833 participants.
Pain catastrophizing is characterized by patients magnifying their fear of painful situations, misinterpreting, and exaggerating the threat of a situation. This fear can give rise to avoidance behavior which again is associated with depression.

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Data collection tools</th>
<th>Extracted terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott et al. (2010) [39]</td>
<td>SF36, Mental health subscale of SF36, also known as MHI-5 is a summary score of five questions investigating anxiety, depression, loss of behavioral/emotional control, and psychological well-being. TAC, Tampa Scale for Kinesiophobia—the fear of movement model suggests that when pain is seen to be threatening, it will promote anxiety and give rise to pain-related fear. This fear can give rise to avoidance behavior which again is associated with depression. CSQ, Three subscales of Coping Strategy Questionnaire were used to assess patients’ current use of coping strategies and assess the use of negative thinking as a reaction to pain.</td>
<td>Mental health</td>
</tr>
<tr>
<td>Anderson et al. (2015) [40]</td>
<td>Diagnose code: Depression. Identified subjects diagnosed with other psychological comorbidity, here anxiety.</td>
<td>Depression</td>
</tr>
<tr>
<td>Archer et al. (2011) [16]</td>
<td>TAC, Tampa Scale for Kinesiophobia—the fear of movement model suggests that when pain is seen to be threatening, it will promote anxiety and give rise to pain-related fear. This fear can give rise to avoidance behavior, which again is associated with depression. PHQ-9, Nine-item Patient Health Questionnaire is a multipurpose instrument for screening, diagnosing, monitoring, and measuring the severity of depression.</td>
<td>Fear of movement</td>
</tr>
<tr>
<td>Havakeshian and Mannion (2013) [41]</td>
<td>MSPQ, Modified Somatic Perception Questionnaire and Modified Zung Self-Rating Depression Scale (SDS) were used together to determine psychological disturbances. FABQ, Fear Avoidance Beliefs Questionnaire was used to test patients’ beliefs about physical activity, and patients fears of activity when experiencing pain. SCQ, Six items on the catastrophizing subscale of the Coping Strategies Questionnaire. Pain catastrophizing is characterized by patients magnifying their fear of painful situations, misinterpreting, and exaggerating the threat of a situation.</td>
<td>Psychological disturbances</td>
</tr>
<tr>
<td>Mancuso et al. (2014) [15]</td>
<td>GDS, Geriatric Depression Scale—assesses depressive symptoms. STAI, Spielber State Trait Anxiety Inventory measures trait and state anxiety. It can be used in clinical settings to diagnose anxiety and to distinguish it from depressive syndromes.</td>
<td>Depression, Anxiety, and together; Psychological comorbidity</td>
</tr>
<tr>
<td>Maratos et al. (2012) [14]</td>
<td>HADS, Hospital Anxiety and Depression Scale obtains anxiety and depression scores, is a 14-item scale, with 7 items related to anxiety and 7 items to depression, developed to detect symptoms of anxiety and depression in somatically ill patients.</td>
<td>Anxiety</td>
</tr>
<tr>
<td>Monticone et al. (2014) [43]</td>
<td>TAC, Tampa Scale for Kinesiophobia—the fear of movement model suggests that when pain is seen to be threatening, it will promote anxiety and give rise to pain-related fear. This fear can give rise to avoidance behavior which again is associated with depression. PCS, Pain Catastrophizing Scale—catastrophizing is defined as a method of cognitive coping and is characterized by negative self-statements, overly negative thoughts and ideation, and patients misinterpreting and exaggerating the threat of a situation.</td>
<td>Mistaken fears</td>
</tr>
<tr>
<td>Papaioannou et al. (2009) [20]</td>
<td>HADS, Hospital Anxiety and Depression Scale obtains anxiety and depression scores, is a 14-item scale, with seven items related to anxiety and seven items to depression, developed to detect symptoms of anxiety and depression in somatically ill patients.</td>
<td>Anxiety</td>
</tr>
<tr>
<td>Parlato et al. (2013) [42]</td>
<td>SDS, Zung Self-Rating Depression Scale, a psychological self-rating test measuring depression severity.</td>
<td>Depression</td>
</tr>
<tr>
<td>Trief et al. (2000) [23]</td>
<td>STAI-T, Spielber Trait Anxiety Inventory measures trait anxiety. SDS, Zung Self-Rating Depression Scale, a psychological self-rating test measuring depression severity.</td>
<td>Anxiety</td>
</tr>
<tr>
<td>Wahlman et al. (2014) [25]</td>
<td>DEPS, Depression Scale. Two focus group discussions</td>
<td>Depression</td>
</tr>
<tr>
<td>Davis et al. (2013) [44]</td>
<td>Individual interviews</td>
<td>Depression, being in hell</td>
</tr>
<tr>
<td>Abyholm and Hjortdahl (1999) [45]</td>
<td>Individual interviews</td>
<td>Depression, being in hell</td>
</tr>
<tr>
<td>Abyholm and Hjortdahl (1999) [46]</td>
<td>Individual interviews</td>
<td>Depression, being in hell</td>
</tr>
</tbody>
</table>
Based on the 75 findings, five categories of factors associated with anxiety and depression both before and after undergoing spine surgery were generated: pain, information, disability, employment, and mental health. In this study, mental health is used to indicate psychological well-being. Examples of findings within the five categories are shown in Table 4.

The experience of pain and the associations with anxiety and depression

Pain is subjective, multidimensional, and associated with anxiety and depression, and can be characterized by chronicity, persistence, or intensity. Quantitative studies report elevated preoperative levels of anxiety and depression in patients with chronic pain [25,41] and show a bidirectional correlation between chronic pain and depression [25]. However, chronic pain can have pain-free periods, creating a sense of relief [45]. Intensity influences anxiety and depression because strategies used to cope with pain fail when pain becomes too intense [45]. The association regarding intensity was strong at 6 weeks and at 3- and 12-month follow-up [16,42]. Furthermore, the association between pain and mental health appeared to reveal temporal variation and was not found to be equally strong throughout the course of treatment. Thus, two quantitative studies indicate that pain is only moderately related to anxiety and depression, as these studies found no relation between use of analgesics and anxiety and depression the first and second day after surgery [20,42]. Depression was found to be relatively independent of pain in the early postoperative phase [42]. Furthermore, a cross-sectional study conducted 1 month before surgery found no correlation between anxiety and depression and pain [39]. However, a prospective cohort study found anxiety and depression to be a natural response to the presence of pain at 1-year follow-up [41], and this is supported by an interview study [45] in which 22 patients with pain for at least 3 years expressed a feeling of change in their personality because pain gave them less joy in life and caused them so much distress that 15 of these 22 patients had considered suicide [45]. However, when pain diminished, there was mental relief, and living was not quite as cumbersome [45]. Two other cohort studies support this relation between pain and anxiety and depression a few days before and 6 and 12 months after surgery [14,25].

Need for information and the associations with anxiety and depression

The need for information was a significant theme that primarily emerged within the qualitative studies. Patients expressed a need for individualized information; both its amount and timing helped them feel less anxious.

In two qualitative studies, patients experienced anxiety about not knowing what to expect [44,46]. Discharge was found to cause high levels of anxiety if patients did not know what to expect [44]. Years after surgical treatment, patients still stated that lack or low quality of information engendered high levels of anxiety [45,46]. Patients in both studies agreed that adequate information was important and should be provided individually. Furthermore, information should be presented in a timely and appropriate manner so that patients do not forget it and are able to understand it, which was also perceived individually [44,46]. Findings in a quantitative study indicate that educating patients to adopt appropriate behaviors also enhances a positive attitude [43].

Disability and the associations with anxiety and depression

Both pre- and postoperative associations between depression, anxiety, and degree of self-reported disability were found in most of the quantitative studies. Patients suffering from anxiety or depression experienced significantly worse disability than less depressed and less anxious patients [14–16,40,41]. The prevalence of both anxiety and depression declined in the postoperative period as physical ability and pain improved [14,25]. This bidirectional association is confirmed in another quantitative study using cognitive behavioral therapy to control catastrophizing and modify “mistaken fears.” This behavioral modification results in a more positive attitude toward exercise programs, which also increased patients’ physical performance [43].

Employment and its association with anxiety and depression

Being employed, using one’s education, and maintaining the feeling of being able to contribute to society positively influence the occurrence of depression. Conversely, depression lowers the rate of patients returning to and sustaining employment.

The relationship between return to work and the occurrence of depression is supported by both quantitative and qualitative findings [23,25,40,45,46]. According to quantitative studies, depressed patients were less likely to be working, both within the first 3 weeks after surgery and within 3 years after surgery [25,40]. Furthermore, those patients with depression who were employed 3 years after surgery were absent from work more often than those not depressed [40]. Regardless of professional background, qualitative studies found that non-employed patients had low self-esteem, felt demoted, and had the feeling of not being able to contribute to society, and the presence of these feelings is mentioned as one of several reasons why some patients considered suicide [45,46].

Mental health and its association with anxiety and depression

Several studies found associations between anxiety, depression, and psychological disturbances like posttraumatic
Table 3
Study characteristics

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Design</th>
<th>Number/surgery/diagnosis</th>
<th>Time of data collection</th>
<th>Data collection/tools</th>
<th>Grading score*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott et al. (2010) [39]</td>
<td>Cross-sectional study</td>
<td>107/Chronic back pain scheduled for lumbar spine fusion.</td>
<td>1 mo before surgery</td>
<td>Demographic and clinical characteristics, VAS, SF 36-MHI-5, TAC, BBQ, SES, three subscales of CSQ, ODI, EQ-5D</td>
<td>100%</td>
</tr>
<tr>
<td>Anderson et al. (2015) [40]</td>
<td>Historical cohort study</td>
<td>2,799/Workers’ compensation patients. Lumbar spine fusion.</td>
<td>Days before surgery, follow-up 2 and 3 y</td>
<td>RTW, medical cost, medical history, all-cause mortality, disability, sociodemographic</td>
<td>100%</td>
</tr>
<tr>
<td>Archer et al. (2011) [16]</td>
<td>Prospective cohort study</td>
<td>141/Degenerative spine conditions. Spinal surgery.</td>
<td>Days before surgery, follow-up 6 wk and 3 mo</td>
<td>Demographic and clinical characteristics, TAC, PHQ-9, BPI, ODI, ND, SF-12</td>
<td>100%</td>
</tr>
<tr>
<td>Havakeshian and Mannion (2013) [41]</td>
<td>Prospective cohort study</td>
<td>159/Decompression surgery.</td>
<td>Days before surgery, follow-up 1 y</td>
<td>Sociodemographic, medical history, MSPQ, SDS, FABQ, six items on the catastrophizing subscale of CSQ, RMQ, LBP, LP</td>
<td>89%</td>
</tr>
<tr>
<td>Mancuso et al. (2014) [15]</td>
<td>Cross-sectional study</td>
<td>713/Patients presented for preoperative testing.</td>
<td>Days before surgery</td>
<td>Demographic and clinical characteristics, ODI, ND, CCI, GDS, STAI, SF-12</td>
<td>85%</td>
</tr>
<tr>
<td>Maratos et al. (2012) [14]</td>
<td>Prospective cohort study</td>
<td>302/Degenerative spine conditions. Spinal surgery.</td>
<td>Days before surgery, follow-up 6 and 12 mo</td>
<td>Demographic data, HADS, SF-36</td>
<td>78%</td>
</tr>
<tr>
<td>Monticone et al. (2014) [43]</td>
<td>Randomized superiority-controlled study</td>
<td>130/Degenerative spine condition. Spinal spine surgery. Assigned to a program consisting of exercises and cognitive-behavioral therapy or exercise alone.</td>
<td>Days before surgery, follow-up 4 wk and 1 y</td>
<td>Demographic and clinical characteristics, ODI, TAC, PCS, NRS, SF-36</td>
<td>100%</td>
</tr>
<tr>
<td>Papaioannou et al. (2009) [20]</td>
<td>Prospective cohort study</td>
<td>61/Degenerative disk disease. Lumbar spine fusion.</td>
<td>1 d before surgery, follow-up 1 or 2 d</td>
<td>Demographic characteristics, analgesic use, PCS, HADS, VRS</td>
<td>78%</td>
</tr>
<tr>
<td>Parlato et al. (2013) [42]</td>
<td>Prospective cohort study</td>
<td>58/Lumbar stenosis. Decompression surgery.</td>
<td>Days before surgery, follow-up 6 and 12 mo</td>
<td>Demographic characteristics, SD, VAS</td>
<td>89%</td>
</tr>
<tr>
<td>Trief et al. (2000) [23]</td>
<td>Case-control study</td>
<td>102/Degenerative spine condition. Lumbar spine surgery.</td>
<td>Days before surgery, follow-up 6 and 12 mo</td>
<td>Demographic data, follow-up working status or maintenance at home, SDS, STAI-T, MSPQ, Ho, DPQ</td>
<td>89%</td>
</tr>
<tr>
<td>Wahlman et al. (2014) [25]</td>
<td>Retrospective cohort study</td>
<td>232/Lumbar spine fusion.</td>
<td>Days before surgery, follow-up 6 and 12 mo</td>
<td>Register data, demographic data, DEPS, ODI, VAS</td>
<td>78%</td>
</tr>
<tr>
<td>Davis et al. (2013) [44]</td>
<td>Qualitative study</td>
<td>7/Stenosis or disc herniation/decompression surgery.</td>
<td>Days after surgical treatment</td>
<td>Two focus group discussions</td>
<td>90%</td>
</tr>
<tr>
<td>Abyholm and Hjortdahl (1999) [45]</td>
<td>Qualitative study</td>
<td>22/Chronic low back pain. Spinal surgery.</td>
<td>Years after surgical treatment</td>
<td>Individual interviews</td>
<td>80%</td>
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<tr>
<td>Abyholm and Hjortdahl (1999) [46]</td>
<td>Qualitative study</td>
<td>22/Chronic low back pain. Spinal surgery.</td>
<td>Years after surgical treatment</td>
<td>Individual interviews</td>
<td>80%</td>
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* Standardized critical appraisal instruments from the Joanna Briggs Institute [13]: VAS, Visual Analog Scale; SF36-MHI-5, The Mental Health Subscale of the Medical Outcome Study Short Form; TAC, Tampa Scale for Kinesiophobia; SES, The Self-Efficacy Scale; ODI, Oswestry Disability Index; EQ-5D, The European Quality of Life Questionnaire; PHQ-9, Nine-Item Patient Health Questionnaire—Depression; BBQ, Back Beliefs Questionnaire; BPI, Brief Pain Inventory; ND, Neck Disability Index; SF-12, 12-Item Short Form Health Survey; MSPQ, Modified Somatic Perception Questionnaire; SDS, Modified Zung Self-Rating Depression Scale; FABQ, Fear Avoidance Beliefs Questionnaire; CSQ, Coping Strategies Questionnaire; RMQ, Roland Morris Questionnaire, LBP, Low Back Pain Rating Scale; LP, Leg Pain Rating Scale; GDS, Geriatric Depression Scale; STAI, Spielberg State Trait Anxiety Inventory; CCI, Charlson Comorbidity Index; HADS, Hospital Anxiety and Depression Scale; SF-36, The Medical Outcomes Study 36-Item Short Form Health Survey; PCS, Pain Catastrophizing Scale; NRS, Numerical Rating Scale; VRS, Verbal Rating Scale; STAI-T, Spielberg Trait Anxiety Inventory; MSPQ, Modified Somatic Perception Questionnaire; Ho, The Cook-Medley Hostility Scale; DPQ, Dallas Pain Questionnaire; DEPS, Depression Self-Test; RTW, return to work.
stress disorder, catastrophizing, worsened mental health scores, stress, both before and after surgery. In a cohort study, depressed patients differed from patients without depression; they had a higher degree of anxiety, higher rate of posttraumatic stress, and a higher rate of psychotherapy utilization [40]. Furthermore, in three quantitative studies, findings indicate that patients with depression also had a higher rate of new-onset anxiety and posttraumatic stress disorder [40], had worse overall mental health scores [15], and were more prone to catastrophizing [20]. A smaller cohort study found no new onset of depression at 3 and 12 months after surgery and concluded that depression at long-term evaluation was due to the relapse of preexisting depression [42]. However, these findings do not correspond to findings from a study including workers’ compensation patients, where 16% of the non-depressed were diagnosed with depression within 3 years after surgery [40].

**Discussion**

Our finding that pain, information, disability, return to work, and mental health are factors associated with anxiety and depression highlight a complexity that can be captured using the theoretical framework of the ICF, thereby avoiding...
reducing the causality of anxiety and depression to a single association.

Maintaining an ICF-based view of the biological, individual, and social explanatory perspectives on the interrelatedness between all identified factors associated with anxiety and depression, we discuss the need for information as a factor that can potentially influence the degree to which the four remaining factors influence anxiety and depression. We find that the cognitive construction of patients’ anticipations or patients’ conceptions, formed by information and thereby knowledge, has a mediating role in the associations between pain, disability, return to work, and mental health, and finally, anxiety and depression. The mediating role of patients’ knowledge and thereby information as a concept in a clinical setting is of potential interest, as spine health-care providers have both the opportunity to influence and facilitate. This will be discussed at greater length later.

A trend in the literature supports the importance of information. Informing patients is known to be a critical component of disease management because the need, mode, and ability to understand are individual, and research indicates that patients who gain knowledge and skills improve their ability to cope and their quality of life [50,51]. A systematic review finds that preoperative information has the potential to reduce preoperative anxiety [52]. Extensive preoperative information has been shown to enhance patients’ knowledge, satisfaction, and quality of life, and to reduce preoperative anxiety and postoperative use of analgesics [10,53,54]. Explaining to patients how to control their fears and modify “mistaken fears” makes them able to adopt more appropriate behaviors and induces a positive attitude [43]. Thus, the mediating role of information on anxiety and depression in patients undergoing surgery is well described [10,52–55]. Patients who adopt a more positive self-image and increased mental health achieve a better quality of life, which may also lower the risk of depression relapse as well as other psychological disturbances [43].

Pain has been seen as a multidimensional construct since 1971, when Melzack [56] defined it as a biomedical component influenced by tissue damage, an evaluative component influenced by coping, and an affective component influenced by anxiety and depression. Based on this model, the association between pain and anxiety or depression is developed in the dynamic interaction between the individual, the individual’s behavior, the information the patients are given, their ability to cope, and environmental factors. Thus, arguing that anxiety and depression are a natural response to the mere presence of pain seems to be a simplification.

Perceived pain the first and second day after surgery might be an expected and accepted result of the operation and would thus not correlate solely with anxiety or depression. Furthermore, correlation between pain and anxiety or depression 1 month before surgery, at the outpatient clinic when the patients were scheduled for surgery, was not evident [39]. Information may be the mediating factor, exemplified in a study that included patients undergoing lumbar spine surgery. When scheduled for surgery, the information they received and thereby the anticipation of pain relief and better physical ability resulted in the patients reporting better quality of life even before surgery [51]. The mediating role of information is substantiated in a second study in which expectations and hopes for future recovery were found to be significant predictors of reduction in depression before hip surgery [57].

During the postoperative period, too, information seems to play a mediating role in the association between pain and anxiety or depression. It was found that patients can start dealing with the consequences of their condition when they know what to expect, and in some cases, even begin a new phase of life [46]. The mediating role of information on anxiety and depression and its association with disability is found to be associated with the cognitive and behavioral aspects of anxiety and depression [14,25,41,42]. The behavior emerging within this group of patients with back pain can be conceptualized as avoidance behavior, and it is one of two responses to pain described by Lethem et al. in 1983 [58]. Avoidance behavior is seen to be derived from fear [59] and, as anxious patients will prioritize thoughts related to their fear, they are predisposed to move with caution. Information that includes elements from cognitive behavioral therapy is known to modify mistaken fears, thereby reducing both anxiety and depression, inducing a positive attitude toward physical performance and self-image and thereby reducing patients’ self-perceived disability in everyday activities [43]. One of the assumptions in cognitive behavioral therapy is that patients act in ways to maintain their thoughts and beliefs, potentially maintaining a maladaptive behavior [60]. When focusing on the cognitive aspect, the goal of information is to make patients adopt more realistic, adaptive perspectives, leading them to feel better emotionally and subsequently move more freely [60]. Functional recovery of patients receiving cognitive behavioral therapy in addition to exercise improves significantly early on in the rehabilitation program, within 3 months [61], and at follow-up 1 year after surgery [43,62].

Expectations concerning return to work are affected by a variety of issues; however, with the use of information, it is possible to help patients create realistic expectations and beliefs concerning their recovery, supporting the patient’s return to work or assisting a new life trajectory [63]. Information provides patients with the possibility of having realistic expectations and beliefs toward treatment and rehabilitation; depression will decrease as quality of life is perceived to be better [51]. In a study that included 168 patients with acute non–life-threatening orthopedic trauma, belief in recovery and perceived pain were identified as predictors for returning to work [64]. Furthermore, a patient’s belief in their own ability predicts recovery independently of physical disability [64].

Clinical implications

Informing patients is not simply a task involving the provision of information or education. As articulated in the
Although this heterogeneity involves clear limitations, it can also be considered an advantage because many spine surgery patients present the same associations between anxiety, depression, and other factors.

The systematic and critical approach is one of the strengths of this review. The systematic work was a collaborative undertaking involving seven researchers, each contributing within their methodological field, and all included studies met at least 75% of the criteria on the JBI checklists to secure the highest possible validity [13]. Sensitivity of findings to the quality appraisal cut point of 75% was found to be high. Further lowering the cut point to 50% would not change the findings of this review as Archer et al. [33], the three excluded studies based on the same study population by de Groot et al. [19,31,32], and the seven studies by Sinikallio et al. and Pakarinen et al. [21,22,26–30], also based on the same study population, found correlations on anxiety and depression as reported in the current review; that is, anxiety and depression were found to be associated with pain and physical impairments (Tables 5 and 6). Thus, these references pinpoint the same associations as presented in this review. If the cut point was raised from 75% to 80%, an additional three quantitative studies would have been excluded: two studies reporting data preoperatively, and 12 months after surgery [14,25], and a third study reporting on data the first and second

### Table 5

<table>
<thead>
<tr>
<th>Appraisal of the included studies with the use of JBI-MAStARI critical appraisal tool for comparable cohort/case-control study</th>
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<td>Y</td>
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</tbody>
</table>

JBI-MAStARI Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument; N, no; NA, not applicable; U, unclear; Y, yes.

Note: MAStARI [13] critical appraisal tool for comparable cohort/case-control studies. Q1. Is the sample representative of patients in the population as a whole? Q2. Are the patients at a similar point in the course of their condition/illness? Q3. Has bias been minimized in relation to selection of cases a whole? Q4. Are confounding factors identified and strategies to deal with them stated? Q5. Are outcomes assessed using objective criteria? Q6. Was measured in a reliable way? Q7. Were appropriate statistical analysis used? Q8. Were outcomes reported data preoperatively, 3 and 12 months after surgery included studies, failure to understand information can be attributed to the timing, amount, and quality of the information. It can, however, also be attributed to the level of health literacy [65]. Health literacy is not only about being able to read information; it also relates to patients being able to understand and effectively use it [65]. Approximately half of patients suffer from low health literacy and are thus unable to acquire, understand, and use the information they are given [65]. This reduced ability correlates with decreased learning abilities, higher mortality rates [66], and low levels of self-efficacy related to accomplishing pre-, peri-, and postoperative tasks regarding orthopedic surgical procedure [67]. Informing patients adequately and effectively is hence a comprehensive task in the health-care system.

### Strengths and limitations

This review includes patients undergoing spine surgery caused by degenerative disorders and encompasses a range of surgical methods and anatomical locations because we found that both the prevalence of anxiety and depression and the association within factors were present despite variation in the type, duration, and complexity of the operation [14,15]. Although this heterogeneity involves clear limitations, it can
day after surgery [20]. Thus, apart from the approximately 600 patients being excluded, only one remaining study in the review would report on associations found the first and second day after surgery. Raising the cut point further and thus above 80%, two of the three qualitative studies would be excluded [45,46], substantially limiting the diversity of studies included, without, however, changing the study findings (Table 7).

A major and quite substantial limitation was the large heterogeneity of the questionnaires used in the studies reviewed and in the terms employed that related to the patients’ anxiety and depression. Furthermore, there is a lack of clarity in the definition of the different terms in several of the studies. Thus, the outcomes of this review are presented as a synthesis between different terms, and a clear definition of the factors anxiety and depression is therefore not possible.

We included a large study among patients receiving workers’ compensation. We are aware that these patients are considered to have more unsatisfactory outcomes than patients not waiting for wage replacement [68]. We found the same factors associated with anxiety and depression. Rather than presenting itself as a limitation, our findings are substantiated by the fact that a diversity of patient categories indicates the same associations.

The influence of anxiety and depression on patients’ evaluation of their own ability is found to be significant, and could lead to bias when using patient-reported outcomes [9,69]. There is a need for a greater awareness of the implications of anxiety and depression mediating the assessed outcome, and there is a need to question the use of self-reported questionnaires as the only proxy for quality and outcome after spine surgery. In addition, if the cognitive and behavioral elements of anxiety and depression mediate patients’ assessed outcome after surgery, they may also do so before surgery. This would cause these patients to be candidates for spine surgery earlier on in their course of illness by presenting a “false” low preoperative physical ability or high degree of pain [15].

With reference to this review there are several scenarios for future research. One of these could be to evaluate the influence of anxiety and depression on patient-reported outcome both before and after surgery.

As to information, spine surgeons and spine care providers have an important impact on communication and the information given. Future research is needed to evaluate the effect of tailored information, taking into account the potential of web-based technologies, health literacy, and the reduced cognitive capacity in a patient group with a high occurrence of symptoms of anxiety and depression. Also, research with focus on optimized pain-treatment algorithms and educational pain and behavior information is needed. Future research evaluating the impact of regulation on workers’ compensation and return-to-work rates on patient-reported outcomes could be interesting. In a New Zealand study, an “early workers compensation” is provided, resulting in a 1-year return-to-work rate of 80% compared with 40% in countries providing

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Note: The questions from the Critical Appraisal Checklist for interpretive & Critical Research (QARI) [13] critical appraisal checklist for interpretive and critical research: Q1. Is there congruity between the stated philosophical perspective and the research methodology? Q2. Is there congruity between the research methodology and the research question or objectives? Q3. Is there congruity between the research methodology and the methods used to collect data? Q4. Is there congruity between the research methodology and the representation and analysis of data? Q5. Is there congruity between the research methodology and the interpretation of results? Q6. Is there a statement locating the researcher culturally or theoretically? Q7. Is the influence of the researcher on the research, and vice versa, addressed? Q8. Are participants and their voices adequately represented? Q9. Is the research ethical according to current criteria, or, for recent studies, is there evidence of ethical approval by an appropriate body? Q10. Do the conclusions drawn in the research report flow from the analysis or interpretation of the data?
a “late compensation” and 74% for “non-compensation patients” [70].

Conclusion

This review is the first to use the integrative review method to identify factors associated with anxiety and depression throughout the course of treatment in patients undergoing spine surgery. Pain, the need for information, disability, return to work, and mental health are found to be factors associated with anxiety and depression in this group of patients. Furthermore, information is found to be a mediating factor in the association between anxiety, depression, and the remaining four factors. With regard to the development of educational aids to reduce anxiety and depression and improve surgical results, the following should be considered: there is a need to address patients’ understanding of pain and their ability to cope; there is a need to inform patients at a time, in a way, and with an informational content suited to the individual; there is a need to address everyday activities, educating patients to be active according to their abilities; there is, in some cases, a need to educate patients in the direction of a new life trajectory; and finally, it seems that addressing these issues will decrease the risk of other psychological disturbances.

Thus, this review emphasizes not only the importance of focusing on biomedical factors to reduce the occurrence of anxiety and depression and to improve the outcome of patients undergoing spine surgery, but also the importance of understanding these patients’ conditions with reference to the biopsychosocial model of the ICF.

Acknowledgment

The authors are grateful to Camilla Meyer, the research librarian at Aarhus University Library, and Hanne Christensen, the medical research librarian, at the Regional Hospital of Viborg, for their valuable contributions to the literature search. Also, sincere thanks are due to the independent charity Helsefonden who supported the genesis of this integrative literature review.

References


[53] Rolving N, Nielsen CV, Christensen FB, Holm R, Bunger CE, Oestergaard LG. Does a preoperative cognitive-behavioral intervention


Appendix B

Paper II
To Use or Not to Use – a Descriptive Study of Lumbar Spine Fusion Patients’ Use of an Internet Support Group

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Abstract

Background: Internet use within healthcare contexts offers possibilities to provide patients with both health information and peer support. Peer support in the form of internet Support Groups (ISGs) are found beneficial in other groups of patients with long-term conditions, decreasing anxiety and depression and bettering health related quality of life and at the same time taking geography out of the equation. Thus, ISG may offer other potential advantages which is not found by face-to-face support. ISG might be beneficial in patients undergoing lumbar spine fusion (LSF) as peer support online might accommodate symptoms of anxiety and depression and decreased satisfaction with social life, which is found within this group of patients. Unfortunately, LSF patients may not belong to a group of patients prone to internet and ISG use. However, knowledge of LSF patients' use of ISG is limited. Objective: This study describes the use of an ISG in Danish patients undergoing instrumented LSF due to degenerative spine disorders. Method: A prospective cohort. Sociodemographic characteristics (gender, age, marital status, employment status, and level of education) and symptom of anxiety and depression were obtained at baseline, 1-5 weeks prior to surgery. The use of the ISG was registered from baseline until 3 months after surgery. Results: A total of 48 participants comprised the study population, with a mean age of 53 years (range 29-77), 54% were female, 85% cohabitating, 69% unemployed, and the majority (69%) had secondary education. Approximately one-third of the participants had symptoms of depression (35%), and anxiety (29%). Forty three of the 48 participants (90%) accessed the ISG. No correlations were found between sociodemographic characteristics and access to the ISG. Women were found more prone as active users, contributing with posts on the ISG ($P=0.04$). Finally, active users, contributing with posts or comments had more pageviews while passive users, users without posts or comments, had more interactions with the ISG ($P<0.001$).

Conclusions: Sociodemographic characteristics were not predictors of ISG use in this study. However, accessibility, usefulness and motivation seem to be important facilitators of ISG use and active use was found to be gender dependant.

Keywords: Lumbar Spine Fusion, Health informatics, Internet support group, eHealth, online support group
Introduction

The aim of this study was to describe the use of an Internet Support Group (ISG) in patients undergoing instrumented lumbar spine fusion (LSF) due to degenerative spine disorders. The ISG is imbedded on a Web-based platform designed to support patients undergoing LSF.

The Internet functions not only as a rich source of health information, it also provides communication-based activities, making it possible for patients to obtain and exchange health information. During the last decade, the body of literature exploring the use of ISG in cancer patients, in patients with depression, HIV/AIDS and other long-term conditions has grown [1-8]. Several of these studies find positive effect on patients’ depression, anxiety and on quality of life [5-8]. ISGs seem not only to have potential in terms of better quality of life, but they also receive positive ratings from users [5-8].

Peer support has been found applicable in the general population [9] and this desire from patients to connect with each other has been found to grow [10]. Furthermore, the availability of the Internet is increasing in Denmark, Australia, the US and in other European countries [11,12,12-15]. The use of social media is evolving rapidly, and health care has the possibility to use the internet to provide patients with peer support. Using the Internet to establish support groups has clear advantages, support can be delivered in the safe environment of the patients’ own home, and the information retrieved from peers can be found and reviewed at a pace and time suited to the individual [8]. Access to health- and disease-related information is made easier for citizens who, due to their health status, cannot participate in face-to-face groups, and for citizens in remote areas, citizens with social anxiety or those who feel uncomfortable disclosing personal experience in a room with others [8,16]. In addition, the ability to remain anonymous might instill courage in people with anxiety or depression, which often are seen as taboo diseases [17]. However, disadvantages do exist; users must have access to the Internet, and in order to be an active and contributing user, the individual must be comfortable reading, writing, and sharing with others.

Introducing ISG to patients undergoing LSF has the potential to create a platform for peer support, taking geography out of the equation and may instill courage in those patients with symptoms of anxiety and depression, which is found in approximately on third of these patients [18-21]. Attending face-to-face meetings within the first weeks after LSF might present some difficulties because these patients are recommended to limit transportation by car, bus, and train during the first 6 weeks after surgery. Furthermore, current practice does not include active rehabilitation until 3 months after surgery. Social life has been found to be a predictor of improvement of overall health-related quality of life in LSF patients [22]. However, studies indicate that these patients more often stay at home, reporting a significant decline in satisfaction with social life [23]. Thus, as LSF patients are limited in their physical abilities and as a consequence are more bound to their homes, and as they are found to have symptoms of anxiety and depression, they seem likely to be able to benefit from the advantages of ISG.

Studies do, however, indicate that not all patients participate equally in ISGs, pointing to yet another and quite substantial challenge. In line with studies on social inequalities in the use of web-information [24], studies find that not all groups of patients are prone to use an ISG; younger patients with higher education and higher income are more frequent users than patients who are older and in the lower socioeconomic groups [5,25]. This inequality is further emphasized because high-income households are more often connected to the internet [11]. This means that patients in the higher age groups and lower socioeconomic groups stands to benefit less from Web-based support. Unfortunately, these characteristics match those of LSF patients. Well half of citizens with a spine condition has primary school or
short-term education as their highest level of education or are outside the labor marked [26]. The highest prevalence of low back pain in Denmark is found in the age group 45-65 years [27]. Thus, although ISG could be beneficial in patients undergoing LSF, research indicates that these patients belong to a group that most likely does not use the Internet and ISG.

To the authors knowledge, the use of an ISG in patients undergoing LSF has not yet been examined. We need to further explore this and the potential disparities if we want to increase the use Internet-based support and at the same time provide equal healthcare for all. Thus, we hope this study will assist future eHealth interventions, as it aims to describe the use of an ISG from 1 to 5 weeks before surgery and until 3 months after surgery in Danish patients undergoing LSF.

**Methods**

**Study design and setting**

Participants in this study were recruited from a larger randomized controlled trial (RCT) which is currently under review and comprised 48 participants assigned to the intervention group.

The study population consisted of patients undergoing first time one- to three-level instrumented LSF due to degenerative disorders. Patients were invited to participate in the study, receiving both written and verbal information, by a study nurse when they attended the outpatient clinic and were scheduled for surgery. Final decision of participation was made at the following baseline visit one to five weeks before surgery, where written consent was collected.

Patients were excluded if they were below the age of 18, if they had a known psychotic disorder, enable to communicate in Danish; or had no access to the Internet. The inclusion was consecutive, and therefore the speed of inclusion was uncertain. This could mean that only a few participants would be included in the beginning of the study. Thus, six former patients were invited as facilitators to start the dialog and to post updates in the common space, creating activity and engaging the first participants when the group first. These six facilitators, continued throughout the study but were not included in the analysis.

A previous study introducing a Web-based platform for patients undergoing total hip replacement found the access rate as low as 61% [28]. With reference to one of the main theories within implementation described by Everett M. Rogers in 1962 [29], it was decided to promote implementation and provide participants with easy access. Thus, patients who were not in possession of a tablet were offered the use of one from baseline and until 3 months after surgery.

Data management and security were approved by the Danish Data protection agency (J.no. 2014-41-3583). In line with the Helsinki Declaration [30], patients were informed about the study both in writing and verbally and had at least 24 hours to consider their participation.

**The Internet support group**

The ISG could be accessed from any browser through a designated website. The ISG was embedded on this website, in which animated information and animated training instructions were part of the collective Web-based platform. Patients were introduced to the ISG at baseline, at which a 15-minute introduction in the use of this website was undertaken by a study nurse. During the introduction, all participants were encouraged to share their experiences, thoughts, and questions on the ISG and all were encouraged to use a respectful tone. Participants were told to use the ISG in a way that made sense to them and fulfilled their needs.

The ISG was closed to the public, and participants logged in using an individual password. A researcher and a study
nurse provided technical support if this was needed, and the researcher intervened if any offensive remarks were posted or if an aggressive tone was used. No mediation of such behavior was ever needed. No intervention or moderation was provided by any of the healthcare professionals.

The ISG consisted of a message board visible for all participants (Figures 1 & 2). In this space, participants could post their experiences, thoughts, or questions for other participants to answer or comment on.

**Figure 1.** The message board visible to all lumbar spine fusion patients assigned to an ISG in a descriptive study with 49 participants at Elective Surgery Centre, Silkeborg Regional Hospital, Central Denmark Region 2015-2017. The board is a reconstruction, names are invented, pictures are stock photos, and the text is written based on inspiration from real posts.
Figure 2. The message board with revealed comments, visible to all lumbar spine fusion patients assigned to a ISG in a descriptive study with 49 participants at Centre of Elective Surgery, Regional Hospital of Silkeborg, Central Denmark Region 2015-2017. This message board is a reconstruction, names are invented, pictures are stock photos, and the text is written based on inspiration from real posts.

On a designated page, each participant could upload a picture, note date of birth and operation, and write a personal or background story. No restrictions were set as to what this personal or background story should include, and no restrictions were made on the length of the post or how frequent participants could write in this space (Figure 3). Everything written on the discussion board was visible for all participants.
Figure 3. Personal page in the ISG platform, with the possibility to upload a picture, note date of birth and operation, and to write a personal background story, in a descriptive study of 49 lumbar spine fusion patients, at Elective Surgery Centre, Silkeborg Regional Hospital, Central Denmark Region 2015-2017. The page is a reconstruction, the name and dates are invented, picture is a stock photo, and the text is written based on inspiration from a real story.

Baseline data collection was done by a study nurse and took place at baseline visit, and comprised gender, age, and sociodemographic background. Marital status was classified as married/cohabiting or living alone (including widow, single or divorced). Educational status was classified into three categories using the International Standard Classification of Education 2011 [31]: basic education (early childhood education, primary education and lower secondary education), secondary education (upper secondary education) and higher education (post-secondary non-tertiary education, short-cycle tertiary education, bachelors or equivalent, masters or equivalent, doctoral or equivalent level). Employment status was classified as one of three categories: 1) employed/full or part-time; 2) pensioner/other (includes participants not employed for other reasons than illness or unemployment, such as housewife, on leave or student) and 3) sick leave/unemployed.

Psychological wellbeing was obtained using self-administered, paper and pencil Hospital Anxiety and Depression Scale (HADS). HADS is a 14-item scale, in two sub-scales for anxiety and for depression. The cut-off point has been
identified at a score of 8/21 for symptoms of anxiety and depression [32]. For anxiety, this gave a specificity of 0.78 and a sensitivity of 0.9. For depression, this gave a specificity of 0.79 and a sensitivity of 0.83 [32].

From baseline until 3 months after surgery, participants’ activity on the ISG was monitored manually. This was done by tracking the use of google analytics, including location data, browser data, device type, event type and event time; user-generated content data, including all posts, comments and stories by individual users; and personal data, including location, access date, date of operation, and from which device the participant gained access.

Activity was measured in interactions, one interaction often comprised a group of pageviews taking place within the same session. Distinctions were made between posts and comments. A post is a new upload of a question, update or other and a comment is an answers or comments written in a thread of an uploaded post.

Participants accessing the ISG without making posts or comments are defined as passive users, and those participants who contributes with posts or comments are defined as active users. The entire group entering the ISG will be referred to as users. Time spent on pages was not utilized because it was not possible to ascertain whether the ISG was used when the pages were open.

Statistical analysis

All data were coded to compute the data statistically and then twice entered into Excel. The data were then transferred to the statistical software program STATA14, where all statistical calculations were done.

Demographics were utilized to describe the sample. Descriptive statistics were done using frequencies and percentages to describe the sample profile and summarize data. Means and standard deviations were reported for continuous variables. Non-parametric data was analyzed using Spearman’s correlation tests to detect correlation between variables. Kruskal-Wallis ranks tests and Wilcoxon rank-sum test were used to establish any significant differences between unordered groups.

Results

During the period from September 2015 to May 2017, a total of 212 consecutive patients assigned for LSF at Silkeborg Regional Hospital were assessed for eligibility before inclusion in the RCT. A total of 98 patients did not enter the study: three changed their residences; 45 declined participation; 22 did not meet the inclusion criteria, one of these with no internet connection. Twenty-eight could not meet the timeframe criteria of the baseline visit.

The remaining 114 were included and randomized one-to-one, either to the intervention group receiving access to the ISG or to a control group. However further nine participants were excluded: three had their operations cancelled; one had the operation moved; three withdrew their consent the second day after surgery; and two had LSF performed without instrumentation (Figure 4).
The study population comprised 48 patients undergoing instrumented LSF; of these 57% were females. The mean age was 53 years (range 29-77). A total of 69% completed secondary education, while 27% had completed basic education, and only 6% had completed higher education. Preoperatively, a total of 41% were on sick leave or for other reasons unemployed, 31% were employed, and 29% were pensioners/other. Thus, approximately 70% of the participants were outside the labor market. The clear majority of participants were married/cohabitating (84%) (Table 1).

A total of 59% (N=29) chose to borrow a tablet. No correlations were found between gender, age, or sociodemographic data or between any of the valuables of use in relation to whether the participant chose to borrow a tablet or not (P>0.45).

The 48 participants had a total of 933 interactions on the ISG during their first 3 months after surgery. A total of 90% (n=43) were users of the ISG and 5 (10%) never used the ISG. The mean number of interactions for the 48 participants was 19.4 (range 0-90, SD19.28); however, the three most active users posted a total of 25% (238) of all interactions.

In the 933 interactions, the total number of pageviews was 2093. The mean number of total pageviews for each of the 48 participants was 42.7 (range 0-312, SD 62.84). Of the 48 participants, a total of 48% participants (n=23) participated with posts or comments. The total number of posts and comments was 288, and the mean number of posts or comments for the 48 participants was 6 (range 0-61, SD 13). Spearman’s rho was preformed, looking for correlation between variables of use of the ISG and age and education. No significant correlations were found (Table 2). Analysis was performed to detect differences between groups (Tables 3 & 4). No differences were found except for gender, indicating that contributing posts was more common in women.
Table 1. Sociodemographic characteristics of 49 lumbar spine fusion patients included in a descriptive study of ISG use, at Centre of Elective Surgery, Regional Hospital of Silkeborg, Central Denmark Region 2015-2017.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22 (46%)</td>
</tr>
<tr>
<td>Female</td>
<td>26 (54%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Mean age (years/range)</td>
<td>53 (29-77)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married/cohabitating</td>
<td>41 (84%)</td>
</tr>
<tr>
<td>Living alone1</td>
<td>7 (15%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Basic education2</td>
<td>12 (25%)</td>
</tr>
<tr>
<td>Secondary education3</td>
<td>33 (69%)</td>
</tr>
<tr>
<td>Higher education4</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
</tr>
<tr>
<td>Employed full/part time</td>
<td>15 (31%)</td>
</tr>
<tr>
<td>Pension/other5</td>
<td>14 (29%)</td>
</tr>
<tr>
<td>Sick leave/unemployed</td>
<td>19 (40%)</td>
</tr>
</tbody>
</table>

1Includes widow, single or divorced, 2Basic education level comprised ISCED levels 0-2, 3Secondary education comprised ISCED levels 3, 4Higher education level comprised ISCED levels 4-8 [31], 5Includes participants not employed for other reasons than illness or unemployment, such as housewife, on leave, or student.

Table 2. Correlation between variables of use and demographic data of 49 lumbar spine fusion patients participating in an ISG, at Regional Hospital of Silkeborg, Central Denmark Region 2015-2017.

<table>
<thead>
<tr>
<th>Interactions</th>
<th>Pageviews</th>
<th>Posts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Spearman’s rho</td>
<td>P Value</td>
</tr>
<tr>
<td>Age</td>
<td>-0.0706</td>
<td>0.63</td>
</tr>
<tr>
<td>Education</td>
<td>-0.0920</td>
<td>0.53</td>
</tr>
</tbody>
</table>

No significant correlations were found between age or education and the variables of ISG use (Spearman correlation).

Table 3. Correlation between activity on the ISG and the participants’ employment status in 48 lumbar spine fusion patients participating in an ISG at Centre of Elective Surgery, Regional Hospital of Silkeborg, Central Denmark Region 2015-2017.

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Rank Sum</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed/full or part time</td>
<td>15</td>
<td>88.00</td>
<td></td>
</tr>
<tr>
<td>Pension/other</td>
<td>14</td>
<td>329.50</td>
<td></td>
</tr>
<tr>
<td>Sick leave/unemployed</td>
<td>19</td>
<td>507.50</td>
<td>0.90</td>
</tr>
<tr>
<td>Pageviews</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed/full or part time</td>
<td>15</td>
<td>388.00</td>
<td></td>
</tr>
<tr>
<td>Pension/other</td>
<td>14</td>
<td>319.50</td>
<td></td>
</tr>
<tr>
<td>Sick leave/unemployed</td>
<td>19</td>
<td>517.30</td>
<td>0.80</td>
</tr>
<tr>
<td>Posts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed/full or part time</td>
<td>15</td>
<td>399.00</td>
<td></td>
</tr>
<tr>
<td>Pension/other</td>
<td>14</td>
<td>344.00</td>
<td></td>
</tr>
<tr>
<td>Sick leave/unemployed</td>
<td>19</td>
<td>481.00</td>
<td>0.82</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed/full or part time</td>
<td>15</td>
<td>370.00</td>
<td></td>
</tr>
<tr>
<td>Pension/other</td>
<td>14</td>
<td>362.50</td>
<td></td>
</tr>
<tr>
<td>Sick leave/unemployed</td>
<td>19</td>
<td>492.00</td>
<td>0.95</td>
</tr>
</tbody>
</table>

No significant correlations were found between employment status and the variables of ISG use (Kruskal-Wallis test).
Table 4. Correlation between activity on the ISG and marital status and gender in 48 lumbar spine fusion patients participating in an ISG at Regional Hospital of Silkeborg, Central Denmark Region 2015-2017.

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Rank Sum</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interaction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>475.5</td>
<td>0.31</td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>749.5</td>
<td></td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>41</td>
<td>1032</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>193</td>
<td>0.85</td>
</tr>
<tr>
<td><strong>Pageviews</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>478.5</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>746.5</td>
<td>0.35</td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>41</td>
<td>1030</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>194</td>
<td>0.87</td>
</tr>
<tr>
<td><strong>Posts</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>442.5</td>
<td>0.04</td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>782.5</td>
<td></td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>41</td>
<td>1036.5</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>188.5</td>
<td>0.71</td>
</tr>
<tr>
<td><strong>Comments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>451</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>774</td>
<td>0.10</td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>41</td>
<td>1062.5</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>7</td>
<td>162.5</td>
<td>0.26</td>
</tr>
</tbody>
</table>

*Significant correlation was found between female gender and the contribution of posts on the ISG (Wilcoxon Rank-sum).*

At baseline, 14 participants (29%) scored eight or more on the HADS anxiety subscale, indicating the presence of symptoms of anxiety, and 17 (35%) on the HADS depression subscale, indicating the presence of symptoms of depression, 8 (16%) of the participants had symptoms of both depression and anxiety, leaving only 25 participants (52%) without either symptoms of anxiety or depression (Table 5).

Table 5. The presence of anxiety and depression at baseline in 48 lumbar spine fusion patients participating in an ISG at Elective Surgery Centre, Silkeborg Regional Hospital, Central Denmark Region 2015-2017.

<table>
<thead>
<tr>
<th>+Anxiety(n)</th>
<th>-Anxiety(n)</th>
<th>Total (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td>-Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>25</td>
<td>34</td>
</tr>
<tr>
<td>Total/n</td>
<td></td>
<td>48</td>
</tr>
</tbody>
</table>

One-third suffered from depression, one-third from anxiety, and half had neither depression nor anxiety.

No significant differences were found between groups regarding the use of the ISG and the presence or absence of anxiety and depression (Table 6). However, participants with symptoms of anxiety tended to be more prone to contribute with posts or comments on the ISG than those without anxiety.

Analysis of user variables of the ISG comparing passive users with active users. Those users who were active had the most pageviews and passive users had the most interactions (Table 7).
Table 6. Use of ISG in participants with or without anxiety and depression at baseline in 48 lumbar spine fusion patients participating in an ISG at Centre of Elective Surgery, Regional Hospital of Silkeborg, Central Denmark Region 2015-2017.

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Rank Sum</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-anxiety</td>
<td>32</td>
<td>841.50</td>
<td>0.85</td>
</tr>
<tr>
<td>+anxiety</td>
<td>14</td>
<td>383.50</td>
<td></td>
</tr>
<tr>
<td>-depression</td>
<td>31</td>
<td>868.50</td>
<td>0.35</td>
</tr>
<tr>
<td>+depression</td>
<td>17</td>
<td>356.50</td>
<td></td>
</tr>
<tr>
<td>Pageviews</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-anxiety</td>
<td>32</td>
<td>830.50</td>
<td>0.67</td>
</tr>
<tr>
<td>+anxiety</td>
<td>14</td>
<td>394.50</td>
<td></td>
</tr>
<tr>
<td>-depression</td>
<td>31</td>
<td>888.00</td>
<td>0.17</td>
</tr>
<tr>
<td>+depression</td>
<td>17</td>
<td>337.00</td>
<td></td>
</tr>
<tr>
<td>Posts &amp; comments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-anxiety</td>
<td>32</td>
<td>773.50</td>
<td>0.07</td>
</tr>
<tr>
<td>+anxiety</td>
<td>14</td>
<td>451.50</td>
<td></td>
</tr>
<tr>
<td>-depression</td>
<td>31</td>
<td>848.00</td>
<td>0.59</td>
</tr>
<tr>
<td>+depression</td>
<td>17</td>
<td>377.00</td>
<td></td>
</tr>
</tbody>
</table>

No significant correlations were found between the presence of anxiety or depression and variables of ISG use (Kruskal-Wallis rank test).

Table 7. Interactions and pageviews in groups who are passive users or active users in 48 participants participating in an ISG at Regional Hospital of Silkeborg, Central Denmark Region 2015-2017.

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Rank Sum</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Passive users</td>
<td>25</td>
<td>485.00</td>
<td>0.0009b</td>
</tr>
<tr>
<td>Active users</td>
<td>23</td>
<td>374.00</td>
<td></td>
</tr>
<tr>
<td>Pageviews</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Passive users</td>
<td>25</td>
<td>463.50</td>
<td>0.0002c</td>
</tr>
<tr>
<td>Active users</td>
<td>23</td>
<td>761.50</td>
<td></td>
</tr>
</tbody>
</table>

Discussion

The findings in this study do not correspond to previous findings, as there was no sociodemographic variable in this study that correlated with the use of the ISG. Others find that socioeconomic status, comprising education and employment status, predicts ISG use [5,25,33,34]. However, corresponding to our findings, lack of such predictors was also found in a recent study published from the UK that included 863 depressed and anxious participants [35]. Some of the explanation for the discrepancy between our findings and the findings of others can be found in the results of an even larger study with data drawn from 2358 participants in the USA [35]. In this study, a differentiation was made between seeking information and engaging in social media; it was concluded that lower socioeconomic status, older age, and male gender were associated with less likelihood to engage in eHealth activities in terms of healthcare and information seeking and that lower education and lower income were associated with a greater likelihood to use health-related social media [35]. Thus, the amount of information that may be retrieved or the amount of interaction that may be expected could have a large predictive value regarding use of an ISG.

Gender distribution was almost equal in our study, with no significant differences between men and women with regard to the use of the ISG, which is in line with previous findings [25,36,37]. However, significantly more women were active users, contributing by uploading posts. This is in line with the findings of others reporting that participation in an ISG together with participants with similar diseases was more predominant amongst women than men [33,38]. Also, women were found to be almost three times as likely to participate in an ISG [33] and were found to be more than four
times as likely than men to be active users, contributing with written uploads [33]. Manierre (2015) offers a few explanations for this discrepancy, focusing on socially constructed patterns of behavior [37]. The division of labor in the home has resulted in women spending more time seeking health information, as they more often look after sick children and spouses [37]. The reason for this is that the pay gap within and between occupations is responsible for larger incomes amongst men. Thus, it rationally makes more sense for the women than the men to take time off, making them more acquainted with and prone to engage in health care information on the Internet [37]. Offering some of the explanation as to why men may be averse to ask questions and post comments in an ISG is that they act according to a set of masculine values: asking questions requires a confession of ignorance or need, which may pose a threat to masculinity [37]. Furthermore, males tend to consider situations to be less fearful and therefore also generating less motivation to ask questions and seek information [37].

According to the Comprehensive Model of Information Seeking, a person's needs or perceptions of risk influence the degree to which the ability to do something about a health problem is considered to be realistic, thereby generating information seeking behavior [39]. That perceived risk influences social behavior is also found in the previously mentioned study by Dean et al (2016), as they found that anxious and depressed participants were more prone to take part in a ISG [35]. Corresponding to those findings, anxious participants in our study were more prone to upload posts and comments. Thus, within this study, sociodemographics cannot be proposed as an important barrier, but the degree of contribution seems to be gender dependent and may be related to mental health.

A greater number of participants accessed the ISG in our study than in other studies evaluating a wider use of ISGs and in participants with other diagnosis [25,35]. There may be several reasons for this high degree of participation. Three possibilities will be explored below: first, patients were offered the use of a tablet, which may have increased the participants’ perceived ease-of-use and accessibility of the trial, which can have facilitated a more positive attitude and frequency of use. That ease-of-use influences acceptance and adoption is in concordance with the theory of the Technology Acceptance Model [40] and the previously mentioned implementation theory by Rogers [29]. The used of tablets increased the accessibility of the trial, and this had a positive influence on acceptance and adoption. If an innovation is designed to be tried out, it will have a more rapid rate of adoption [29]. Second, all participants in this study agreed to participate, knowing that the outcome of randomization could mean that they would have to relate to a Web-based platform, with an ISG as a part of the intervention. Agreeing to these terms may have created more motivated users. A third possible explanation for the high percentage of use could be related to the ISG being embedded on a website, where information and training instructions were available as well. Such a broad assortment of support may be appealing and useful for a wide range of participants, attracting both those seeking information and those seeking health-related social media. Perceived usefulness is also in accordance with the Technology Acceptance Model and implementation theories and is found to support a positive attitude and a behavioural intention toward use of a new technology [29,40]. Thus, accessibility, motivation, and perceived usefulness seem to be important facilitators, increasing ISG use.

A small number of the participants in this study were responsible for the majority of interactions. The three most active users contributed 25% of the total number of interactions. This phenomenon that a few contribute a lot is known as the peer leader phenomenon, characterized by a high posting frequency. This tendency is found to the extent that 1% of participants are seen to contribute 75% of all posts [41]. Such peer leaders identify themselves as active help providers, tending to provide a high level of social support, which contributes to an increased effect of the ISG if social
support underpins the improvement [41]. It is not possible to reach conclusions regarding social behavior and the content of posts and comments in the present study, as this would fall outside the scope of this study. Approximately half of the participants in this study (48%) contributed by posting or making comments. It is known that members of online groups often begin their membership as visitors or so-called lurkers, who just observe, and that not all members shift from being visitors to active users [42]. Some retain a passive behavior as members mainly interested in the information they can access through the online group [42]. In this study the passive users are those with the most pageviews, which may indicate that were interested in the information they could retrieve. It is not possible to determine how this behavior would evolve in this ISG beyond 3 months after surgery when data collection stopped. It is possible that the fact that interactions within Internet-based interventions consist mainly of text has an impact on patterns of use to the extent that only half of the users were active and contributors in this study. This type of online interaction does require that participants are comfortable writing and reading information online. eHealth literacy (defined as the ability to seek, find, understand, and appraise health information from electronic sources and apply knowledge gained to address or solve a health problem [43] is known to correlate with social position, older age, and chronicity of disease [33], and may be one of the reasons why some of the participants in this study did not contribute actively to the ISG. It is suggested that education might be a more salient proxy for ISG use than income, indicating that determinants of eHealth literacy may be important predictors [33]. It was not possible to find correlations in this study confirming the level of education as a predictive factor, the reason for this might be found in the high percentage of participants (69%) with a secondary education. It seems plausible; however, that eHealth literacy must be taken into consideration when developing Internet interventions. Failure to do so could increase the already existing inequality of healthcare. Further research should be done accessing eHealth literacy and its influence on eHealth engagement across social groups.

Limitations

The current study has several limitations First of all, adding a unique user ID to the platform’s user accounts in order to automatically identify behavior on the ISG might have provided more accurate data and a clearer picture of events than that provided in our manually generated process. The number of participants is small, limiting the strength of the analysis and making it difficult to draw statistically sound conclusions. However, our sample does not deviate markedly from the Danish population who report having a spinal condition in relation to gender, age, educational level, and employment status [27]. Also, the prevalence of both anxiety and depression in this sample of LSF patients is equal to that found in the literature among a similar group of patients [18,20,21,44]. However, further research with a larger group of participants should be done and might uncover further knowledge on the use of an ISG in patients undergoing LSF. All participants not in possession of a tablet were offered to borrow one and thus, well half of the participants chose to lend such device clearly having an influence on the use of the ISG and on the generalizability of the study results. All the participants did not access the ISG at the same time; the recruitment process was consecutive and in periods slow. It is not possible to know which influence this had on the frequency of use. In order to accommodate the slow recruitment process six former patients were invited to help engage participants, the role of these six patients is not further uncovered within this study, however their role of moderators may have had an influence on the usage and also on the quality of the study. Furthermore, with influence on the activity on the ISG, all participants were aware that their
interactions were being studied and thus, some might be reluctant to engage in the ISG. Activity on the ISG is seen as a positive contribution; however, the value of the different contributions was not taken into account. Thus, looking at the content of posts and comments could in addition to the results of this paper contribute to the knowledge of behavior within an ISGs provided in a professional context, with no professional supervision or moderation, which seems lacking in the literature.

The full potential of Internet use within health care has not yet been reached, e.g., with regard to dissemination of information, establishing health community networks, blogging, establishing support groups, and so forth. It is important to acknowledge that this global availability of information and support comes with difficulties. We need to strive to accommodate these difficulties by providing high quality eHealth assessable to all. Thus, reaching for the potential and boundlessly reach of the World Wide Web requires new skills and solid knowledge.

**Conclusions**

This paper contributes to the literature on the use of Internet support groups within health care and especially within the group of patients undergoing LSF. It was not possible to find determinants for the use of ISG among this group of patients; however, the high use of an ISG in this study confirms that an ISG is relevant for patients undergoing LSF. Socially constructed patterns of behavior may make women more prone to be contributors. The perceived risk of spinal surgery experienced by anxious participants may likewise make them more prone to ask questions and to contribute actively. Socioeconomic status cannot be considered as an important barrier. However, accessibility, perceived usefulness, and motivation seem to be important facilitators increasing the use of an ISG.

**Acknowledgement**

The authors are grateful to VISIKON for a very rewarding collaboration and highly valuable contributions in developing the Web-based platform. Also, sincere thanks to all the clinicians, patients, and their relatives who contributed in the development of the platform. Finally, a kind and sincere thanks to the facilitators, who made the platform, seem alive when the first participants arrived.

**Conflict of Interest**

VISIKON has produced both the animations and the Web-based platform and has contributed to covering the expenses related to development and production of the platform and the ISG. However, they have had no influence on the planning, the implementation, or the evaluation of the study. Janni Strøm, Malene Laursen, Lene Bastrup Jørgensen, Claus Vinther Nielsen declare that they have no conflict of interest.
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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 months 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 $10,000 to remunerate a dedicated investigator. The authors have no conflict of interest to declare. Results: There was no statistically significant difference within the w-SPIINA group and the control group in HADS at 3-month follow-up ($p > 0.37$). Minimal clinically important differences (MCIDs) in HADS scores were not reached in the intervention group. The MCID was reached in HADS-A in the control group at 3 months. In both groups, MCIDs were reached in LBPRS, and EQ-5D-5L at follow-up. The MCID in ODI was reached at 3 months in the control group. No statistically significant differences were found between groups with regard to the overall outcomes.
Conclusion: Providing patients with access to w-SPIINA in addition to a standard information regimen has no additional effect on HADS and patient-reported outcomes 3 or 6 months after surgery. Some findings do indicate that web-based support could be applicable in this group of patients.

Key words: Lumbar spine fusion; Anxiety; Depression; Web-based platform; Randomized trial, Information; Animation
BACKGROUND
The present study examines the effect of a web-based Spine Platform featuring Interaction and Information by Animation (w-SPIINA) on symptoms of anxiety and depression, back and leg pain, disability and health-related quality of life in patients undergoing instrumented lumbar spine fusion (LSF) due to disc degeneration or spondylolisthesis. 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 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 post-surgical 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.

The aim of this study 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, i.e., instrumented posterolateral fusion (PLF) or transforaminal interbody fusion (TLIF).
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 visit 1 to 5 weeks before surgery. 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 ClinicalTrials.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 and their support persons 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 and information session, patients and their support person had 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. Patients were informed that they could use w-SPIINA according to their individual needs; however, no demands on use were made. Furthermore, to avoid there being only one or two patients in the internet support group (ISG) at the beginning of the study, six former patients were invited to participate as facilitators in the ISG, providing peer support, answering questions and create activity. These six were not included in the analysis.

W-SPIINA consisted of animated information, animated training instructions, an ISG, and a diary. All the information was also provided in writing including a section with frequently asked questions. The animated narratives and instructions attempted to influence the patients’ ability to recall the information provided and designed to reduce the complexity of information and thereby hopefully accommodate the possible challenges due to a low degree of health literacy. The information was animated based on the current literature stating that pictographs and educative animation video optimizes patients’ acquisition of knowledge [19-23]. Principles from CBT and hence the animations included non-catastrophic 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 and 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-min, two-dimensional animations, in 17 sequences.
explaining the course of treatment from initial preparation to surgery to post-surgical 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]. 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 a web-based, interactive technology, geography is taken out of the equation, patients are 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 and outcome measures were collected by medical reports and self-reporting questionnaires: gender, age, body mass index (BMI), smoking, educational-, employment and marital status, primary diagnosis, symptoms of anxiety and depression, back and leg pain, disability, and health-related quality of life.

Symptoms of anxiety and depression were evaluated the day before surgery and 2 days, 3 and 6 months after surgery. Finally, back and leg pain, disability and health-related quality of life were evaluated 2 days and 3 and 6 months after surgery. Per- and postoperative complications were registered until 3 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 content data, and personal data, including location, access date, date of operation, and from which device the patient gained access.

**Primary Outcome**

The hospital anxiety and depression Scale (HADS), a self-reported questionnaire, was used to obtain an anxiety and depression score. 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 non-psychiatric 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 intention-to-treat 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. Due to the nonparametric distribution of parameters, nonparametric statistics were applied.

**RESULTS**

**Participant flow**
A total of 212 consecutive patients were assessed for eligibility; 98 did not enter the study (Figure 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 (Figure 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 because all withdrawals had been randomized to the intervention group. All women with a mean age of 65 (range 37–80), and 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.
Figure 1. Patient recruitment and flow

**Enrollment**
Assessed for eligibility (N=212)

Excluded (n=98)
- Not meeting inclusion criteria (n=22)
- Declined participation (n=45)
- <1 week or >5 weeks to surgery (n=28)
- Moved before operation (n=3)

Eligible for Randomisation (N=114)

**Allocation**
Allocated to control group (n=57)
Allocated to intervention group (n=57)

Excluded (n=6)
- Moved surgery (n=3)
- Cancelled surgery (n=3)

Analysis
Baseline n=51
1 day before surgery n=51 (100%)
2 days after surgery n=51 (100%)

Excluded (n=2)
- Medical condition (n=1)
- Lost to follow-up (n=1)

3 months after surgery n=49 (96%)
- HADS 90%
- ODI 92%
- Pain 94%
- EQ-SD-SL 94%

6 months after surgery n=49 (96%)
- HADS 88%
- ODI 90%
- Pain 92%
- EQ-SD-SL 88%

Baseline n=48
1 day before surgery n=48 (100%)
2 days after surgery n=48 (100%)

Excluded (n=9)
- Cancelled surgery (n=3)
- Moved surgery (n=1)
- Withdrew (n=3)
- Changed surgery (n=2)

Analysis
3 months after surgery n=45 (95%)
- HADS 94%
- ODI 94%
- Pain 92%
- EQ-SD-SL 92%

6 months after surgery n=45 (93%)
- HADS 90%
- ODI 90%
- Pain 88%
- EQ-SD-SL 85%

Excluded (n=3)
- Medical condition (n=1)
- Withdrew consent (n=2)
The overall mean number of days from baseline to surgery was 18 (range 7–36). The two groups were comparable at baseline (Table 1). Only the distribution of gender seems diverse, as 44% in the intervention group were male compared to 28% in the control group. There was, however, no statistical difference with regard to gender, anxiety, and depression ($p>0.05$). 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.

**Table 1. Background Patient Data**

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Total (n=99)</th>
<th>Intervention group (n=48)</th>
<th>Control group (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>64 (65)</td>
<td>26 (54)</td>
<td>38 (75)</td>
</tr>
<tr>
<td>Age, mean yr. (range)</td>
<td>54 (29-79)</td>
<td>53 (29-77)</td>
<td>55 (30-79)</td>
</tr>
<tr>
<td>BMI &gt; 30, n (%)</td>
<td>26 (26)</td>
<td>15 (31)</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Smoking, n (%)</td>
<td>19 (19)</td>
<td>7 (15)</td>
<td>12 (24)</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/cohabitating</td>
<td>81 (82)</td>
<td>41 (85)</td>
<td>40 (78)</td>
</tr>
<tr>
<td>Living alone¹</td>
<td>18 (18)</td>
<td>7 (15)</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic education²</td>
<td>22 (22)</td>
<td>12 (25)</td>
<td>10 (20)</td>
</tr>
<tr>
<td>Secondary education³</td>
<td>73 (74)</td>
<td>33 (69)</td>
<td>40 (78)</td>
</tr>
<tr>
<td>Higher education⁴</td>
<td>4 (4)</td>
<td>3 (6)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Employment status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>33 (33)</td>
<td>15 (31)</td>
<td>18 (35)</td>
</tr>
<tr>
<td>Sick leave/disability pension/unemployed⁵</td>
<td>39 (39)</td>
<td>23 (48)</td>
<td>16 (31)</td>
</tr>
<tr>
<td>Retirement/student</td>
<td>27 (27)</td>
<td>10 (21)</td>
<td>17 (33)</td>
</tr>
<tr>
<td>Indication for fusion, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>35 (35)</td>
<td>16 (33)</td>
<td>19 (37)</td>
</tr>
<tr>
<td>Degenerative disease</td>
<td>64 (65)</td>
<td>32 (66)</td>
<td>32 (63)</td>
</tr>
<tr>
<td>Anxiety and depression (HADS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety (HADS-A) (&gt;8), n (%)</td>
<td>32 (33)</td>
<td>14 (29)</td>
<td>18 (37)</td>
</tr>
<tr>
<td>Depression (HADS-D) (&gt;8), n (%)</td>
<td>26 (27)</td>
<td>17 (35)</td>
<td>11 (22)</td>
</tr>
<tr>
<td>HADS-A score, median (IQR⁶)</td>
<td>6 [4 to 9]</td>
<td>6 [4 to 8]</td>
<td>6 [4 to 9]</td>
</tr>
<tr>
<td>HADS-D score, median (IQR)</td>
<td>5 [3 to 8]</td>
<td>5.5 [3 to 8.5]</td>
<td>5 [2 to 7]</td>
</tr>
<tr>
<td>Disability (ODI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>47 [32 to 56]</td>
<td>48 [30 to 54]</td>
<td>49 [32 to 60]</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td>Leg pain right now</td>
<td>5 [3 to 7]</td>
<td>5 [3 to 7]</td>
<td>5.5 [3 to 8]</td>
</tr>
<tr>
<td>Worst back pain within the last 14 days</td>
<td>8 [7 to 9]</td>
<td>8 [7 to 9]</td>
<td>8 [7 to 9]</td>
</tr>
<tr>
<td>Worst leg pain within the last 14 days</td>
<td>8 [5 to 9]</td>
<td>8 [6 to 9]</td>
<td>8 [5 to 9]</td>
</tr>
<tr>
<td>Mean back pain within the last 14 days</td>
<td>6 [5 to 7]</td>
<td>6 [5 to 7]</td>
<td>7 [5 to 7]</td>
</tr>
<tr>
<td>Mean leg pain within the last 14 days</td>
<td>6 [4 to 8]</td>
<td>5.5 [4.5 to 7]</td>
<td>6 [3 to 8]</td>
</tr>
<tr>
<td>Quality of life (EQ-5D 5L), index score median (IQR)</td>
<td>.56 [.46 to .68]</td>
<td>.59 [.42 to .68]</td>
<td>.56 [.48 to .64]</td>
</tr>
<tr>
<td>Length of stay, mean (range)</td>
<td>5.1 (2-18)</td>
<td>4.9 (2-18)</td>
<td>5.3 (2-13)</td>
</tr>
<tr>
<td>Surgical procedure, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterolateral fusion (PLF)</td>
<td>94 (95)</td>
<td>46 (96)</td>
<td>48 (94)</td>
</tr>
<tr>
<td>Transforminal interbody fusion (TLIF)</td>
<td>5 (5)</td>
<td>2 (4)</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Complications, n (%)</td>
<td>10 (10)</td>
<td>5 (10)</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Dural lesion, n (%)</td>
<td>5 (5)</td>
<td>3 (6)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Length of stay within this group, mean (range)</td>
<td>8.2 (4-18)</td>
<td>9.8 (3-13)</td>
<td></td>
</tr>
</tbody>
</table>

1Includes widows, single or divorced, 2Basic education level comprised ISCED levels 0–2 (early childhood education, primary education, and lower secondary education) 3Secondary education comprised ISCED levels 3 (upper secondary education), 4Higher 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) [43], 5Includes patients not employed for other reasons than illness or unemployment, such as housewife, on leave, or student. 6IQR indicates interquartile range (25th and 75th percentile).

**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 diary was used a total of 293 times, and 3357 events were registered in the ISG, thus a total of 4306 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-A and HADS-D, 1 day before surgery or 2 days or 3, and 6 months after surgery. The changes in HADS did not reach the MCID in the intervention group at any of the predefined time points. However, the MCID in the anxiety subscale was reached in the control group at 3 months but declining again, and thus, the change did not reach the MCID at 6 months (Table 2). 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). Figure 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 ≤0.05), but no significant difference in pain (p for all tests ≥0.05).
Table 2. Effect of w-SPIINA on symptoms of anxiety and depression, disability, pain, and health-related quality of life

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Score at follow-up</th>
<th>N</th>
<th>Control group</th>
<th>Score at follow-up</th>
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<th>Between-group diff.</th>
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<td>4 [1 to 8]</td>
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<td>7 [6 to 9]</td>
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<td>Time After Surgery</td>
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<td>ODI</td>
<td>EQ-5D-5L</td>
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<td>34 [17 to 43] 80 [63 to 87] 47 26 [11-40] 76 [59 to 87] 43 0.25</td>
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</table>

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; Low Back Pain Rating Scale (LBPRS); EQ-5D-5L, Health-related quality of life questionnaire.

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

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
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<tbody>
<tr>
<td><strong>HADS-A (&gt;8) n (%)</strong></td>
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<tr>
<td>Baseline</td>
<td>14 (29%)</td>
<td>18 (37%)</td>
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<tr>
<td>3 months</td>
<td>11 (24%)</td>
<td>11 (22%)</td>
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<tr>
<td>6 months</td>
<td>12 (28%)</td>
<td>13 (28%)</td>
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<tr>
<td><strong>HADS-D (&gt;8) n (%)</strong></td>
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<tr>
<td>Baseline</td>
<td>17 (35%)</td>
<td>11 (22%)</td>
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<tr>
<td>3 months</td>
<td>8 (18%)</td>
<td>8 (17%)</td>
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<tr>
<td>6 months</td>
<td>11 (26%)</td>
<td>12 (26%)</td>
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</table>

According to ODI scores, the MCID was not achieved during follow-up in either of the two groups, except at 3 months in the control group. The MCID with regard to LBPRS and in EQ-5D-5L was, however, reached in both groups at 3 and 6 months follow-up except for “leg pain right now” at 3 months in the intervention group. 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 ($p=0.01$) 2 days after surgery in the control group than in the intervention group.

Box plots displaying the performance of ODI, EQ-5D-5L, and LBPRS at all predefined time points in both groups are seen in Figures 3–5.

Figure 3. Oswestry Disability Index, box plot at the predefined time points.
**Figure 4.** EQ5D-5L index-score, box plot at the predefined time points

One representing the best health and -0.624, representing the worst health.

**Figure 5.** Low Back Pain Rating Scale, box plot at the predefined time points.

(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.

**DISCUSSION**

Adding w-SPIINA to a usual standard informational regimen did not significantly reduce symptoms of anxiety and depression in the intervention group at any of the predefined time points. In the control group, the MCID was reached on the anxiety sub-scale at 3-month follow-up but declining below the cutoff MCID at 6 months. Finally, there were no significant differences between intervention and control groups. Secondly, 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.

Challenges of w-SPIINA effect

The outcome parameters applied in the evaluation of w-SPIINA: The frequent use by patients could indicate that w-SPIINA was not perceived to be without value. All included patients used w-SPIINA, and there were approximately 4300 events (ISG 3357, Animations 656, and Diary 293). Most patients returned to w-SPIINA several times during recovery, which could indicate a perceived usefulness. 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 the possible value of using w-SPIINA in the patient group can be found in the literature, as qualitative studies have shown that patients do find value in the use of ISGs, which also represents the most frequently used feature of w-SPIINA. Qualitative studies have shown that patients who use an ISG receive useful information, gain social and emotional support, help others, and connect with peers in the same situation [44-47]. Collectively, this has been described as being empowering for patients [48].

The amount of information: The comprehensive animations focused on the provision of information; however, the information did not induce a significant reduction of anxiety 2 days before surgery as has been found by Kesänen et al. (2017) [16] and Chuang et al. (2016) [49], which might be due to information overload. Both the study by Kesänen et al. (2017) [16] and that by Chuang et al. (2016) [49] aimed to reduce surgery-related anxiety by optimizing preoperative information with focus only on surgery-related issues and key points of post-operative 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 animated training instructions, an ISG, and a diary. Thus, an explanation for the lack of an effect of w-SPIINA before surgery and 2 days after surgery as found by Kesänen et al. (2017) [16] and Chuang et al. (2016) [49] could be due to a 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 [50]. 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 [50]. This information overload could be an influential factor at all the predefined timepoints. 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 given, as well as to the large diversity of modes and content [51]. This review included 14 interventional trials, using different modes of information (audio, audiovisual, leaflets, websites, imagery, and multimedia) providing preoperative education to various surgical patients orthopedic, coronary, abdominal, urinary, cancer surgery. Of these 14 studies, eight found a significant reduction in preoperative anxiety [51].

The study population: Two-thirds of the patients included in this study did not present severe or moderate (8+) caseness of anxiety or depression at baseline, which might have influenced the visibility of a potential effect in the one-third presenting
a greater degree of symptoms. Future research, exploring the effect of w-SPIINA in presenting moderate to severe symptom of anxiety and depression at baseline would be of interest. In the current study, the overall change and number of patients with moderate to severe caseness (8+) was too low for analysis, because the differences found could be attributed chance.

The setting in which w-SPIINA was added: 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 and no difference between groups presented itself. The 2-hour joint information session has been developed locally over more than a decade and continuously evaluated and changed according to changes in the clinical setting or demands from patients or support persons. The constellation, the content, and mode of this session were based on some of the same considerations as the development of w-SPIINA, providing verbal, visual, and written information seeking to enhance understanding, involve support persons, and optimize 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 map the content and to explore the effect of an already existing joint information session could be an interesting perspective in future research to clarify whether w-SPIINA adds to this, could replace it, and might even explain the lack of effect of w-SPIINA.

The content of w-SPIINA: 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 [52]. This review uncovered and found 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 [52]. 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.

The content of w-SPIINA also included principles from CBT because three studies presented positive results in outcome parameters when CBT sessions were added to the rehabilitation program after LSF [2,14,53]. 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 the results reported by Abbott et al. or Monticone et al. [2,53], 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 [2,53]. 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 context in which w-SPINA was applied: 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-SPINA may first have become apparent later. Imbedding an ISG in w-SPINA was intended to provide patients with peer support and thereby hopefully resemble the effects on disability found by Christensen et al. [29]. However, in contrast to the short follow-up after w-SPINA, positive results on daily functioning found by Christensen et al., presented themselves 2 years after surgery [29] and thus, the effects of w-SPINA on daily functioning might still emerge. ISG was also added to w-SPINA 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 after using w-SPINA, 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 especially in cancer patients. These studies found an overall positive effect of an ISG on psychosocial outcomes [54-56]. There are, however, substantial differences between the ISG used in these studies and the one used in w-SPINA: the number of patients who used w-SPINA 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 12–14% 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 [57] and to increase dissatisfaction with outcomes independent of physical outcomes [58,59]. 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 pre-, postoperatively and in the early rehabilitation period by featuring social interaction and animated information in a randomized controlled trial. In this setting, patients with degenerative spine disorders undergoing LSF achieved a clinical significant improvement with respect to pain and health-related quality of life at 3 and 6 months. On the other hand, there was no clinically significant change in disability measured using the ODI; however it is important to bear in mind that 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-SPINA 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-SPINA combined with frequent use and further with a higher usability than reported in other studies evaluating ISGs [60,61]. 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. However, due to the nature of the intervention, it was not possible to blind either patients or researchers. 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 [62,63], it is doubtful that this small difference in the included and not included could have had an effect on the generalizability of the study.

**CONCLUSION**

Providing patients with access to w-SPIINA in addition to a standard 2-hour joint 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.
REFERENCES


[60] Dean J, Potts HW, Barker C. Direction to an Internet Support Group Compared With Online Expressive Writing for People With Depression And Anxiety: A Randomized Trial. JMIR Ment Health 2016 May 17;3(2):e12PMID: 27189142,DOI: 10.2196/mental.5133 [doi].


Declaration of co-authorship

Full name of the PhD student:

This declaration concerns the following article/manuscript:

Title: Anxiety and depression in spine surgery—a systematic integrative review

Authors: Janni Stenm, Merete Bender Bjerrum, Claus Vinther Nielsen, Cecilie Nerby Thisted, Tove Lise Nielsen, Malene Laursen, Lene Bastrup Jørgensen

The article/manuscript is: Published [ ] Accepted [X] Submitted [ ] In preparation [ ]

If published, state full reference:

If accepted or submitted, state journal: The Spine Journal

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No [X] Yes [ ] If yes, give details:

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B. Has done most of the work (67-90 %)
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F. N/A

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Signatures of first- and last author, and main supervisor

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Declaration of co-authorship

Full name of the PhD student: Janni Strøm

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Signature of the PhD student
Declaration of co-authorship

Full name of the PhD student: Janni Strøm

This declaration concerns the following article/manuscript:

| Title: | 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 |
| Authors: | Janni Strøm, Claus Vinther Nielsen, Lene Bastrup Jørgensen, Malene Laursen |

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