Turun yliopisto
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EMPOWERING EDUCATION IN SURGICAL CARE OF PATIENTS WITH SPINAL STENOSIS

Jukka Kesänen

TURUN YLIOPISTON JULKAISUJA – ANNALES UNIVERSITATIS TURKUENSIS
Sarja - ser. D osa - tom. 1343 | Medica - Odontologica | Turku 2018

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Sarja D 1343

ISBN 978-951-29-7191-6 (PRINT)
ISBN 978-951-29-7192-3 (PDF)
ISSN 0355-9483 (Print)
ISSN 2343-3213 (Online)

Suomen yliopistopaino Oy - Tampere 2018

To Tuulikki

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Empowering education in surgical care of patients with spinal stenosis
University of Turku, Faculty of Medicine, Nursing Science, Finland
Annales Universitas Turkuensis, Turku 2018

ABSTRACT

Patients undergoing surgery for lumbar spinal stenosis have many preoperative educational expectations due to the complexity of the care pathway. Although empowering patient education (EPE) has proven effective in many patient groups, no previous literature exists on its use in spinal stenosis patients.

The purpose of the present study was (A) to describe the use of knowledge tests in patient education, and (B) to assess the impact of a specific patient education intervention on the empowerment of patients undergoing surgery for lumbar spinal stenosis. The aim was to improve the quality of patient education in this patient group.

In this randomised controlled double blinded clinical trial, 100 spinal stenosis patients were randomised into either the intervention group (IG) or the control group (CG). The intervention (Knowledge Test Feedback Intervention, KTFI) was conducted on an average 9 days before surgery, and consisted of an empowering telephone discourse based on a specifically designed knowledge test (KNOWBACK Test). Primary outcome variables were (A) preoperative knowledge level (cognitive outcome), and (B) preoperative anxiety (clinical outcome). As secondary outcomes, verbal and visual understanding of the surgical procedure as well as health-related quality of life (HRQoL), disability and pain were measured. The data were gathered at admission to hospital, at discharge, and at three and six months after surgery.

A significantly higher preoperative knowledge level was noted in the IG compared to the CG. Preoperative anxiety reduced more in the IG than in the CG, but there was no statistically significant difference between the study groups at any of the measuring time points. Verbal and visual understanding of the surgical procedure increased in both study groups during follow-up with no significant differences between the groups. Similarly, HRQoL, disability and pain improved in both groups after surgery; the differences between the groups were not statistically significant.

In conclusion, empowering knowledge feedback was an effective preoperative patient education method in increasing the patients´ knowledge level. Our results suggest that it may reduce preoperative anxiety. However, this finding did not reach statistical significance between the two study groups. The increased knowledge level was not reflected in the clinical outcome of surgery.

Key words: *empowerment, empowering patient education, empowering discourse, outcomes of patient education, knowledge feedback, lumbar spinal stenosis, surgery.*

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Spinaalistenoosileikkaukseen tulevien potilaiden voimavaraistumista tukeva potilasohjaus
Turun yliopisto, Lääketieteellinen tiedekunta, Hoitotiede, Suomi
Annales Universitas Turkuensis, Turku 2018

TIIVISTELMÄ

Lannerangan spinaalistenoosileikkaukseen tulevilla potilailla on runsaasti tiedollisia odotuksia hoitopolun moninaisuudesta johtuen. Vaikka voimavaraistumista tukeva potilasohjaus on osoittautunut tehokkaaksi useissa potilasryhmissä, sen käytöstä selkäleikkauspotilailla ei juurikaan ole tutkimustietoa.

Tutkimuksen tarkoituksena oli (A) selvittää tietotestien rooli potilasohjauksessa ja (B) arvioida tätä tutkimusta varten suunnitellun potilasohjausmenetelmän (Tietotesti-Palaute - Interventio, TTPI) vaikutusta spinaalistenoosipotilaan voimavaraistumisprosessiin sekä kognitiivisten (tiedon taso ja toimenpiteen ymmärtäminen) että kliinisten tulosmuuttujien (preoperatiivinen ahdistus, elämänlaatu, toimintakyky ja kipu) kautta.

Tässä satunnaistetussa kontrolloidussa kaksoissokkoutetussa kliinisessä tutkimuksessa 100 spinaalistenoosileikkaukseen tulevaa potilasta satunnaistettiin joko interventio- tai kontrolliryhmään. TTPI toteutettiin keskimäärin 9 päivää ennen suunniteltua leikkausta ja se koostui puhelimitse toteutetusta voimavaraistumista tukevasta keskustelusta. Keskustelu pohjautui potilaan täyttämään tätä tutkimusta varten kehitettyyn tietotestiin (KNOWBACK-testi). Primaaritulosmuuttujina käytettiin (A) voimavaraistumista tukevan tiedon tasoa (kognitiivinen tulosmuuttuja) ja (B) leikkausta edeltävän ahdistuksen tasoa (kliininen tulosmuuttuja). Sekundaarisia tulosmuuttujia olivat toimenpiteen ymmärrys verbaalisesti ja visuaalisesti kuvattuna, elämänlaatu, toimintakyky ja kipu. Tietoa kerättiin potilailta sairaalan tullessa ja sieltä kotiutuessa, sekä kolmen ja kuuden kuukauden kuluttua leikkauksesta.

Interventioryhmässä todettiin tilastollisesti merkittävä voimavaraistumista tukevan tiedon tason nousu. Leikkausta edeltävä ahdistus lieveni merkittävästi koeryhmässä, mutta tutkimusryhmien välillä ei missään vaiheessa todettu merkittävää eroa. lievittyminen kontrolliryhmään verrattuna. Kirurgisen toimenpiteen verbaalinen ja visuaalinen ymmärrys parani kummassakin tutkimusryhmässä seurannan aikana. Elämänlaadussa, toimintakyvyssä ja kivussa todettiin merkittävä parantuminen kummassakin ryhmässä, mutta ryhmien välillä ei ollut tilastollisesti merkittäviä eroja.

Johtopäätöksenä voidaan todeta, että TTPI paransi potilaiden voimavaraistumista tukevan tiedon tasoa ja mahdollisesti lievitti preoperatiivista ahdistusta. Leikkauksen kliiniseen lopputulokseen tällä ei kuitenkaan vaikuttanut olevan merkitystä.

Avainsanat: *voimavaraistuminen, voimavaraistumista tukeva potilasohjaus, voimavaraistumista tukeva ohjauskeskustelu, palaute tiedosta, potilasohjauksen tuloksellisuus, spinaalistenoosi, leikkaushoito.*

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LIST OF ABBREVIATIONS

CG	Control group
CVI	Content Validity Index
EPE	Empowering patient education
IG	Intervention group
Kela	The Social Insurance Institution of Finland
KTFI	Knowledge Test Feedback Intervention
LSS	Lumbar spinal stenosis
ODI	Oswestry Disability Index
OECD	Organization for Economic Co-operation and Development
RCT	Randomised controlled trial
STAI	Spielberger's State-Trait Anxiety Inventory
STAI-Y1	Spielberger's State-Trait Anxiety Inventory, state anxiety scale
T0	Data collection at baseline
T1	Data collection at admission to the hospital
T2	Data collection on the day before discharge from the hospital
T3	Data collection three months after surgery
T4	Data collection six months after surgery
VAS	Visual Analog Scale

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications, which are referred to in the text with Roman numerals I–IV.

I. Kesänen J, Leino-Kilpi H, Arifulla D, Siekkinen M & Valkeapää K. 2014. Knowledge tests in patient education – A systematic review. *Nursing & Health Sciences,* 16, 262–273.

II. Kesänen J, Leino-Kilpi H, Lund T, Montin L, Puukka P & Valkeapää K. 2016. The Knowledge Test Feedback Intervention (KTFI) increases knowledge level of spinal stenosis patients before surgery – a randomized controlled follow-up trial. *Patient Education and Counseling,* 99, 1984–1991.

III. Kesänen J, Leino-Kilpi H, Lund T, Montin L, Puukka P & Valkeapää K 2017. Spinal stenosis patients' visual and verbal description of the understanding of their surgery. *Orthopaedic Nursing*. Under review.

IV. Kesänen J, Leino-Kilpi H, Lund T, Montin L, Puukka P & Valkeapää K 2017. Increased preoperative knowledge reduces surgery-related anxiety – A randomized clinical trial in 100 spinal stenosis patients. *European Spine Journal,* 26, 2580–2586.

1 INTRODUCTION

Empowerment has been defined as an individual's freedom to choose and act (The World Bank 2017). Education is one way of supporting the empowerment process (Freire 1998; The World Bank 2017). In healthcare, empowerment means an individual patient´s ability to control his/her own health (WHO 1998), and it is recognized as a core value in international (European Commission 2014; WHO 2013) (WHO 2013; European Commission 2014) and Finnish national (Government 2015; STM 2011) health policies. Patients´ empowerment process can be developed by means of patient education (Feste & Anderson 1995; Heikkinen et al. 2008; Ingadóttir & Zoëga 2017; Johansson et al. 2007; Kuokkanen & Leino-Kilpi 2000; Ryhänen et al. 2012). Moreover, patient education may have an essential role in answering the challenges and requirements of modern healthcare. Many member countries of the Organization for Economic Co-operation and Development (OECD) are seeking ways to reduce the costs of health care whilst increasing or at least maintaining the quality of care. As an example, a need to shorten the average length of hospital stay has been suggested (OECD 2015). The average length of hospital stay has decreased from 6.8 to 6.4 days in Finland and from 6.7 to 6.6 days in the European Union between 2005 and 2015 (OECD 2017). With shorter hospital stays patients are expected to be able to control their health autonomously. Further, situations where patient education is essential expand with new treatments being introduced to clinical practice. (Redman, 2008; Mitchell, 2011.)

Patients have a legal and ethical right to high-quality patient education to be able to make informed consent and gain control over their own health. In the United States, according to the "American Hospital Association's Patient Bill of Rights" (from 1973, replaced with "The Patient Care Partnership" in 2003) patients are entitled to factual information on their diagnosis, treatment and prognosis (AHA 2003). In Finland, patients´ right for adequate patient eduction has been confirmed legally: the law requires health care professionals to provide adequate patient education based on the individual patient´s preferences to enable independent decision-making (Act 785/1992). Furthermore, the ethical codes of practice expect nurses to support their patient´s autonomy based on sufficient knowledge (Finnish Nurses Association 1996; International Council of Nurses 2012).

In patient education, it is essential to assess the patient´s actual existing knowledge throughout the learning experience. Patient´s learning needs and expectations are assessed in the beginning, during and after the learning process to analyze the gap between the desired and existing knowledge. This information should then be used to plan the education, to observe its progress, to evaluate the outcomes (Bloom et al. 1971; Bastable 2008; McDonald 2007; Ingadóttir & Zoëga 2017), and to correct any possible misconceptions regarding e.g. decision-making (Franz et al. 2015). Furthermore, some patients may search the Internet for

information about their health problem. This information undoubtedly varies in quality and trustfulness, thus further justifying assessment of actual knowledge (Baker et al. 2010).

In surgical treatment, the patient´s body is invasively penetrated and in this way harmed before healing. Moreover, decision making may be carried out under uncertain conditions (Ferreres 2013). These unique characteristics bring challenges to preoperative patient education when preparing the patient for the surgical procedure and the recovery period (Ma et al. 2017). In these unique circumstances, it is not surprising that surgical patients have many preoperative educational expectations. They specifically expect individualized education adjusted to their age, gender, the planned surgical procedure, and the support from their family and community (McMurray et al. 2007). Previous research has shown that these expectations are not met with our current clinical practices (Johansson et al. 2005; Johansson Stark 2016; Klemetti et al. 2015; Montin et al. 2010; Rankinen et al. 2007; Suhonen & Leino-Kilpi 2006) and further development of patient education is needed (Eloranta et al. 2016; Ingadóttir 2016; Johansson et al. 2005; Suhonen & Leino-Kilpi 2006)(Johansson et al. 2003; Suhonen & Leino-Kilpi 2006; Eloranta et al. 2016; Ingadóttir 2016). The increasing emphasis on patient autonomy also calls for improved patient education based on individual needs and expectations (Redman 2008).

Although empowering patient education has proven effective in many surgical patient groups (Heikkinen et al. 2008; Johansson et al. 2007; Ryhänen et al. 2012; Suhonen & Leino-Kilpi 2006) (Suhonen & Leino-Kilpi 2006; Johansson et al. 2007; Heikkinen et al. 2008; Ryhänen et al. 2012) the framework of empowerment has not been applied to patient education in adult spine surgery patients (Bong & Park, 2006; Deyo et al., 2000; Deyo, 2010; Lurie et al., 2011; McGregor, Doré, Morris, Morris, & Jamrozik, 2011; Ng & Gibson, 2011; Papanastassiou, Anderson, Barber, Conover, & Castellvi, 2011; Phelan et al., 2001; Rolving, Nielsen, et al., 2015; Spunt et al., 1996). In LSS, the informed consent process is complex due to several uncertainties: many conservative and surgical treatment options exist; the outcomes of different treatments vary and may be unpredictable; surgical treatment is prone to complications as opposed to conservative treatment (Ma et al. 2017). Further, patients undergoing surgery for LSS may have unrealistic expectations (Franz et al. 2015; Toyone et al. 2005) regarding surgical treatment leading to dissatisfaction with the outcome of surgery (Toyone et al. 2005). On the other hand, realistic expectations may lead to greater satisfaction with the care process (Rönnberg et al. 2007). In conclusion, an obvious need for improved patient education before surgery for LSS exists.

2 BACKGROUND

This chapter describes the theoretical framework of the current study in two parts: (1) main concepts of the study will be defined, and (2) relevant literature will be reviewed. The main concepts include patients undergoing surgery for LSS, patient-reported clinical outcomes of LSS surgery (preoperative anxiety, health-related quality of life, disability and pain), and the different aspects of empowerment (empowering patient education, empowering knowledge, empowering discourse, knowledge feedback, understanding of the surgical procedure). The relationship between these concepts is illustrated in Figure 1. The literature review describes knowledge feedback from the perspective of empowering patient education. First, the theoretical background of an intervention based on a knowledge test is discussed, and then the outcomes of empowering patient education in surgical care are summarized.

The literature search was divided into four stages. First, a systematic review on the use of knowledge tests in patient education was undertaken. Second, a literature review on knowledge feedback interventions in patient education was conducted. The third literature review treated patients´ understanding of the surgical procedure, and finally, the outcomes of empowering patient education in surgery were reviewed.

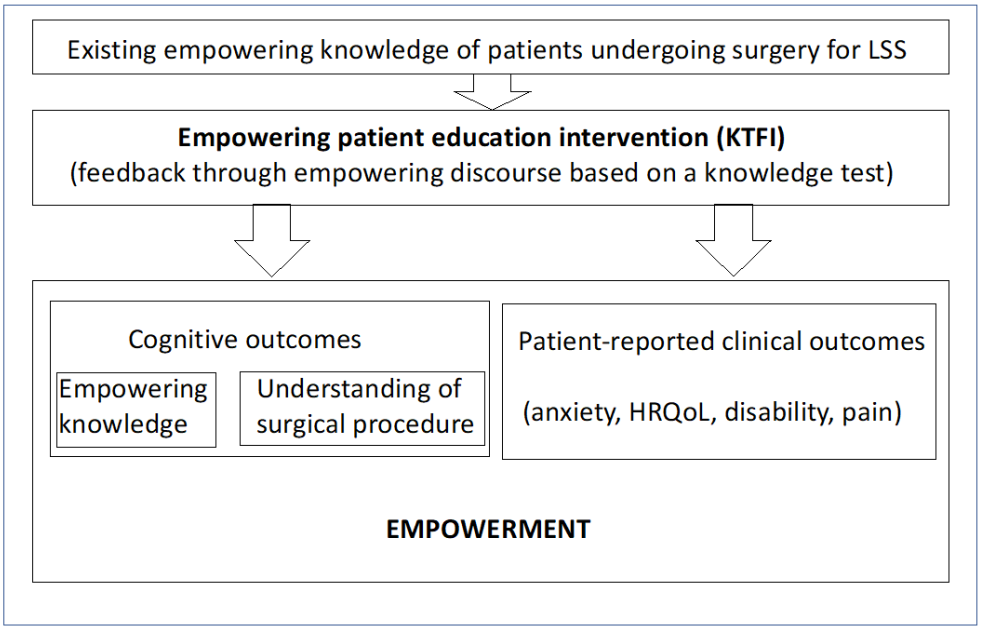

Figure 1. Relationships between the study concepts (LSS = lumbar spinal stenosis, KTFI = Knowledge Test Feedback Intervention)

2.1 Main concepts of the study

2.1.1 Patient with lumbar spinal stenosis

Lumbar spinal stenosis (LSS) is an increasing global health problem (Battié et al. 2012; Deyo 2010; Wong et al. 2017) with approximately 10 % of US population estimated to be affected by year 2021 (Nick 2011). Better diagnostic tools and the aging of population have contributed to the significant increase in LSS diagnosis (Benoist 2002). In Finland, 2133 periods of care were reported for LSS surgery in 2013 (National Institute for Health and Welfare 2016).

LSS is defined as narrowing of the spinal canal causing compression of the associated neuromuscular structures. The most common etiology is degeneration leading to joint hypertrophy, loss of intervertebral disc height, disc bulging, osteophyte formation and hypertrophy of the ligament flavum (Atlas & Delitto 2006). Heavy manual labor and diabetes mellitus in males and housekeeping in females seem to increase the risk of degenerative LSS (Abbas et al. 2013). Radiologically verified LSS does not necessarily cause clinical symptoms, but if symptomatic, the most common clinical manifestations include leg pain (Chad 2007) and neurological symptoms exacerbated by walking (Tomkins-Lane & Haig 2012). Symptomatic LSS may lead to avoidance behavior, reduced activity, disability and decreased quality of life (Battié et al. 2012; Deyo 2010).

Conservative treatment for LSS encompasses exercise, manipulation, mobilization, physical therapy, pain medication, acupuncture, bracing, education and cognitive-behavioral treatments. Current evidence recommends surgery for those patients with significant symptoms who do not improve after conservative treatment (Deyo 2010; Haig 2010; Inoue et al. 2016). In older patients, decompression (with or without fusion) for LSS is the most common surgical procedure of the spine (Deyo 2010). The most common surgical options include decompression with or without spinal fusion. No clear evidence suggests superiority of surgical over conservative treatment. However, the reported rate of complications with surgical treatment has varied from 10 to 24 % while no serious complications have been observed with conservative treatment (Zaina et al. 2016). A recent systematic review suggested a specially designed exercise program after surgery for LSS (McGregor et al., 2013).

In surgical care, the identification of a patient´s actual or potential health problems requires a holistic approach (Harvey 2005). Spine surgery patients have several specific characteristics: spinal disorders affect mobility and limit the activities of daily living; patients may experience changes in bowel and bladder function, as well as in sexual function (Harvey 2005; Strayer 2005); mood disorders are common in this patient group (Falavigna et al. 2012). In nursing care, possible complications must be identified during postoperative observation (Harvey 2005). All these issues need to be addressed when planning,

implementing and evaluating the nursing care of spine surgery patients, including patient education (Harvey 2005; Strayer 2005).

Clinical outcome parameters of LSS surgery

The ultimate goal of LSS surgery is to improve the patient´s health-related quality of life (HRQoL) by reducing disability and relieving pain, (McCormick et al. 2013). Patient education has been shown to have a positive impact on preoperative anxiety (Lee et al. 2016; Lin et al. 2016; Sjöling et al. 2003; Trummer et al. 2006). In this study, the concepts anxiety, HRQoL, disability and pain are defined as follows:

Anxiety (state anxiety) is a transient emotional state with feelings of apprehension and tension due to increased activity of the autonomic nervous system. The intensity of state anxiety varies over time (Spielberger 1972). In the current study, we focused on anxiety during the preoperative phase.

HRQoL is defined as the impact of health on a person´s well-being in physical, mental and social dimensions, as well as on his/her ability to perform activities of daily living and work-related functions. (Hays & Morales, 2001).

Disability can be described as a person´s functional health status. Disease specific disability assessment provides an overview of the impact of symptoms and the effect of treatment on the patient's everyday life (Kopec 2000; Fairbank et al. 1980).

LSS may cause **low back pain** and radiating **leg pain**. Pain intensity does not correlate with severity of radiological degenerative findings, but rather pain perception and sensitivity to pain is an individual characteristic (Kim et al. 2013).

2.1.2 Empowerment

The theoretical framework of the current study is based on patient empowerment. Empowerment is a process leading to patients being able to gain control over their own health (Rappaport 1984; Gibson 1991). Patients feel empowered when they possess knowledge that meets their expectations and preferences, and they feel capable of using that knowledge to decisions on their health, and taking care of themselves (Anderson et al., 1995; Anderson et al., 2005; Fumagalli et al., 2015; Funnell et al., 1991; Heikkinen et al., 2007; Leino-Kilpi, Luoto, & Katajisto, 1998; Leino-Kilpi et al., 1999; Sigurdardottir et al., 2015). A common definition of empowerment combines ability, motivation, and power opportunities (Fumagalli et al. 2015). The framework used herein emphasizes patients´ rights and responsibilities over their own health. (Funnell et al. 1991).

As an active learning process (Ellis-Stoll & Popkess-Vawter 1998), empowerment can be promoted through educational activities that support patients´ personal growth and development (Feste & Anderson 1995; Kuokkanen & Leino-Kilpi 2000). The **empowering patient education (EPE)** aims at increasing the patient´s knowledge about his/her health problems. It can be defined as individually tailored education providing empowering knowledge about the bio-physiological, functional, financial, experiential, ethical and social aspects of health. (Heikkinen et al. 2008; Johansson et al. 2004; Klemetti et al. 2016; Leino-Kilpi et al. 1998; Leino-Kilpi et al. 1999; Rankinen et al. 2007; Ryhänen et al. 2012). The knowledge should be adapted according to individual preferences, and it should cover the whole care process (preoperative phase, hospital stay and postoperative convalescence period) using appropriate education strategies and methods (Johansson et al. 2007).

Diverse EPE methods are needed as surgical patients have varying learning expectations on which the content and extent of education must be adjusted. In previous literature, several methods of EPE have been described: concept map for orthopedic patients (Johansson et al. 2007), internet-based education for ambulatory orthopaedic patients' (Heikkinen et al. 2008), electronic knowledge test feedback (Siekkinen et al. 2014), care pathway for breast cancer patients (Ryhänen et al. 2012), and a game-based learning system about postoperative pain management (Ingadottir et al. 2017).

2.1.2.1 Knowledge feedback

Feedback is a powerful tool for learning (Hattie & Timperley 2007; Shute 2007; Thurlings et al. 2012). Feedback comprises of information addressing the accuracy of an answer or a performance, and any possible errors or misconceptions. Feedback constitutes an integral part of the learning process, and it has to be included in the learning context (Kulhavy et al. 1985). Feedback can be provided by an educator, a peer, or a publication. It can also be based on reflection as a consequence of performance (Hattie & Timperley 2007). Four elements can be identified in feedback: 1) learner´s actual knowledge, 2) learner´s desired knowledge, 3) comparison between actual and desired knowledge, and 4) mechanism to close the gap between actual and desired knowledge (Thurlings et al. 2012).

The purpose of feedback is to support the learner to identify the goal, to recognize the gap between the actual and desired knowledge, and to take the necessary steps to close that gap (Shute 2007; Thurlings et al. 2013). Moreover, the feedback mechanism is closely linked to motivation to learn. It may also reduce the cognitive load especially for those learners with learning problems (Shute 2007). Feedback processes are complex and include many variables; they should be sufficiently challenging, but should always be objective, and given with a positive and respectful tone. Finally, feedback should be goal-oriented and frequent (Thurlings et al. 2013).

Thurlings et al. (2012) describe the six dimensions of effective feedback: (1) goal-oriented vs person-oriented; (2) specific vs general; (3) detailed vs vague; (4) corrective vs non-corrective; (5) positive vs negative; (6) timing. Goal-orientation has proven more effective than person-orientation as the latter does not typically direct the learning process towards the goal (Hattie & Timperley 2007). Specific feedback on strengths and weaknesses is more effective than general feedback (Black & Wiliam 1998). Feedback should guide the learning process towards verifiable outcomes through detailed advice rather than simple messages on the correctness of the answers (Scheeler et al. 2004; Shute 2007). A corrective feedback comparing the learner´s performance to defined learning goals helps the learner to move forward in the process more effectively than non-corrective feedback (i.e. merely indicating that something is wrong without giving advice on what the learner should do differently to correct it) (Scheeler et al. 2004; Brookhart 2008). The amount of corrective guidance an individual learner can use defines the appropriate extent of feedback. The educator should continuously evaluate the individual goals and the progression of the learning process, whereas the learner himself or herself needs to identify the steps necessary for reaching the goals (Brookhart 2008). Effective feedback should be balanced for negative and positive comments (Thurlings et al. 2012). The tone should always be respectful for the learner and his/her work (Brookhart 2008). No consensus exists regarding the best timing for feedback; it can be either immediate or delayed. One literature review on more than one hundred articles suggested that feedback should be immediate for knowledge (facts) and slightly delayed for more complex content that requires conceptual thinking (Shute 2007). Feedback should be timely such that the learner is aware of the learning goals, and has an opportunity to react on the feedback (Brookhart 2008).

In the current study, we used formative feedback (continuous feedback during the education process to determine that it is on track towards the desired goals) provided by a nurse about the patient´s actual knowledge. A summary of feedback as a patient education method is provided in chapter 2.2.2.

2.1.2.2 Empowering discourse

In the current study, the concept of empowering discourse was used in the communication between the nurse and the patients.

The empowering discourse (Kettunen et al. 2001; Poskiparta et al. 2001; Virtanen et al. 2007; Virtanen et al. 2013) promotes the patient´s awareness of his/her health-related issues through interaction with a nurse (Feste & Anderson 1995). By linking new knowledge to previous knowledge, the patient will learn to manage both new and existing health problems in novel ways (Kettunen et al. 2001). On one hand, the patient receives feedback on his/her actual knowledge and knowledge gaps thus directing (Hattie & Timperley 2007) and adjusting the educational activities towards the desired goals (Bastable 2008). The educator,

on the other hand, will receive information to tailor the learning process according to the patient´s needs (Khan et al. 2001).

Empowering discourse aims at improved sense of inner control and strength through equal conversation between the nurse and the patient. The nurse's role is to act as an initiator and facilitator of a positive and respectful atmosphere, especially in the very beginning of the educational session (Barrere 2007; Funk et al. 2011; Logan et al. 2008; Nygårdh et al. 2012; Tveiten & Severinsson 2006). During the discussion proper, the nurse encourages the patient to take an active role by active listening and open-ended questions (Barrere 2007; Funk et al. 2011; Jangland et al. 2011; Tveiten & Severinsson 2006).

Individualized discourse based on information of the patient´s current circumstances will promote his/her knowledge base and autonomy (Kettunen et al. 2001). In an empowering discourse, both the patient and the nurse have an essential role, and they both bring their own expertise and experiences into the discourse. The nurse gives her/his expertise for the use of the patient (Funk et al. 2011; Logan et al. 2008; Tveiten & Knutsen 2011; Virtanen et al. 2007). The defining characteristics of an empowering discourse include tone and length. A calm and confidential tone encourages the patient to actively participate in the discourse. The length of the discourse is related to the topic and patient expectations (Tveiten & Meyer 2009).

To the authors´ knowledge no previous study has used empowering discourse as a feedback mechanism.

2.1.2.3 Understanding of the surgical procedure

No simple definition exists for the concept of understanding. The Oxford Dictionary (2005) describes it as the "power of abstract thought" or the "individual's perception or judgement of a situation" using the term comprehension as a synonym. From the perspective of information transfer, understanding can be considered in the context of the value chain of knowledge. The value chain of knowledge is a hierarchical model of increasing value from data to wisdom. Data are symbols without meaning. Information makes sense of data. Knowledge is the useful, appropriate and dynamic collection of information resulting in instructions. Understanding supports the transition from lower levels up in the value chain of information. In EPE, understanding provides the precondition for using knowledge in the management of a health problem (wisdom). (Ackoff, 1989; Bellinger, Castro and Mills, 2004; Rowley, 2007.)

As EPE is based on the learning theory of constructivism (Kuokkanen & Leino-Kilpi 2000), understanding needs to be examined from the perspective of constructive learning theories. Understanding is one stage in the individual construction of a knowledge structure, either acquired or built in the learner´s mind. Understanding shows different levels of completeness

depending on the quality of the patient's cognitive structures, i.e. how elaborate, and well-differentiated they are (Edmondson 2005; AlDahdouh et al. 2015; Piaget 1968; Perry 1999). The art of constructing cognitive structures cannot be taught, but the ability to build them can be promoted through education (Piaget 1968; Perry 1999). As the real-life phenomena are complex, the educator´s role is to encourage learning through providing rich and diverse learning experiences. (AlDahdouh et al. 2015). For surgical patients these should improve the ability to obtain, process and act upon patient education to make sound decisions and follow instructions during preparations for surgical care and postoperative recovery (Miller et al. 2011; Zhang et al. 2017).

In the current study, understanding is assessed as the patient´s understanding of the surgical procedure by a written description of the procedure and a drawing of the incision. Literature review of patients´ understanding of their surgical procedure can be found in chapter 2.3.1.2.

2.2 Previous literature on the theoretical background of intervention

This chapter describes the theoretical background of the educational intervention developed for the current study. Briefly, the intervention consists of a feedback session based on a knowledge test using the technique of empowering discourse. First, a systematic literature review was conducted to examine the use of knowledge tests in patient education. Then, literature on knowledge feedback as an educational method was summarized.

2.2.1 Knowledge tests in patient education (I)

A systematic literature review was conducted to explore the use of knowledge tests in patient education. The methods of the literature review are described in detail in chapter 4.1 and original publication I. The following chapter summarizes the results of the review.

In the updated systematic literature review, 22 studies (Appendix 1) were found in addition to the 53 studies in original publication I. The context was a chronic health problem in 16 studies (des Bordes et al. 2017; Chiou & Chung 2012; Clark et al. 2015; Cleeren et al. 2014; Emery et al. 2015; Feicke et al. 2014; Goossens et al. 2014; Heinrich et al. 2012; Hägglund et al. 2015; Hendriks et al. 2013; Kommuri et al. 2012; Koonce et al. 2015; Larsen et al. 2014; Melamed et al. 2014; O'Brien et al. 2014; Siekkinen et al. 2014; Stafford et al. 2012; Verret et al. 2012). Five of the studies dealt with surgical patient education in the following clinical scenarios: bunion surgery (Batuyong et al. 2014), mastectomy (Cho et al. 2013), ostomy (Crawford et al. 2012) gynaecology (Ellett et al. 1993) and renal transplantation (Urstad et al. 2012).

The updated literature search further identified 19 new knowledge tests. Nine of these tests were previously developed and validated, whereas 10 knowledge tests were specifically

developed for the study in question (Appendix 2). There was a large variety in how the development process of these knowledge tests was described. According to the quality criteria of knowledge tests (Terwee et al. 2007), the development and validation process was adequately reported for the Coronary Syndrome Index (Riegel et al. 2007), the Diabetes Knowledge Test (Heinrich et al. 2012), and the Osteoporosis Knowledge Questionnaire (Pande et al. 2000). Some studies provided no information on the development and validation of the test (Cho et al. 2013; Cleeren et al. 2014; Crawford et al. 2012; Kommuri et al. 2012). The knowledge tests were mostly based on literature, expert opinion and educational content; very seldom patients were involved in the development process.

The number of items in the knowledge tests varied from 6 to 34 with either multiple choice questions or dichotomous true-false statements. The content most commonly focused on the bio-physiological and functional dimensions of empowering knowledge (Johansson et al. 2007; Leino-Kilpi et al. 1998; Rankinen et al. 2007; Ryhänen et al. 2012). The knowledge tests were mainly used to measure the outcomes of patient education interventions as a summative assessment (Bloom et al. 1971; McDonald 2007) at the end of an educational activity.

In conclusion, knowledge tests have previously been used to measure knowledge level after patient education interventions. The mean number of test questions was 20, and the most common format was true-false statements. The content of the knowledge tests was related to a particular health problem and focused mainly on the bio-physiological and functional dimensions of empowering knowledge (Smith et al. 2012). The tests were usually constructed for the study in question with evaluation of content validity and internal consistency (I).

2.2.2 Knowledge feedback in patient education interventions

To study the use of knowledge feedback in patient education interventions, a literature search was made using the MEDLINE (PubMed), CINAHL (Ebsco), and ERIC (Ebsco) databases with the following search terms: “Feedback”, “patient education”, “patient counseling/counselling”, “patient teaching”, “patient learning”, and “patient information”. We limited the search to peer-reviewed original research articles in the English language published in 2007 or later. The results were classified according to feedback strategies modified from Brookhart (2008) and outcomes (Appendix 3).

In previous patient education literature, the focus of feedback has been either knowledge level (Siekkinen et al. 2014; Tait et al. 2014), performance (Cheung et al. 2015; Toumas-Shehata et al. 2014; Mehring et al. 2013; van Straten et al. 2008), bio-physiological measurements (Wu et al. 2013; Climov et al. 2014; Gopalan et al. 2014) or health behaviour (Hay et al. 2007; Schumann et al. 2008; Jouriles et al. 2010; Trinks et al. 2010; Barnett et al. 2010; Merchant et al. 2011; ter Bogt et al. 2009).

Feedback has been given orally (face-to-face or by telephone) (Cheung et al. 2015; Martens et al. 2013), written (Gopalan et al. 2014; Jouriles et al. 2010; Wu et al. 2013) or electronically e.g. as an immediate response to an on-line questionnaire (Mehring et al. 2013; Merchant et al. 2011; Schumann et al. 2008; Siekkinen et al. 2014; van Straten et al. 2008; Tait et al. 2014; Trinks et al. 2010). The format of knowledge and performance feedback was usually corrective (Cheung et al. 2015; Siekkinen et al. 2014; Tait et al. 2014; Toumas-Shehata et al. 2014), but also motivational for the bio-physiological and health behavior domains (Barnett et al. 2010; ter Bogt et al. 2009; Climov et al. 2014; Gopalan et al. 2014; Hay et al. 2007; Martens et al. 2013; Mehring et al. 2013; Merchant et al. 2011; Schumann et al. 2008; van Straten et al. 2008; Trinks et al. 2010; Wu et al. 2013).

The timing of feedback has been either immediate or delayed. Especially for performance immediate feedback has proven effective, e.g. in assessing the status of joints in rheumatoid arthritis (Cheung et al. 2015) or mastering the inhalation technique (Toumas-Shehata et al. 2014). Immediate knowledge feedback has also been shown to increase the knowledge level. (Siekkinen et al. 2014).

2.3 Previous literature on outcomes of patient education

The following chapter summarizes the outcomes of patient education with special emphasis on surgical EPE according to the research questions outlined in Chapter 3. The results are reported as cognitive outcomes (empowering knowledge and understanding of the surgical procedure) and clinical outcomes.

2.3.1 Cognitive outcomes

In the following chapter, current literature on empowering knowledge level and understanding of the surgical procedure as cognitive outcomes is summarized.

2.3.1.1 Empowering knowledge level

The literature review on empowering knowledge level as an outcome after an educational intervention was undertaken with “empower*”, “surger*”, “surgical”, “patient education”, “patient counseling/counselling”, “patient teaching”, “patient instruction”, “intervention” and, “method” as search terms on MEDLINE (PubMed), CINAHL (Ebsco), and ERIC (Ebsco). The search was limited to peer-reviewed original research articles in the English language published not earlier than 2007.

Patient education interventions have led to increased knowledge levels in many patient groups (I). With EPE the knowledge level can be assessed in more detail using the different dimensions of empowering knowledge. Research has shown varying levels of knowledge

gain after EPE: patients undergoing ambulatory surgery (Heikkinen et al. 2008), heart surgery (Ingadóttir & Zoëga 2017) and hip arthroplasty (Johansson et al. 2007) have demonstrated higher knowledge levels on the bio-physiological and functional dimensions of empowering.

Empowering knowledge can be evaluated also from an individual patient´s perspective as to how his/her knowledge expectations were fulfilled. Orthopaedic patients have fundamental knowledge expectations on the bio-physiological and functional dimensions of empowering knowledge (Valkeapää et al. 2014). Although surgical patients do not acquire as much knowledge as they expect (Rankinen et al. 2007), the expectations are best fulfilled on the bio-physiological and functional dimensions, and least on the financial dimension (Klemetti et al. 2015). EPE interventions have been shown to provide the patients with a positive learning experience (Johansson et al. 2007; Ingadottir et al. 2017).

2.3.1.2 Understanding of surgical procedure

The following chapter summarizes previous literature on understanding of the surgical procedure. A literature search on MEDLINE (PubMed), CINAHL (Ebsco), and ERIC (Ebsco) was undertaken using the following search terms: “patient”,” understanding”,” comprehension”, “consciousness”, “procedure”, “operation”, “surgical”, and “surgery”. Only original research articles published in peer-reviewed journals in the English language in 2007 or later were included.

Surgical patients have demonstrated significant gaps in their understanding of the expected outcomes of the planned surgery (Cohen et al. 2016; Waryasz et al. 2017), the postoperative care (Waryasz et al. 2017; Kadakia et al. 2013), the risks and alternative options (Schwartz et al. 2013), as well as the anatomy (Waryasz et al. 2017; Kadakia et al. 2013). Furthermore, misperceptions regarding alternative treatment options and outcomes have been reported (Dathatri et al. 2014).

In previous literature, understanding has been described both quantitatively and qualitatively. Structured questionnaires with multiple choice answers (Borello et al. 2016; Johnson et al. 2011) or true-false statements (Bowers et al. 2017) have been used to measure factual knowledge related to surgical care. Further, short answers to open-ended questions have been scored and quantified (Edlund et al. 2015; King-Marshall et al. 2016; Tsahakis et al. 2014). Structured interviews (Schwartz et al. 2013) have been used to assess patients´ ability to verbalize the patient education they received and demonstrate the skills they were taught (Thomas & Sethares 2008). Chatma et al (2013) used a 7-point Likert scale to measure how patients perceived their knowledge level (from ”feeling not at all informed” to ”feeling very well informed”).

2.3.2 Clinical outcomes of surgical EPE

Previous literature on clinical outcomes of surgical EPE was searched on MEDLINE (PubMed), CINAHL (Ebsco), and ERIC (Ebsco) databases using the following search terms: "surger*", "surgical", "patient education", "patient counselling", "patient teaching", "patient instruction", "intervention" and, "method". The search was limited to peer-reviewed original research articles in English language published in 2007 or later.

EPE has been shown to promote patients´ ability to self-manage chronic diseases(i.e. Butterworth et al. 2012; Davies et al. 2008; Jia et al. 2012; Kommuri et al. 2012). In surgical patients, EPE has led to (Trummer et al. 2006; Zieren et al. 2007) improved decision-making (Johansson et al. 2007), increased empowerment (Johansson et al. 2010), better communication between patients and health care professionals (Trummer et al. 2006), higher satisfaction with patient education (Johansson et al. 2007), higher opinion of the quality of nursing care (Leino-Kilpi et al. 2015), and better postoperative HRQoL (Koekenbier et al. 2016).

2.4 Summary of literature review

The above literature review was undertaken to clarify the concepts related to empowerment of patients undergoing surgery for LSS. In this patient group, the care process is complex and patients have many knowledge expectations regarding decision-making, preparing for surgery, recovering from surgery and rehabilitation. EPE has been effective in many patient groups in increasing knowledge level, strengthening self-care abilities and empowerment, increasing satisfaction for care, and allowing faster recovery from surgery. Several different methods of EPE have been used; all share the common feature of the patient playing an active role.

According to learning theories, appropriate feedback promotes learning. Knowledge feedback has an essential role in education striving for deeper understanding (Hattie & Timperley 2007). In patient education, feedback of actual knowledge has proven an equally powerful element. Understanding (i.e. awareness, knowledge, skills) enables patients to actively and equally participate in their own care, and is thus an essential step towards empowerment (Falk-Rafael 2001; Falk-Rafael 1995).

In patient education literature, no consensus has been reached on the definition of "understanding". It is also unclear what the measures of understanding actually measure - knowledge or deeper understanding of relevant phenomena. Moreover, terms like information, knowledge, understanding and awareness have been used as synonyms (e.g. Chatman et al., 2013; Kadakia et al., 2013).

To date few studies have addressed EPE in patients undergoing surgery for LSS. Patient education in this group has mainly focused on medical issues within the bio-physiological and functional dimensions of empowering knowledge using written or electronic education material. As the ultimate goal of surgery in LSS is to improve patients´ HRQoL by reducing disability and relieving pain, the impact of EPE on HRQoL, disability and pain will be the focus of the present study (McCormick et al. 2013). Moreover, preoperative anxiety will be measured, as mood disorders are common among patients with spinal disorders (Falavigna et al. 2012). Improved preoperative knowledge has been shown to relieve surgery-related anxiety (Lee et al. 2016; Lin et al. 2016; Sjöling et al. 2003; Trummer et al. 2006). Preoperative education has improved postoperative pain management and thus relieved pain (Sjöling et al. 2003). In summary, as a proxy to patient empowerment we measured both cognitive and patient-reported clinical outcomes.

3 PURPOSE, AIM AND RESEARCH QUESTIONS

The purpose of the present study was (A) to describe the use of knowledge tests in patient education, and (B) to assess the impact of a specific patient education intervention on the empowerment of patients undergoing surgery for LSS. The aim was to improve the quality of education in this patient group.

The following research question was asked in the literature review on knowledge tests (I, update in Chapter 2.2.1 of the summary): What is the development process, structure, content, functional role and quality of knowledge tests available to date?

The following questions were phrased to study the impact of the patient education intervention:

1) What is the impact of the intervention on the patients´ knowledge level? (II)
2) What is the impact of the intervention on the patients' verbal and visual understanding of the surgery? (III)
3) What is the impact of the intervention on the patient-reported clinical outcomes (preoperative anxiety, HRQoL, disability and pain)? (IV)

The following hypotheses were tested:

1) The intervention increases the patients´ knowledge level more than routine patient education (II).
2) The intervention improves the patients´ verbal and visual understanding of the surgery more than routine patient education (III).
3) The intervention (a) decreases the preoperative anxiety more than routine patient education and has a larger impact on (b) the postoperative HRQoL, (c) disability, and (d) pain (IV).

4 MATERIALS AND METHODS

The present research project consisted of two parts: the systematic review (Chapter 4.1) and the intervention study (Chapter 4.2). The following chapter summarizes the design of the study and describes the study sample and the intervention, as well as outlines the relevant ethical considerations. In addition, the development of the knowledge test (KNOWBACK Test) and the educational intervention (Knowledge Test Feedback Intervention, KTFI) are presented.

4.1 Strategy of the systematic review

In this chapter, the strategy of the systematic review is described. For more detailed description, please see original publication I. The update of the systematic review is discussed in chapter 2.2.1.

The original literature search was conducted using the international databases Medline (PubMed), Cinahl (Ovid), PsycINFO and ERIC from 2000 to February 2012 (I). The following search terms were used: *"patient education", "patient counselling", "patient teaching", "patient learning", "patient information", "knowledge test", "knowledge questionnaire", "knowledge inquire", "knowledge scale", "knowledge instrument", "knowledge measurement"*, and *"health problem-specific knowledge*". In addition to the database search, a manual search was conducted from the reference lists of the selected studies. The search was updated in September 2017 using the same exclusion and inclusion criteria than in the original analysis.

4.2 Randomized controlled trial

4.2.1 Design, setting and sampling

Design and setting

The clinical part of the study project was a randomised controlled double blinded follow-up trial (Figure 2) conducted in an orthopedic hospital in Southern Finland between April 2011 and January 2013.

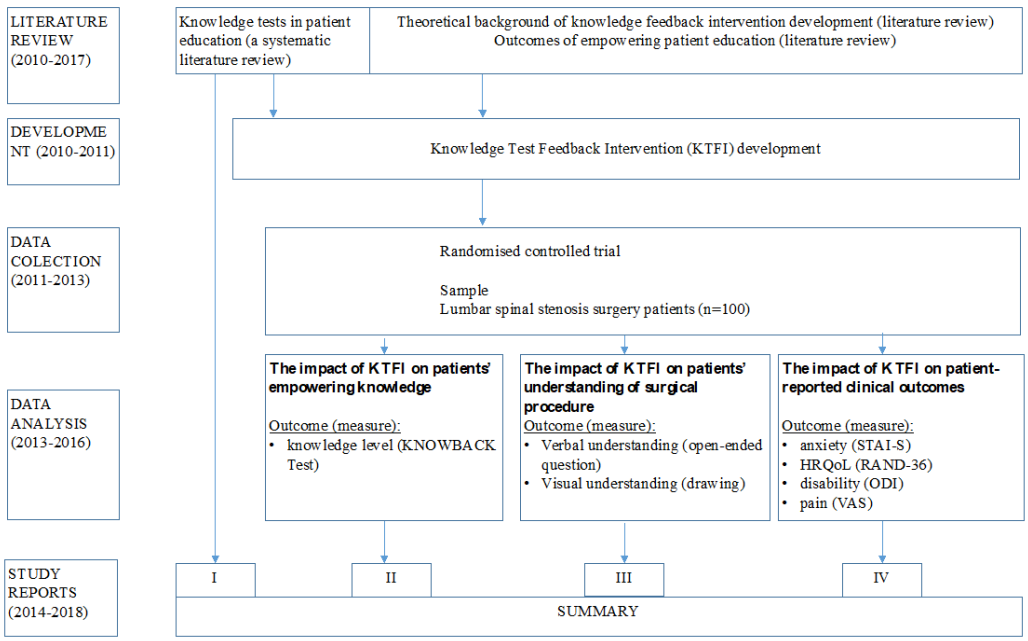

Figure 2. Design of the research project

Sampling

The study sample consisted of patients undergoing surgery for LSS. Inclusion criteria were as follows: 1) Age 18 years or over, 2) Undergoing surgery because of LSS, 3) Informed consent to participate in the study 4) Proficient in Finnish language, 4) Contactable by telephone. Exclusion criteria were inability to self-care or to use a telephone.

Sample size calculation was based on Spielberger's State-Trait Anxiety Inventory for Adults (Spielberger et al. 1983) (the primary clinical outcome measure), as the primary cognitive outcome measure (*i.e.* knowledge level measured by the knowledge test) was newly developed and could not thus be used for this purpose. Power calculation with a two-group t-test revealed that with 100 participants the study has an 80% power to detect a change of 3 points (Bringman et al. 2009) between the groups ($p = 0.05$) in anxiety allowing a 15% dropout rate.

Either the research nurse or the principal investigator recruited the patients from the outpatient clinic after the decision for surgery or by telephone in case the treatment decision was made based on a referral letter. The patients received both oral and written information about the study and gave their written informed consent.

A total of 147 patients were screened for participation (Figure 3). Of the 132 eligible patients, 32 declined to participate. 100 patients were randomized after informed consent and baseline data collection. In the IG, three patients later withdrew their participation. In the CG, two surgeries were cancelled due to the patients´ improved condition. In addition, six patients from the CG did not participate in the follow-up, and two patients in the CG died during the follow-up. Thus, 47 patients in the IG and 40 patients in the CG completed the follow-up resulting in an overall dropout rate of 13%.

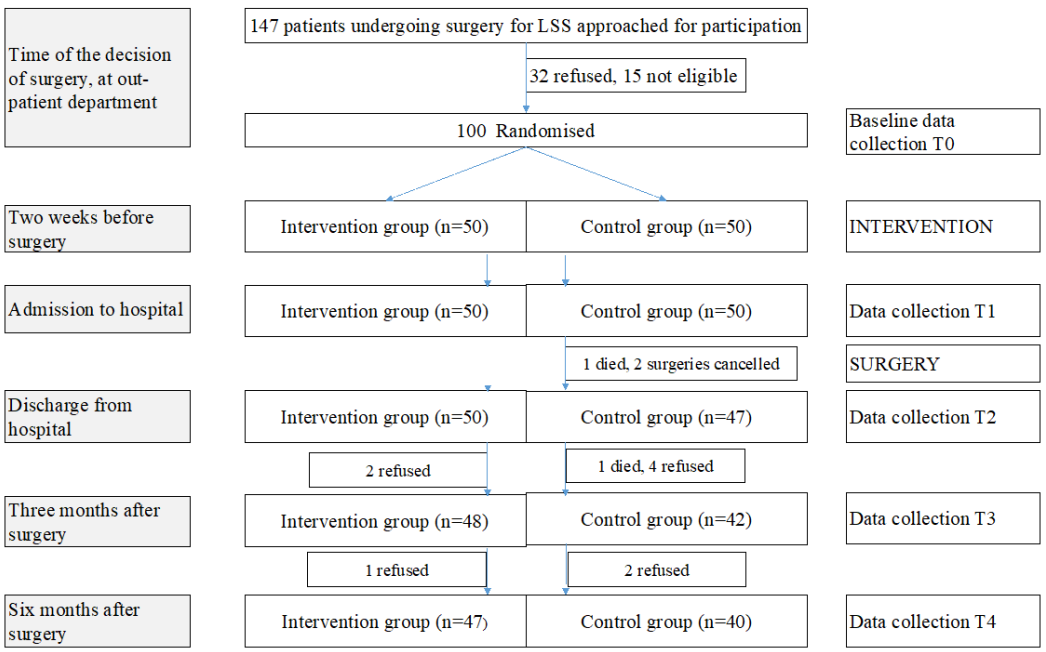

Figure 3. Study flow

The **randomisation** was conducted by the research nurse using the minimization method (Treasure & MacRae 1999) with MINIM software® (https://www-users.york.ac.uk/~mb55/guide/minim.htm) with age, gender and educational level as balancing factors. In previous literature, educational level has correlated positively to knowledge level (Urnes et al. 2008), and older age and female gender have shown negative correlation to knowledge about the surgical procedure (Rankinen et al. 2007). The group allocation produced by the computer was recorded in the study chart protected with a password.

The study was designed as double blinded. The patients were informed that the purpose of the study was to assess an education program, but they were not aware of two different study arms (Moseley et al. 2004; Morris & Nelson 2007). The research nurse who conducted the

randomisation and the intervention did not take part in the patient care. The health care professionals involved in the care of the patients were not aware of the group allocations.

4.2.2 Intervention and control

The intervention group (IG) received the specifically designed patient education intervention (Knowledge Test Feedback Intervention, KTFI) in addition to routine patient education. The KTFI (Figure 4) consisted of an empowering telephone discourse (Virtanen et al. 2007; Virtanen et al. 2013) concentrating on feedback on the knowledge test (KNOWBACK Test) completed at baseline.

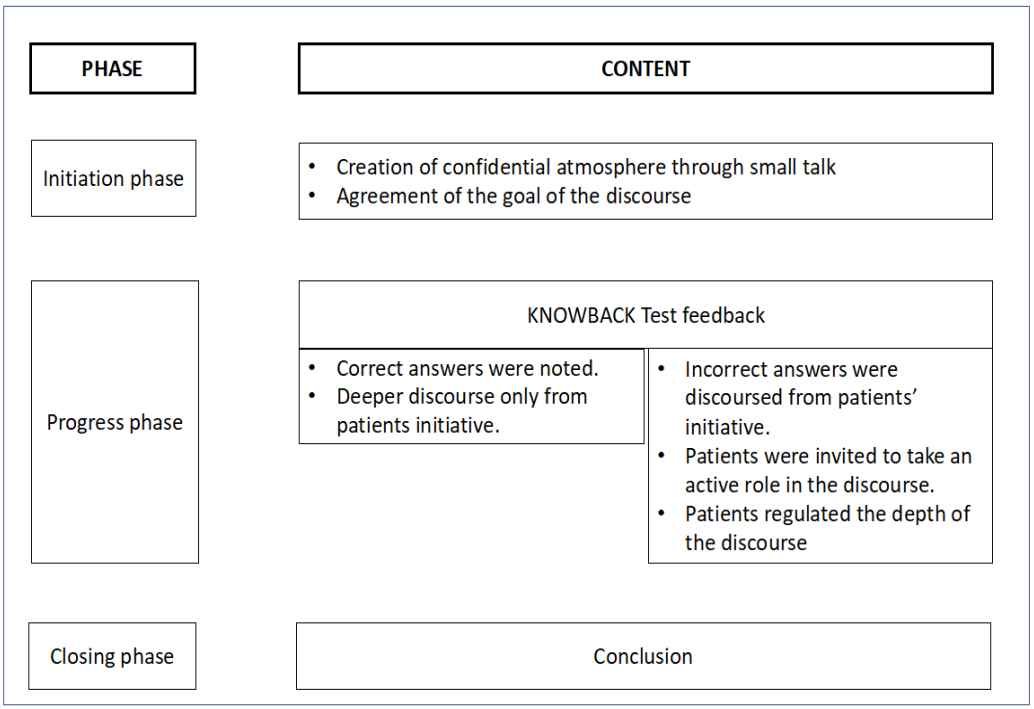

Figure 4. Knowledge Test Feedback Intervention (modified from Virtanen et al. 2007)

The empowering discourse consisted of three phases (Virtanen et al. 2007). In the (1) initiation phase, the nurse started the discourse with small talk to create a confidential atmosphere. The goal of the discourse was agreed upon. Patients were invited to take part in the discussion by posing open-ended questions. In the (2) progress phase, the discourse was based on the KNOWBACK-Test completed at baseline. The correct answers were noted and

the patients were given an opportunity to comment the items. The incorrect answers were handled such that the patients were invited to reflect on the items and discuss them with the research nurse. The patients regulated the depth of the discourse on an item level. The research nurse invited the patients to make their own conclusions and to participate in the decision-making. In the (3) closing phase, the discourse was concluded by ensuring that the goal was reached. The detailed structure of the KTFI is presented in Table 2 of Original publication II.

KTFI was piloted with two patients in the beginning of the study. The original study plan was modified according to patient preference in that instead of completing the baseline questionnaires at the outpatient clinic, the patients completed them at home and mailed them to the research secretary.

At admission to hospital the patients in the IG assessed the **feasibility** (clarity, intelligibility, adequacy) of the KTFI (II) using an existing instrument modified for the purposes of the present study (Klemetti et al. 2010). The instrument evaluated 3 items on a 5-point Likert scale. The IG rated the feasibility of the intervention as 4.5 (SD 0.62, range 2.7–5.0) on a scale 0–5 at T1. The Cronbach´s alpha coefficient of the instrument was 0.8.

Control

In addition to routine patient education, the control group (CG) had a telephone discussion with the research nurse on their health history (personal data, diseases, medication, previous operations, allergies, diets, and functional status).

The routine preoperative patient education was not standardized. The multiprofessional education consisted of surgeon's information about the disease, different treatment options, the surgery, possible complications, and expected outcomes. A staff nurse gave instructions on how to prepare for the surgery. Before surgery at the hospital the patient met an anesthesiologist and a physiotherapist. The routine patient education was mainly oral with some written material with general information on preparations for surgery.

4.2.3 Data collection and outcome instruments

The patients gave the baseline data and the demographic information (gender, age, marital status, employment status, educational level, whether working in health care) after decision for surgery and written informed consent (T0). They completed the questionnaires at home and mailed them to the research secretary. The Knowledge Test Feedback Intervention (KTFI) was planned at two weeks before surgery; the actual time interval between the intervention and surgery was on an average 9 days (range 3-32) mainly due to a short waiting list and unforeseen changes.

The follow-up questionnaires were filled in at admission to hospital (T1) on the day of surgery or the day before, and on the day before discharge (T2). The length of hospital stays averaged 7 days (range 3-16 days). At three (T3) and six (T4) months after surgery the patients completed the follow-up questionnaires at home and again mailed them back to the research secretary. For overview of the data collection see Figure 3; the outcome instruments used in the present study are summarized in Table 1.

Table 1. Outcome instruments of the study

Variable	Instrument	Items	Items in subscales		Response scales	Measurement time				
						T0	T1	T2	T3	T4
Empowering knowledge level	KNOWBACK Test	27	Bio-physiological Functional Experiential Ethical Social Financial	9 6 3 3 3 3	Scale 0-1 1=correct 0=false 0=do not know	x	x	x	x	x
Verbal understanding of surgical procedure	Open ended question	1			Scale 0-1 1=correct 0=false	x	x	x	x	x
Visual understanding of surgical procedure	Drawing	1			Scale 0-1 1=correct 0=false	x	x	x	x	x
State anxiety	STAI	20			Scale 1-4 1=not at all 4very much so	x	x	x		
HRQoL	RAND-36	36	General health Physical functioning Role functioning/physical Role functioning/emotional Vitality Mental health Social functioning Bodily pain Change in health	5 10 4 3 4 5 2 2 1	Scale 0-100 A high score defines a more favourable HRQoL.	x			x	x
Disability	ODI	10			Scale 0-100 0=no disability 100=maximum disability	x			x	x
Pain	Visual analog scale (VAS)	1			Scale 0-100 0=no pain 100= worst pain imaginable	x			x	x

4.2.3.1 KNOWBACK Test

The **knowledge level** was measured with a 27-item ”True-False-I do not know” scaled KNOWBACK Test specifically developed for this study (Figure 5, Appendix 4). The test was designed to measure the level of empowering knowledge and it was built around the conceptual framework of empowering patient education and the pathway of spine surgery patients. The six-dimensional empowering knowledge framework (bio-physiological, functional, experiential, social, ethical and financial) (Leino-Kilpi et al. 1998; Leino-Kilpi et al. 1999; Rankinen et al. 2007; Johansson et al. 2004) was completed with knowledge

related to surgery of spinal stenosis, specifically issues around the disease (etiology, symptoms, diagnosis, treatment) and the surgical process (pre-, peri- and postoperatively).

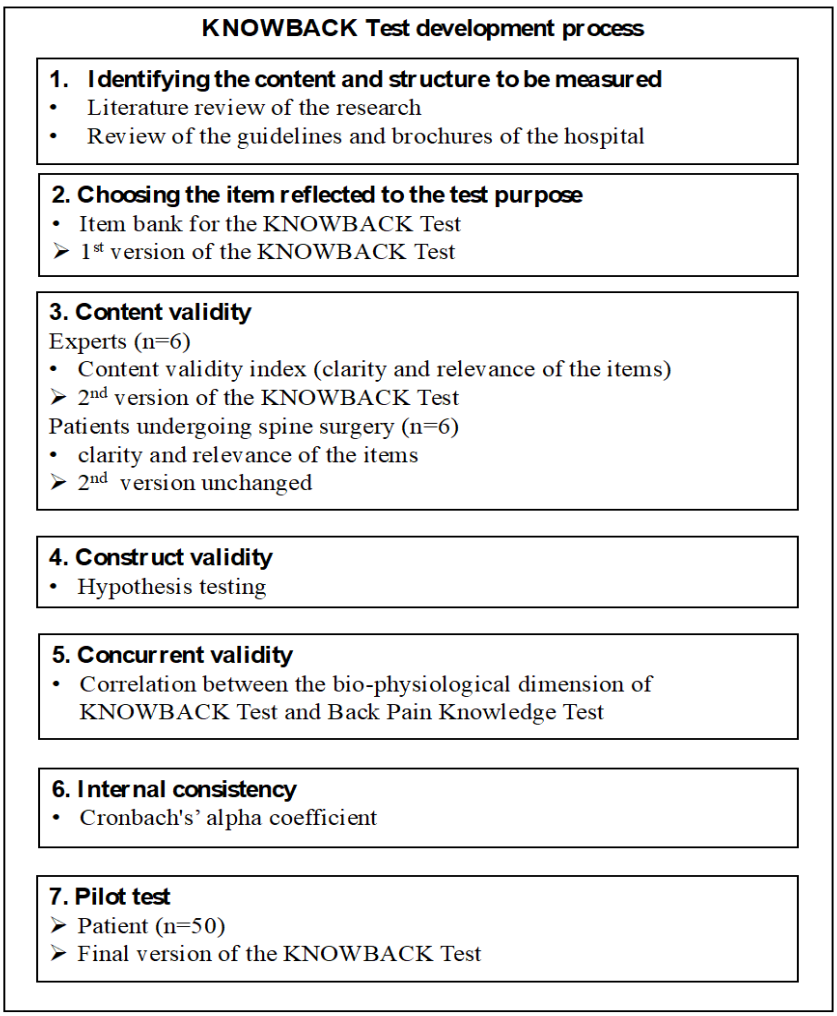

Figure 5. Development of KNOWBACK Test

To minimize the burden of answering the questionnaire, "True-False-I do not know" items (Erblich et al. 2005) were generated according to the following guidelines: statements had to deal with issues clearly relevant to spine surgery patients; all items were written as declarative statements; the statements used good grammar and avoided medical jargon; the statements had to be relatively short, and univocally true or false. (Grove, Burns and Gray, 2013.)

The items of the KNOWBACK Test were generated based on literature and the educational material of the hospital. In addition, three statements came from another knowledge test (Heikkinen et al. 2008). The preliminary version of the KNOWBACK Test was further reworded by the research group, and the appropriate items were selected. At this stage, the test consisted of 28 items covering the six subscales of empowering knowledge: bio-physiological (10 items; e.g. etiology, symptoms, treatment, complications), functional (6 items; e.g. mobility, rehabilitation, rest, nutrition), social (3 items; patient union, family and work), experiential (3 items; emotions, attitude), ethical (3 items; rights, participation in decision making and confidentiality), and financial (3 items; costs and social benefits). The KNOWBACK Test total score is calculated by assessing a score of one for a correct response and zero for an incorrect or do not know response. An evidence-based manual for KNOWBACK Test answers was constructed.

Content validity describes the ability of an instrument to adequately cover the different domains of the phenomenon (Polit & Beck 2008). To define the content validity of the KNOWBACK Test two expert panels were formed, the first with health care professionals and the other with patients.

The expert panel consisted of six experts (Lynn 1986) with a minimum 10 year experience in the surgical care of spine surgery patients. On an item level, they assessed the relevance and clarity of the statements on a 4-point Likert scale (1=irrelevant/unclear, 4=highly relevant, very clear). They also had the possibility to give written feedback on each item. The results were then discussed at a panel meeting. The Content validity index (CVI) is calculated by dividing the number of raters giving an item a score of 3 or 4 by the number of experts. CVI 0.6 or higher is considered satisfactory (Lynn 1986). Because the expert panel was relatively small, we modified the process such that each member of the panel had to score an item as 3 or 4 for it to be accepted for the knowledge test. The panel negotiated until consensus was reached. One item concerned the possibility of waking up during the surgery. This item was excluded from the test as it was deemed too frightening. Three further items we reworded for clarity. No missing areas were identified by the expert panel.

The patient panel consisted of 4 patients undergoing spine surgery and 1 significant other. The patients filled in the test questionnaire before their planned surgery. The day before the discharge they were asked to assess the knowledge test for clarity and relevance. In all 27 items, the CVI was at least 0.80, although patients recognized the fact that some items (e.g. smoking, obesity, and work) might have different levels of relevance to individual patients. The length of the test was regarded suitable. The patients mentioned ”exercise instructions” as a missing area in the test items.

Construct validity determines whether the instrument actually measures the theoretical concept it purports to measure (Grove et al. 2013). Construct validity should be assessed by

testing some predefined hypotheses, e.g. expected correlations between measures or expected differences in scores between known groups (Terwee et al. 2007; Kirshner & Guyatt 1985). The hypothesis to test the construct validity of KNOWBACK Test was as follows: the intervention group scores higher than the control group. This hypothesis was later confirmed (II).

Concurrent validity refers to a correlation between the newly developed test and an established criterion (Polit & Beck 2008). The concurrent validity of the bio-physiological dimension of the KNOWBACK Test was evaluated against the Back Pain Knowledge Test (Phelan et al. 2001). The Back Pain Knowledge test consists of 17 items with true-false-do not know choices. Responses are coded as 1 if correct and 0 if incorrect or ”do not know”. The content of the items is pathology, treatment options, outcomes of surgical and non-surgical care. The patients filled in both questionnaires simultaneously. Spearman correlations between KNOWBACK Test and Back Pain Knowledge Test were calculated. A statistically significant correlation ranging from 0.37 to 0.63 ($p < .0001–0.008$) was established between the bio-physiological subscale of the KNOWBACK Test and the Back Pain Knowledge Test at the different measurement points (II).

Internal consistency refers to the extent in which the items measure the same characteristic or construct. The internal consistency of the KNOWBACK Test was evaluated using the Cronbach´s alpha coefficient (Polit & Beck 2008). A minimally acceptable coefficient was set at 0.70 (Nunnally & Bernstein 1994). In the current study, the alpha was 0.6 in the T0 measure of the IG, in all other measurement points the alpha ranged from 0.7 to 0.8 (Table 2).

Table 2. Cronbach’s alpha coefficient for KNOWBACK Test

Measurement point	**T0**		**T1**		**T2**		**T3**		**T4**	
Group	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG
Cronbach’s alpha	0.6	0.7	0.7	0.7	0.7	0.7	0.8	0.7	0.8	0.7

IG = Intervention group, CG = Control group

4.2.4.2 Open-ended question of verbal understanding of surgical procedure

Verbal understanding of the surgical procedure was assessed with the patient´s ability to verbally describe the planned or performed surgery (T0-T4) (Thomas & Sethares 2008). Patients were asked to describe their surgical procedure in writing in as much detail as possible (Appendix 5). For a correct answer, the patient had to be able to describe all aspects of the surgery: decompression of the spinal canal and fusion (either with or without instrumentation) if such was planned/performed. A correct answer was scored as 1 and an

incorrect answer as 0; in unclear cases the research nurse consulted the spine surgeon in charge of the patient´s care.

4.2.3.3 Drawing of visual understanding of surgical procedure

Drawings made by patients can be used to assess patients´ perception and experience of a health problem, but also their understanding of different health issues. In previous literature, drawings have been used e.g. to assess understanding of the anatomy of the heart, damages caused by a myocardial infarction, and symptoms of heart disease in patients with heart conditions (Broadbent et al. 2006; Guillemin 2004; Reynolds et al. 2007). In patients with chronic obstructive pulmonary disease, the understanding of anatomic structures and physiological effects (Luthy et al. 2013) and in patients with cancer, the tumor and anatomy (Hoogerwerf et al. 2012; van Leeuwen et al. 2015) was assessed with drawings. Drawings can also be used as a diagnostic aid, e.g. the clock-drawing test for neurological patients (Agrell & Dehljn 1998) (Table 3).

Table 3. Assessment criteria of adult patients' drawings (modified from van Leeuwen et al. 2015)

Focus	**Assessment criteria**
Drawing characteristics	Size of drawing area Use of colours Completeness of drawing
Anatomy, physiology and pathophysiology	Correct anatomy of an organ Symptoms Size of the damaged area Shape of a tumour Physical changes caused by a disease Pain
Experience	Expression of emotions Societal impact

In the present study, visual understanding was assessed with drawings made by the patients (T0-T4). The patients were asked to draw the operation wound on a human body chart as accurately as possible (Appendix 5). The criteria for a correct answer were: (1) a 1-2 cm vertical (2) straight line (3) posteriorly in the middle of the lumbar spine. Marking of the possible bone harvest site was not required. A correct answer scored 1 point and an incorrect drawing 0.

4.2.3.4 Spielberger's State-Trait Anxiety Inventory (STAI-Y1)

State anxiety was measured using the Finnish version of Spielberger´s State-Trait Anxiety Inventory (STAI-Y1) at T0–T2 (Appendix 6). STAI is one of the most common validated instruments in use to measure anxiety, and it has been proven valid (Rossi & Pourtois 2012). STAI-State is a 20-item self-report scale measuring situational anxiety. With a 4-point Likert scale varying from 1 (not at all) to 4 (very much) the sum score can vary between 20 and 80. A higher score indicates an increased anxiety level with scores categorized to low 20–39, medium 40–59 and high anxiety 60–80 (Spielberger et al. 1983). In the present study, the Cronbach´s alpha for STAI-State was 0.9 at baseline (T0).

4.2.3.5 Rand 36-Item Health Survey 1.0 (Rand-36)

The validated Finnish version of Rand 36-Item Health Survey 1.0 (RAND-36) (Aalto et al. 1999) was used to assess HRQoL (at T0, T3, T4)) (Appendix7). RAND-36 has eight subscales related to different domains of HRQoL: general health, physical functioning, mental health, social functioning, vitality, bodily pain, physical role functioning, and emotional role functioning. Each domain scores between 0 and 100, where higher scores indicate better HRQoL. Minimally clinically important difference (MCID) for RAND-36 has typically been in the range of 3 to 5 (Hays, Sherbourne, & Mazel, 1993). In the current study, the Cronbach´s alpha varied between 0.7 and 0.9 for the different subscales of RAND-36.

4.2.3.6 Oswestry Disability Index (ODI)

Disability was assessed using the Finnish version of the spine specific outcome measure, the Oswestry Disability Index (ODI) at T0, T3 and T4 (Appendix 8). ODI is a self-report 10-item questionnaire concentrating on the effect of pain in the activities of daily living. Each item is scored from 0 to 5, and the sum score is presented as percentage of the maximum sum score ranging from 0 (no disability) to 100 (maximum disability). A minimum of 15-point change in the score has been recommended as MCID. (Fairbank et al. 1980.) For the present study, the Cronbach´s alpha was 0.9 at T0

4.2.3.7 Visual analog scale (VAS)

Pain was assessed by evaluating the patient´s back and leg pain separately with a visual analog scale (VAS) at T0, T3 and T4. VAS is a 10-cm horizontal line without gradation, where the patient marks the spot characterizing his/her pain between ”no pain” (left terminus) and ”worst pain imaginable” (right terminus). The score is reported in centimetres with higher scores indicating worse pain.

4.2.4 Statistical analysis

The participants' background factors were presented descriptively as frequencies and percentages or means and standard deviations. The differences between the study groups were analyzed with t-test for normally distributed numeric variables. Not normally distributed variables were analyzed with Wilcoxon two-sample test. Chi-square or Fisher's test was applied for categorical variables.

All response variables (knowledge level indicated by the KNOWBACK Test, patient reported clinical outcome variables anxiety, HRQoL, disability and pain, verbal and visual understanding of the surgical procedure) were analyzed with two way repeated measures analysis of variance (ANOVA) with the group (IG, CG) as a between-subject factor, and the time point (T0, T1, T2, T3, T4) as a within-subject factor. Pairwise comparisons between the time points were performed using Tukey-Kramer adjustment. (II, III and IV)

Because all group*time interactions for knowledge level indicated by the KNOWBACK Test were significant, the groups were additionally analyzed with repeated measures ANOVA separately. (II)

In analysis of the verbal and visual understanding of the surgical procedure the potential effect of the background variables was adjusted for by using background variables as covariates. In addition, the groups were compared with t-test in each time point and the repeated-measures ANOVA was performed separately in both groups. (III)

Internal consistency of the KNOWBACK Test and the patient reported clinical outcome variables were evaluated using Cronbach's alpha coefficient. For concurrent validity Spearman correlations between KNOWBACK Test and Back Pain Knowledge Test were calculated. The data were analyzed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA). P-values of less than 0.05 were chosen as statistically significant.

4.2.5 Ethical issues

The research project was conducted in accordance with the Finnish national legislation and the ethical principles of research (Medical Research Act 488/1999; TENK, 2009, 2013; WMA Declaration of Helsinki, 2013) The ethical committee of the hospital district approved the study design on November 1, 2010 (Dnr. 280/13/03/02/2010). All relevant permissions were obtained from the hospital where the study was conducted and from the copyright owners of the outcome instruments used. The patients were provided both oral and written information about the study (purpose of the research, their role in the research, the voluntary basis of participation, discontinuation of their participation) before their written informed consent. (WMA Declaration of Helsinki 2013). A detailed description of the study design

was not included due to blinding. The study was registered at Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12611000417987 (http://www.anzctr.org.au/). Each original publication includes a discussion of ethical questions relevant for that specific part of the project.

5 RESULTS

The following chapter summarizes the results of the research project. First validation of the knowledge test (KNOWBACK) is presented. Then the results of the intervention study are presented as follows: description of the participants, cognitive outcomes (empowering knowledge, visual and verbal understanding of the surgical procedure) and patient-reported clinical outcomes (anxiety, HRQoL, disability and pain). The results of the systematic literature review (”Knowledge tests in patient education”) as well as the updated review can be found in chapter 2.2.1.

5.1 Validation of KNOWBACK Test

The systematic literature review revealed the scarcity of evidence on the use of knowledge tests in patient education. Specifically, no data could be found on the role of knowledge tests in the preoperative education of spinal stenosis patients.

The development of the KNOWBACK Test has been described in detail in chapter 4.2.3.1. The content validity was assessed according to Lynn (1986), and was rated as satisfactory by both the expert and the patient panel. As concurrent validity measure we used the previously published Back Pain Knowledge Test. A statistically significant correlation (range 0.37–0.63; $p < .0001–0.008$) was established between the bio-physiological subscale of the KNOWBACK Test and the Back Pain Knowledge Test at the different measurement points.

The KNOWBACK Test was further piloted in an unrelated group of 50 patients undergoing spine surgery. The total scores varied between 7 and 21 (possible range 0-27), with a wide range of correct answers (0-100%) on an item level. The item with 100% correct answers concerned earlier experiences with surgery; it was included in the final test for completeness of the theoretical framework. No floor or ceiling effect was noticed based on the pilot study (McHorney & Tarlov 1995).

5.2 Intervention study

This chapter presents the results of the intervention study as follows: description of the participants, cognitive outcomes (empowering knowledge, visual and verbal understanding of the surgical procedure) and patient-reported clinical outcomes (anxiety, HRQoL, disability and pain).

5.2.1 Description of the participants

There were no statistically significant differences between the two study groups at baseline. The mean age was slightly more than 60 years. The majority of patients were female (IG: n = 33, 66 %; CG n = 31, 62 %), and about fourth of the participants were living alone (IG: n = 12, 24 %; CG: n = 15, 30 %). Nearly half of the participants had at least college level education (IG: n = 24, 48 %; CG: n = 21, 44 %) and slightly less than one third of them still participated in the labor market (IG: n = 15, 30 %; CG: n = 13, 26 %). In addition to the decompression, a third of the patients underwent a concomitant fusion (IG: n = 17, 34 %; CG: n = 15, 31 %). (Table 4.)

Table 4. Patient background factors at baseline as numbers and percentages unless otherwise indicated

Background factor	Intervention group (n=50) n (%)	Control group (n=50) n (%)	p-value
Gender			
Female	33 (66)	31 (62)	0.677*
Age			
Mean; years (SD)	61.9 (12.5)	63.0 (11.9)	0.654†
Home status			
Live alone	12 (24)	15 (30)	0.091*
Employment status			
Employed	15 (30)	13 (26)	0.259*
Highest basic education			
Nine years or less	37 (74)	39 (78)	0.879*
Twelve years	13 (26)	11 (22)	
Professional education [1)]			0.792*
Primary	13 (26)	11 (23)	
Secondary	13 (26)	16 (33)	
Tertiary	24 (48)	21 (44)	
Payer			0.479*
Patient	13 (26)	13 (27)	
Municipality	29 (58)	32 (65)	
Other	8 (16)	4 (8)	
Working in health care (yes)	10 (20)	13 (26)	0.476*
Hospital stay			
Mean; days (SD)	7.1 (2.4)	7.5 (2.6)	0.446†
Surgery type			
Decompression			
- only	32 (64)	33 (69)	0.520*
- with fusion	17 (34)	15 (31)	0.725*
Fusion only	1 (2)	0	
Duration of surgery			
Mean; minutes (SD)	148 (71)	145 (63)	0.839†
Previous spinal surgery	17 (34)	16 (33)	0.986*
Previous other surgery	39 (80)	45 (92)	0.100*
Duration of empowering discourse of the intervention group Mean; minutes (range)	21 (8-65)		
Duration of telephone discussion of the control group Mean; minutes (range)		14 (4-29)	

[1)] The classification of educational level (Kalenius 2014).

*Pearson Chi-square for comparing proportions

† Student's *t* test for independent samples

5.2.3 Cognitive outcomes (II, III)

At baseline (T0) **the empowering knowledge level** was 49.6% (SD 14.4) in the IG and 51.5% (SD 16.6) in the CG; the difference between the groups (–1.9%; CI 95% –7.9;–4.0) was not statistically significant ($p = 0.52$). In the IG, the knowledge level increased after the intervention (T1) with 30 percentage points to 78.7% (CI 95% 26.8;33.8, $p < 0.0001$). No statistically significant change in the CG occurred until after the operation, when a slight increase of 5.7%-points (CI 95% 2.1;9.4, $p < 0.002$) was observed at discharge (T2). During follow-up, no statistically significant changes within or between the study groups emerged. (Figure 6 and II: Table 4.)

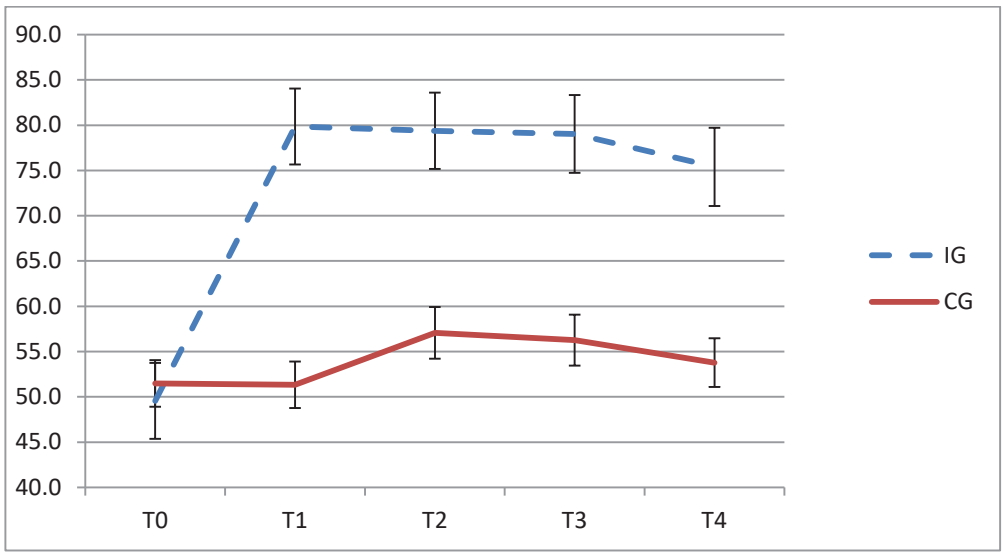

Figure 6. Percentages of correct answers in the KNOWBACK Test with 95% confidence intervals

At baseline (T0), the knowledge level in both study groups on the different dimensions of empowering knowledge was on an average 50% with the exception of experiential knowledge where the knowledge level was high (83,3% in the IG; 84,0% in the CG). In the IG, the knowledge level increased after the intervention (T1) in all dimensions except the experiential dimension. In the CG, a statistically significant increase of knowledge was noted in the bio-physiological and functional dimensions during the hospitalization (T2). (II: Table 4.)

Between the groups, there was no difference in any dimension of the empowering knowledge at baseline (T0), ($p \geq 0.58$ for between group differences on all subscales). At admission to

hospital (T1, after the intervention), the knowledge level increased significantly more in the IG compared to the CG on the bio-physiological (3.2 vs 0.1, $p < 0.0001$, CI 95% 2.0;4,2, scale 0–9), functional (2.0 vs 0.1,$p > 0.0001$; CI 95% 1.3;2.9, scale 0–6), social (1.2 vs –0.2 ($p < 0.0001$, CI 95% 0.8;2.9, scale 0–3) and ethical (1.6 vs 0.0 $p < 0.0001$, CI 95% 0.8–2.0, scale 0–3) dimensions of empowering knowledge. These differences remained relatively stable throughout the follow-up ($p \leq 0.038$ for all differences of subscales between the groups). (Figure 7 and II: Table 4.)

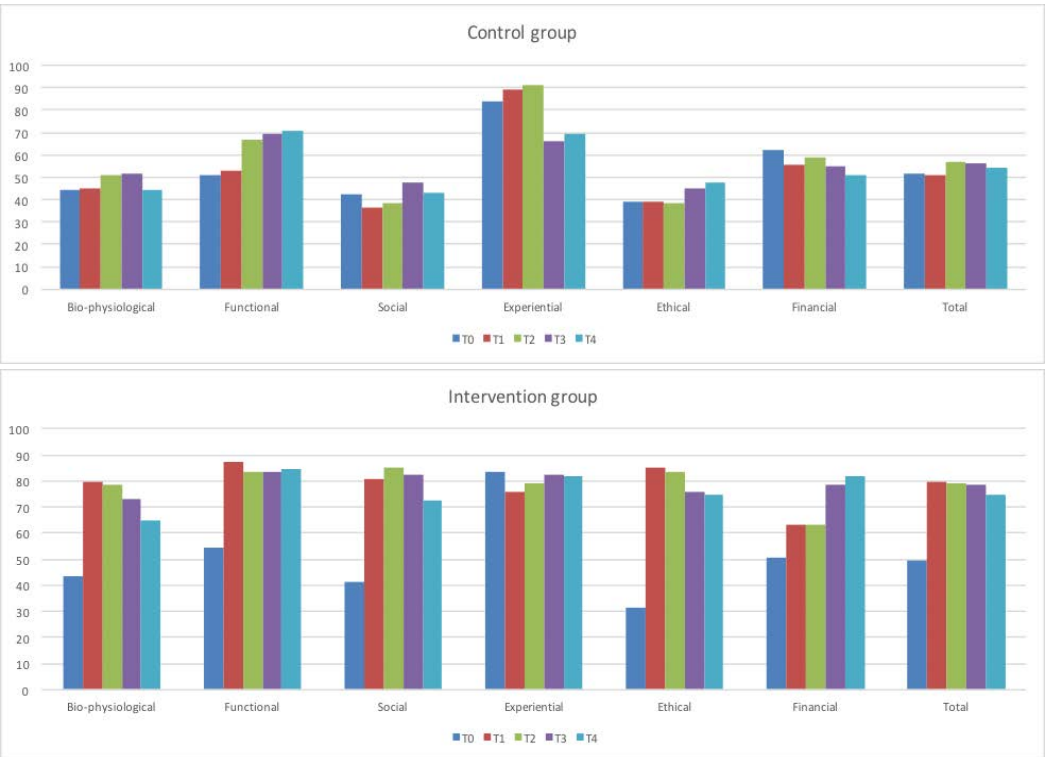

Figure 7. Percentages of correct answers on the different dimensions of empowering knowledge, as well as the total of the KNOWBACK Test.

Patients' verbal understanding of surgical procedure (the percentage of patients who could describe their surgical procedure correctly) increased from 58% at T0 to 69% at T4 in the IG, and in the CG from 43% at T0 to 74% at T4 ($p_{time} = 0.0003$). A significant increase in the verbal understanding was seen in both groups after the surgery (T2). The differences between the study groups were not statistically significant at any of the measurement points (the range of p_{group} was between 0.68 at T0 and 1.0 at T2–T4). Age, gender, duration of

hospital stay or knowledge level at baseline did not affect the verbal understanding. (III: Table 3.)

Patients' visual understanding of surgical procedure (the percentage of patients who could draw their surgical incision correctly) increased from 59% at T0 to 95% at T4 in the IG, and in the CG from 58% at T0 to 90% at T4 ($p_{time} < 0.0001$). A significant increase in the visual understanding was seen in both groups after the surgery (T2). The differences between the study groups were not statistically significant at any of the measurement points (the range of p_{group} was between 0.87 at T1 and 1.0 at T0, T2–14). Age, gender, duration of hospital stay or knowledge level at baseline did not affect the visual understanding. (III: Table 3.)

5.2.4 Patient-reported clinical outcomes (IV)

At baseline, both study groups experienced medium level of **anxiety** with no statistically significant difference between the groups (p = 0.98; CI 95% –4.6,9.4). From baseline to discharge from hospital (T0-T2) the anxiety level decreased statistically significantly in both groups (in the IG from 44.0 to 34.3 and in the CG from 41.9 to 34.9, $p_{time} = 0.0001$). In the IG, lower levels of anxiety were measured already after the intervention, i.e. at admission to hospital, with a decrease of the STAI score of 5.2 ($p_{T0–T1} = 0.0011$; CI 95% 2.6,1.9). In the CG, a statistically significant relief of anxiety was not seen until after the surgery; the decrease in the STAI score was 5.4 from admission to discharge (T1-T2) ($p_{T1-T2} = 0.0008$; CI 95% 2.8,7.9). However, there was no statistically significant difference in the level of anxiety between the two study groups at any of the measurement points ($p_{interaction} = 0.1790$) (IV: Figure 2 and Table 3.)

At baseline, the lowest **HRQoL** was noted in physical role functioning (IG 19.5 (SD 33.7); CG 22.5 (SD 35.2)), bodily pain (31.5 (SD 18.6); 28.4 (SD 24.1)), and vitality (34.9 (SD 10.6), 38.7 (SD 20.0)) with no statistically significant differences between the study groups. During follow-up a significant improvement was noticed in all domains of HRQoL in both groups ($p_{group} \leq .0002$). The changes in HRQoL were beyond the suggested MCID for RAND-36 (Hays et al. 1993) in all domains. A weak (statistically not significant) trend towards faster recovery at 3 month follow-up (T3) was noticed in the IG in social functioning (10.6), vitality (7.1) and, emotional role functioning (7.5). (IV: Table 4 and Figure 3.)

At baseline, the Oswestry **disability** index (ODI) was 42.3 (SD 16.6) in the IG and 44.7 (SD 15.5) in the CG. A statistically significant improvement in the activities of daily living was noticed in both study groups during follow-up ($p_{group} < .0001$); the ODI decreased to 24.2 (SD16.6) and 24.6 (SD 18.8) in the IG and CG at T4, respectively. The improvement in ODI occurred mainly during the first three months after surgery (by T3). The difference between the groups was not significant at any of the measurement points. (IV: Table 4 and Figure 4.)

Back pain was relieved statistically significantly ($p_{group} < 0{,}0001$) within the IG from (T0) 69.1 (SD 22.5) to (T4) 33.2 (SD 28.9) and within the CG from (T0) 62.6 (SD 25.0) to (T4) 29.2 (SD 29.4) with no significant differences between the two groups ($p_{interaction} = 0.9972$) (Table 5 and IV: Figure 5).

Leg pain was relieved statistically significantly ($p_{group} < 0{,}0001$) within the IG from (T0) 70.1 (SD 21.6) to (T4) 35.4 (SD 30.1) and within the CG from (T0) 70.9 (SD 23.2) to (T4) 33.3 (SD 31.0) with no statistically significant difference between the two groups ($p_{interaction} = 0.8037$) (Table 5 and IV: Figure 5).

Table 5. Improvement of back and leg pain in the study groups and differences between the groups

Variable		Baseline T0		Change T0–T3		Change T3–T4			
Scale	Group	mean (SD)	n	mean (95% CI)	n	mean (95% CI)	n	p_{time} *1	$p_{interaction}$ *2
VAS									
Back pain	Intervention	69.1 (22.5)	47	–41.9 (–54.6,–29.2)	37	5.1 (–3.1,13.2)	35	<.0001	0.9972
0–100	Control	62.6 (25.0)	49	–31.3 (–44.7,–17.9)	35	–1.6 (–10.6,7.5)	29		
	Difference	6.6		10.6		6.6			
	p_{group}	0.1807		0.2494		0.2713			
Leg pain	Intervention	70.1 (21.6)	45	–43.6 (–53.8,–33.3)	33	4.2 (–4.2,12.8)	31	<.0001	0.8037
0–100	Control	70.9 (23.2)	45	–42.9 (–58.2,–27.6)	28	10.2 (–1.8,22.4)	22		
	Difference	0.7		0.6		6.0			
	p_{group}	0.8770		0.9443		0.3852			

*1 Difference within the group over time
*2 Difference between the groups over time

5.3 Summary

1. The literature review (I) identified few previous study with measurement of knowledge level as an outcome after a patient education intervention where feedback was an essential element. A validated and reliable knowledge test (KNOWBACK Test) was developed to measure the empowering knowledge of patients undergoing surgery for LSS; it also formed the basis of the Knowledge Test Feedback Intervention (KTFI)
2. The KTFI increased significantly the empowering knowledge of patients undergoing surgery for LSS in the bio-physiological, functional and ethical dimensions (II). The knowledge level remained stable throughout the follow-up.
3. Patients´ verbal and visual understanding of the surgical procedure increased in both study groups during follow-up with no statistically significant differences between the groups (III). The highest measure of correct description was 64% for the verbal and 91% for the visual understanding.

4. After KTFI the preoperative anxiety decreased in the IG but the between group comparisons did not reach statistical significance at any of the measurement points. Moreover, no statistically significant difference in the clinical outcome of surgery emerged between the two study groups during the 6-month follow-up. (IV). This did not reflect in the clinical outcome of the surgery during 6-month follow-up

6 DISCUSSION

In the following chapter, the main results of the present study are discussed in the light of previously published literature. Moreover, the validity and reliability of the study are discussed. Further, implications for clinical practice, administration and education, as well as suggestions for future research are presented.

6.1 Discussion of results

In the present study, a new patient education method, KTFI, was developed and studied in a group of patients undergoing surgery for LSS. The purpose of the present study was (A) to describe the use of knowledge tests in patient education, and (B) to assess the impact of a specific patient education intervention on the empowerment of patients undergoing surgery for LSS.

Knowledge tests in patient education and KTFI

Knowledge tests have been widely used in patient education, but mainly to measure knowledge level for research purposes. Very few studies have used feedback as a means of patient education. In the present study, feedback was given through an empowering discourse based on an individual patient´s actual knowledge level. The development of the knowledge test (KNOWBACK Test) started with identification of the relevant evidence-based content that needed to be covered. Constructing an unambiguous knowledge test on a true - false scale was challenging, as many decisions on the surgical treatment of LSS are individually tailored. Thus, the empowering discourse with the research nurse was deemed essential

The empowering discourse was used as a means of giving feedback to the patients on their performance in the knowledge test. To the author´s knowledge, empowering discourse has not been used for this purpose in previous studies. Feedback is a complex process with several variables to consider. Effective feedback should be fair, neutral, unbiased, objective and future-oriented, and given in a positive and respectful tone. As these are core elements in empowering discourse as well (Thurlings et al. 2012; Thurlings et al. 2013; Virtanen et al. 2007; Virtanen et al. 2013), the KTFI based on a structured knowledge test and empowering discourse can be argued to fulfill the requirements of adequate feedback. The balance between positive and negative comments varied as it was based on the individual patient´s performance in the knowledge test. However, the tone of the empowering discourse was always positive and respectful. Although no ideal point of time for feedback has been identified (Shute 2007), immediate feedback has been recommended in educational literature (Thurlings et al. 2013). In the present study, the time between the baseline

measurement of the knowledge level and the feedback intervention (KTFI) was not controlled.

Feasibility is important for the clinical implementation of any new intervention (Pearson et al. 2005). The patients rated the feasibility of the KTFI high. It would have been interesting to assess the feasibility of the KTFI from the perspective of nurses, as their role in conducting the intervention is crucial. However, this remains the focus of future research.

The KTFI proved to be a simple low-technology patient education method with relatively few resource requirements. The only technology needed was a telephone, and the time resource spent was on an average 21 minutes per patient. It can even be argued that the KTFI saves resources by closing the patients´ knowledge gap regarding the surgery.

Overview of results from the perspective of study hypothesis

In the present study, we assessed the patients´ empowerment through cognitive outcomes. The first hypothesis was that the KTFI increases the patients´ knowledge level more than standard patient education. The hypothesis was confirmed as the knowledge level in the IG increased significantly after the intervention and remained stable during the follow-up. The second hypothesis was that the KTFI improves the patients´ verbal and visual understanding of their surgical procedure more than standard patient education. This hypothesis could not be confirmed, as no difference between the study groups could be seen at any of the measurement points.

The empowerment was further assessed using patient-reported clinical outcome measures. The hypotheses were that the KTFI (a) decreases preoperative anxiety and has a beneficial impact on postoperative (b) HRQoL, (c) disability, and (d) pain. These hypotheses could be confirmed only partially: while there was a decrease in the preoperative anxiety level after the KTFI this did not reflect in the postoperative clinical outcomes. In conclusion, in this group of LSS patients undergoing surgery, the KTFI promoted the empowering process through knowledge gain resulting in decreased preoperative anxiety.

Cognitive outcomes

The KTFI increased the patients´ empowering knowledge level which is in line with existing literature. In most previous studies, advanced patient education methods have been shown to increase patients´ knowledge level more than standard patient education (I and Appendix 2).

Considering the effect of the KTFI on the different dimensions of empowering knowledge, a significant improvement in the IG compared to the CG was noted in the bio-physiological, functional, social and ethical, but not in the experiential and financial dimensions. In their

study on ambulatory orthopedic patients, Heikkinen et al (2008) noticed a significant improvement in the functional and ethical dimensions of empowering knowledge after an internet-based patient education program compared to standard care. It is remarkable that in the present study improvement was not achieved in some of the dimensions, even though the intervention covered the whole spectrum of empowering knowledge.

Almost all of our patients had previously experienced some type of surgery which might have contributed to the relatively high knowledge level at baseline. Standard patient education has traditionally concentrated on disease-centered issues, i.e. the bio-physiological and functional dimensions of empowering knowledge (I; Charalambous et al. 2017). Accordingly, the knowledge level of our CG patients in these dimensions increased during the hospitalization. Previous studies have shown that patients expect a broad empowering knowledge basis (Leino-Kilpi et al. 1998; Rankinen et al. 2007; Suhonen & Leino-Kilpi 2006; Suhonen et al. 2012). However, many studies, including the present study, have confirmed the difficulty of addressing all the dimensions of empowering knowledge even with meticulously designed patient education interventions (Johansson et al. 2003; Johansson Stark et al. 2014; Leino-Kilpi et al. 1999; Rankinen et al. 2007). Designing such patient education interventions remains essential to promote patients´ empowerment.

The KTFI did not improve the patients´ verbal and visual understanding of the surgical procedure as compared to standard patient education. The understanding increased in both study groups during follow-up which is most probably due to the surgeon explaining the surgical procedure to the patient. However, the fact that about nearly every third patients still could not verbally describe their surgical procedure afterwards needs special attention in future patient education interventions.

The measures for verbal and visual understanding of the surgical procedure were chosen for practical reasons, as we hypothesized that understanding the surgical procedure and the location of the incision would affect the recovery and postoperative rehabilitation. Wound management (e.g. observation of healing) requires special attention as the patient cannot directly see the wound. Moreover, as the selected surgical technique affects the ambulation and rehabilitation periods, understanding the surgical procedure may promote the patients´ ability and motivation to follow the postoperative instructions.
In some previous studies, educational interventions have increased the patients´ understanding of their surgical procedure (Borello et al. 2016; Bowers et al. 2017; Tsahakis et al. 2014). In the present study, the KTFI did not improve the patients´ understanding of the surgical procedure compared to standard patient education. There is no way of knowing the reason for this, but the KTFI did not include any specific education on the planned surgical procedure or the location of the incision, as the assumption was that empowering knowledge per se would promote the patients´ understanding of the surgical procedure.

The present study suggests a positive impact of KTFI on preoperative anxiety. The preoperative **anxiety** decreased significantly in the IG after the intervention. In the CG, a significant improvement in the anxiety level was not seen until after the surgery. However, we were not able to demonstrate any statistically significant difference in anxiety level between the two study groups at any of the measurement points. In previous studies, preoperative patient education has reduced anxiety in patients undergoing cardiac (Sørlie et al. 2007) and orthopaedic (Jlala et al. 2010) surgery. Advanced preoperative education on anesthesia and knowledge of the surgical procedure have been shown to reduce preoperative anxiety, although the results have not been uniform (Fraval et al. 2015; Hendriks et al. 2014; Huber et al. 2013; Lin et al. 2016; Tou et al. 2013). Lower levels of anxiety may reduce postoperative pain and analgesic requirements (Aouad et al. 2016; Ocalan et al. 2015). Anxiety has also been associated with poorer clinical outcomes after spine surgery (Flexman et al. 2016). Preoperative anxiety may also demonstrate cultural differences which should be taken into account; psychoeducation (Granziera et al. 2013; Shahmansouri et al. 2014) and religious support (Hosseini et al. 2013) have been suggested.

No differences between the two study groups could be demonstrated in the patient-reported clinical outcomes of **HRQoL, disability and pain**. All these parameters showed a significant improvement in both groups most probably due to the surgery (Rampersaud et al. 2011; Sobottke et al. 2017), i.e. decompression of the neural structures. In previous literature, patients´ knowledge level had a positive impact on HRQoL after orthopedic (Koekenbier et al. 2016) and hernia (Zieren et al. 2007) surgery. An advanced rehabilitation program including patient education resulted in faster recovery after spine surgery in terms of both HRQoL (Rolving et al. 2016) and disability (Rolving et al. 2015; Mannion et al. 2007).

6.2 Validity and reliability

In the following chapter, the validity and reliability of the entire research project are discussed according to the standards of a quantitative study design (Dane 2011; Grove et al. 2013; Polit & Beck 2008). The validity of this research will be evaluated from the following aspects: (1) statistical conclusion validity, (2) internal validity, (3) construct validity, and (4) external validity (Grove et al. 2013).

In experimental research, the fundamental question relates to causality, i.e. did the intervention cause the effect. The criteria to ensure causality include that the cause must precede the effect in time; an empirical relationship must exist between the cause and the effect; the causation is not due to any extraneous factors (Polit & Beck 2008). The validity and reliability of the study refer to the quality of the study design, the intervention, the outcome instruments, the data and its analysis. Validity signifies the truthfulness and

accuracy of the study. Reliability, on the other hand, refers to the consistency, stability and repeatability of the measures of the study (Dane 2011). In a quantitative study, a controlled study design, representativeness of the study sample, a structured intervention, and precise measurements are emphasized. In the present study, we chose the randomized controlled study design to assess the effectiveness of a specific patient education intervention (Grove et al. 2013).

The **statistical conclusion validity** refers to the degree with which the conclusions about the relationships among variables are correct, i.e. that there exists a true relationship between them (Polit & Beck 2008). In the present study, the theoretical relationship between the dependent and independent variables was confirmed based on existing literature; preoperative patient education has been shown to affect patients´ knowledge level (Heikkinen et al. 2008; Lee et al. 2016; Lin et al. 2016; Sjöling et al. 2003; Trummer et al. 2006; Johansson et al. 2007; Leino-Kilpi et al. 2015) which in turn has had an impact on preoperative anxiety (Lee et al. 2016; Lin et al. 2016; Sjöling et al. 2003), postoperative HRQoL (Zieren et al. 2007), postoperative disability (Rolving et al. 2015) and postoperative pain (Sjöling et al. 2003).

To avoid false statistical conclusions between independent and dependent variables the following threats were considered (Grove et al. 2013):

Statistical power was ensured with sample size calculation. It was based on STAI-State (Spielberger et al. 1983), the primary clinical outcome of the intervention study, as the primary cognitive outcome (knowledge level) was measured with the KNOWBACK Test specifically designed for this study. We could not find any MCID for STAI-State, and thus used a change of 3 points between two groups as a basis for the sample size calculation according to a previous Swedish study (Bringman et al. 2009). In another study published when the present study was already designed, a change of 5 points in STAI-State was used (Granziera et al. 2013). The drop-out rate during follow-up did not exceed the limits of the sample size calculation ensuring the power of the present study to detect significant differences between the study groups (Grove et al. 2013).

To avoid *violating assumptions of statistical tests* in order to guarantee meaningful interpretations of the study results, we considered the assumptions of each statistical test, e.g. the level of measurement and the distribution of variables (Grove et al. 2013; Polit 2010).

Making numerous multiple statistical comparisons (*fishing*) may lead to a Type I error (a true null hypothesis is rejected) as the significant result may occur by chance (Grove et al. 2013). To avoid this problem, a clear plan for the statistical analysis was included in the study protocol.

Reliability of the measures refers to the study's ability to detect true differences or changes. In the present study, the Cronbach's coefficient alphas measuring the internal consistency (Polit & Beck 2008) were adequate for all measures. For KNOWBACK Test, Cronbach's alpha was 0.6 at baseline, and varied between 0.7 and 0.8 for all other measures. This can be considered acceptable for a new instrument. (Grove et al. 2013; Nunnally & Bernstein 1994.)

Reliability of treatment implication was enhanced with one research nurse conducting all the interventions and the general telephone discussions with the CG patients. The nurse was specifically educated in implementing the intervention. As the study was conducted in a hospital setting, the time period between the intervention and admission to hospital (T1) varied. However, this has not affected the outcome of patient education in elective surgery (Borello et al. 2016).

Random irrelevancies in the study setting include any extraneous variables that might have an impact on the measurement of the dependent variable (Grove et al. 2013). In the present study, this was controlled by appointing in advance a specific time for the intervention to guarantee an undisturbed environment. However, as the intervention was conducted via telephone and not face-to-face, we could not completely control the environment.

The internal validity indicates that the independent variable has truly caused the effect on the dependent variable (Polit & Beck 2008; Grove et al. 2013). To strengthen the internal validity of the present study, we chose the RCT design, as quality-experimental and correlational studies are more prone to threats of internal validity (Polit & Beck 2008). The possible threats to internal validity were further controlled as follows:

History as a threat means that an unplanned event at the time of the intervention influences the responses of the participants to the intervention (Grove et al. 2013; Polit & Beck 2008). We could not control patients´ independent information seeking from sources other than the intervention, but this threat should have affected both study groups in a similar way.

Ambiguity about the direction of causal influence can be controlled with a RCT design, because the intervention is conducted before measuring the outcome variables. (Polit & Beck 2008).

In case of *selection bias*, differences in the outcomes may be due to group differences rather than the intervention. Selection bias may occur if the study groups are not equal, or if many of the participants do not receive the treatment. (Polit & Beck 2008.) In the present study, randomisation resulted in similar study groups regarding demographic factors and baseline measures. Furthermore, all participants in the IG received the allocated intervention.

Attrition rate during follow-up was 14% which is considered a small risk for bias. Attrition rates exceeding 20% cause concern for possible bias. Moreover, risk of bias increases if the

drop-out rate between the study groups is unbalanced. (Polit & Beck 2008; Grove et al. 2013.)

Maturation bias refers to the possible effect of time on the observed results. Especially in surgical care the postoperative recovery may explain the outcome. (Polit & Beck 2008; Grove et al. 2013.) In the present study, surgery was treated as an intermediate variable that had an effect on the outcomes. As the study groups were equal, the effect of surgery was controlled.

Although the present study included five separate measurement points, the risk of *testing effect* is unlikely as the outcome variables concerned knowledge and the patient´s actual health status. Studies using variables such as opinions or attitudes are more prone to testing effect (Polit & Beck 2008). On the other hand, it is possible that remembering the right answers of the knowledge test may cause bias. To control this recall bias, a time interval of two weeks has been suggested between repeated measurements (Grove et al. 2013). As the present study was conducted in a clinical setting, we could not control the time between the intervention and T1 measure, but there were no significant differences between the two study groups in this regard.

The *instrumentation bias* concerns the measuring instruments and methods (Polit & Beck 2008). We used predefined outcome tools at each measurement point. The use of several outcome instruments might have lead to less accurate measures due to fatigue. Despite the time-consuming measurements, the answers were logical and did not suggest any inaccuracies.

The construct validity refers to the degree with which the test measures what it claims to measure. The theoretical framework of the present study is based on previous literature. The most significant threats for the validity of the study were as follows (Grove et al. 2013; Polit & Beck 2008):

Hawthorne effect is present when the participants being aware of the research affects their behavior. We tried to reduce the Hawthorne effect by blinding the patients (Polit & Beck 2008); they were aware of the research, but not of the detailed study design, e.g. that there were two separate study groups. As ”placebo” care, the CG received a telephone discussion with the research nurse about their health history. The possibility that the outcome measures may have become part of the intervention cannot be excluded as the patients might have reflected on the questionnaires.

Researchers' expectations may affect the study construct (Polit & Beck 2008). This threat was controlled by training the research nurse in the technique of the intervention. The research nurse who conducted the intervention did not participate in patient care, and all the

other health care professionals involved were blinded regarding the group allocation. The possible confounding variable in the theoretical framework was the nurse- patient interaction in the IG; this was controlled with the telephone discussion between the research nurse and the patients in the CG.

The fact that the KTFI is a new intervention developed specifically for this study, may cause a *novelty effect*, i.e. both participants as well as researchers may alter their behavior and they may have different attitudes towards the intervention (Polit & Beck 2008). The advantage of our study protocol was that one research nurse conducted all the interventions.

Compensatory effect is present when healthcare professionals try to compensate the benefits of the intervention to the control group (Polit & Beck 2008). The threat of a compensatory effect was controlled with a rigorous study protocol where the telephone discussion with the CG participants was conducted according to a predefined check list.

Contamination occurs if participants in the control group receive components of the actual intervention (Polit & Beck 2008). In the present study, the intervention was strictly restricted to the IG patients. We could not control contamination between the study groups during the hospital stay; patients might have discussed with each other issues related to the KTFI. As the patients were not aware of their group allocation or the detailed study protocol, it is unlikely that this would have affected the study results.

To increase construct validity, the use of multiple measurement methods and methods of measurement recording has been suggested (Grove et al. 2013). In the present study, the possible effects of empowerment were studied with several outcome parameters (anxiety, HRQoL, disability, pain).

The external validity refers to the generalizability of the observed relationships (Polit & Beck 2008). The study sample should be representative of the population. Our patients were recruited according to predefined inclusion criteria, and randomization resulted in two balanced study groups (Polit & Beck 2008). The education level of our patients did not differ from the average Finnish population in the same age group (Kalenius 2014). Our patients were slightly younger compared to previous studies (Lurie et al. 2011; Strömqvist et al. 2013) and national statistics (National Institute for Health and Welfare 2016). From the perspective of learning, this does not necessarily pose a threat to generalization. The inclusion criteria of sufficient Finnish language restricts the generalization of the results to language minorities.

Validity and reliability of the Knowledge Test Feedback Intervention

Careful design and testing of the intervention strengthens the validity and reliability of the study (Conn et al. 2001). In the development of the KTFI, several aspects of validity and

reliability were considered. The conceptual basis of the KTFI reflects on the construct between the purpose of the empowering patient education and the outcome measures (Dawning & Haladyna 2006; Pittman & Bakas 2010). The literature on the theoretical construct between the KTFI (Chapter 2.4), the outcomes and the related interventions (Johansson et al. 2010; Johansson et al. 2007; Heikkinen et al. 2008; Ryhänen et al. 2012) was reviewed to understand the knowledge expectations of patients undergoing surgery for LSS, and the relationship between preoperative patient education and measured outcomes.

Clinical interventions in natural settings are prone to *extraneous variations* (Fogg & Gross 2000; Polit & Beck 2008). To ensure the validity and reliability when *delivering* (Conn et al. 2001; Fogg & Gross 2000) the KTFI, the KNOWBACK Test was used as the framework of the intervention. The framework of KNOWBACK Test is empowering knowledge, and it was specifically developed according to the knowledge expectations of patients undergoing surgery for LSS. The KTFI was piloted with a group of patients undergoing surgery for LSS, who did not propose any changes to the intervention. The delivery of the KTFI was standardized around the content of the KNOWBACK Test. As empowering patient education focuses on the needs of the patient, the depth of the empowering discourse was regulated by the patient. This has been shown to promote learning (Kettunen et al. 2001; Virtanen et al. 2007). The patients were informed about the overall purpose of the study, but they were blinded regarding the group allocation. The health care professionals involved in the care of the patients were blinded regarding the group allocation and the content of the intervention. The patients in the CG received a general telephone discussion based on their health history.

6.3 Implications for future

Based on the study results, the following implications for clinical practice, administration and nursing education can be presented. Further, suggestions for future research are discussed.

Implications for clinical practice

- Knowledge is a prerequisite for patient empowerment (Anderson et al. 2005; Leino-Kilpi et al. 1999). In general, patient education interventions have been shown to increase the knowledge level (I), and empowering patient education specifically has proven effective against several outcome measures (Suhonen & Leino-Kilpi 2006; Heikkinen et al. 2008; Ingadottir et al. 2017; Ryhänen et al. 2012; Siekkinen et al. 2014). The diverse learning strategies of individual patients require efficient and feasible patient education methods (Willingham et al. 2015; An & Carr 2017; Nizami et al. 2017; Laszewski et al. 2016). The KTFI is an effective and inexpensive

low-technology intervention that can be used for preoperative education of patients undergoing surgery for LSS.

- Empowering discourse consists of an individualized interaction between a patient and a health care professional. Their roles are essentially equal and reflect mutual respect. The goal of the discourse is to increase the patient´s awareness of any relevant health-related issues, and to help him/her gain new knowledge that can be linked to existing knowledge. Thus, patients learn to manage both new and familiar health problems in new ways. (i.e. Virtanen et al. 2007.) During the empowering discourse, health care professionals can also assess patients´ knowledge and opinions. In the present study, the KNOWBACK Test was used on one hand as a check list for the empowering discourse with feedback, and on the other hand as a measure of the patients´ existing knowledge. The concept behind the KNOWBACK Test was standardized patient education covering all dimensions of empowering knowledge.
- The present study highlights the role of knowledge feedback in patient education. Feedback is a powerful component of education and supports learning. In the present study, feedback about their empowering knowledge on surgical care improved the knowledge level of patients undergoing surgery for LSS. Thus, knowledge feedback can be considered an effective patient education method. A systematic review (I) suggested that patients do not get feedback on their knowledge level. Patient learning could be enhanced by introducing systematic feedback into patient education.
- Patients´ understanding of the surgical procedure forms the basis for cognitive structures related to surgical care (Edmondson 2005; AlDahdouh et al. 2015; Piaget 1968; Perry 1999; Kuokkanen & Leino-Kilpi 2000). Many studies, including the present study, have shown that patients do not understand their surgical procedure and may even have misconceptions about the surgery. Therefore, it is essential that patient education ensures understanding of the surgical procedure. In the assessment of understanding, different methods can be used, e.g. patients may be asked to explain the procedure with their own words or with a drawing.

Implication for administration

- Patient education is an integral part of nursing and health care (AHA 2003; Act785/1992 n.d.; Finnish Nurses Association 1996; International Council of Nurses 2012). It is connected to the quality of nursing care (Leino-Kilpi et al. 2015). Therefore, the KNOWBACK Test can be used as an indicator of quality of nursing care. A regular monitoring of the results of the KNOWBACK Test may reveal trends in the quality of patient education, and could be included among other quality indicators of health care.

Implications for education

- The KTFI is developed and tested for patient education, but the method might be beneficial e.g. for nursing education. As the KNOWBACK Test was effective in measuring the empowering knowledge level of patients undergoing surgery for LSS, it could be used in surgical nursing education as a check list for preoperative patient education. The results of the study showed lack of understanding of the surgical procedure in patients with LSS undergoing surgery. This is a significant finding underlining the importance of appropriate education methods to support patient empowerment.

Suggestions for research

- The literature review highlighted the confusion in the use of concepts knowledge and understanding. In some occasions, the use of these concepts is clearly overlapping. The connection between knowledge and understanding warrants further research.
- The results of the present study have corroborated the results of previous studies showing lack of understanding of the surgical procedure. There is a need for further patient education research to develop effective methods that promote understanding. Moreover, accurate assessment methods of understanding are essential when promoting practices towards patient empowerment.
- The KTFI might be valid for other geographical regions, but issues related to context and cultural differences would need to be addressed first.
- We could not define the ideal timing for preoperative education intervention. This is an area for future research.
- Patients expect new technologies to be introduced into health care. More research is needed to develop novel technological solutions, e.g. the KTFI could be modified into an e-learning format.
- Although drawings allow an in-depth qualitative description of patients´ understanding and interpretation of their health problem, they are seldom used among adult patients. In this study, a simple drawing was successfully used to assess patients´ understanding of the incision. Based on our experience, drawings can be suggested as an additional data collection method for other disciplines as well

The present study provided new knowledge on the empowerment of patients undergoing surgery for LSS. The study highlighted the effectiveness of an intervention (KTFI) based on a knowledge test (KNOWBACK Test) with feedback in the preoperative education of surgical LSS patients. Specifically, an increase in the preoperative empowering knowledge level.

7 CONCLUSIONS

Patients have high knowledge expectations on all dimensions of empowering knowledge. Traditional patient education has concentrated on the bio-physiological and functional dimensions of empowering knowledge. KTFI, as compared to standard patient education, was proven effective in a group of patients undergoing surgery for LSS resulting in an increase in the bio-physiological, functional, ethical and social dimensions of empowering knowledge. Moreover, preoperative anxiety was relieved after the intervention. Preoperative anxiety may have negative effects both before and after surgery. Although our results suggest that KTFI may reduce preoperative anxiety, no definite conclusions can be made until supportive evidence from further studies.

In education literature, feedback has been mentioned as an important factor in learning. KTFI consists of an empowering discourse based on knowledge test feedback. This structured feedback intervention was proven valid, reliable and feasible in promoting patient empowerment. The principles of empowering discourse allow modifying the feedback according to patient preferences and existing knowledge level. KTFI requires only moderate resources.

ACKNOWLEDGEMENTS

This study was carried out at the Department of Nursing Science, University of Turku. I have had a privilege to receive guidance, support, inspiration and encouragement from many people. I would like to express my thanks to you all, although I cannot not mane you all individually here.

First I would like to express my sincerest and deepest gratitude to my principal supervisor, Adjunct Professor Kirsi Valkeapää, PN, PhD, for your excellent and supportive guidance throughout this project. Your support and guidance has been intelligent and constructive and you have empowered me through these years. I'm also deeply grateful to my second supervisor Professor Helena Leino-Kilpi, RN, PhD your wide expertise in the research, topic and supervision. This has been valuable aid in my studies.

I would like to send my heartfelt gratitude to the members of my thesis follow-up committee members for their support and guidance. I would like to thank Teija Lund, MD, for your great impact on the whole research process. Specially I would like to thank you for your help in reporting and checking the English language during the study. Also, warm thanks go to senior lecturer Liisa Montin, PhD, who was the first person to encouraged me to start this project and you have supported and advised me on many ways during this process.

I respectfully thank the official reviewers Professor Jonathan D. Lurie and Adjunct professor Meeri Koivula for their careful review and constructive criticism of my thesis which helped me to improve and complete the manuscript of thesis. I thank statistical expert Pauli Puukka, MSocSc, for your patient guidance with statistics and handling of the entire data.

I wish to express my warmest thanks to the all patients who participated in my research. I would also to thank research nurse Riikka Ruuskanen, RN, for your careful and indispensable work in data collection. Also, grateful thanks I would like to send secretary Ella Haaranen for your role in the research. I wish sincere thank my former work organisation, Hospital Orton, and our team there for all support and co-operation during the research project. I am extremely grateful to all personnel, especially my former Director of nursing Sini-Vuokko Korpela, Head nurse Heidi Juhola-Aarnio, Head nurse Heli Ruottu, former Director of Reserch Institute Dietrich Schlenzka, Head of Research Institute Leena Ristolainen, Docent Timo Yrjönen and Heikki Österman, MD for encouragement me to research and support during the process.

I would also thank the members of the seminar group and research programme of Empowering Patient Education have encouraged me and shared experiences with me during this project. Professor Riitta Suhonen has provided her skilful guidance in seminars.

Professor Sanna Salanterä has taught me valuable knowledge in clinical nursing science and supported my study in the meeting of research programme. Heli Virtanen PhD has provided me comprehensive insight to the empowering discourse. In particular, I thank doctoral student Niina Eklöf for being in “samassa veneessä” and for being a priceless ally during these years and motivating to continue the study process by means of endless discussions and working together. I warmly thank Mervi Siekkinen, PhD, for co-authoring and peer support. I also wish to thank my co-author Dinah Arifulla, MNSc, for her impact on systematic literature review.

My warmest gratitude I owe to my family, mother, Mika, Leena, Nico and Joonas. You have always supported me to achieve this goal.

The study was financially supported by the Finnish Nurse Association; University of Turku, Faculty of Medicine; The Finnish Association of Nursing Research; University of Turku, Turku Graduate School of Clinical Sciences; Research funds from specified government transfers (EVO) granted by South-West Hospital District and Hospital Orton; The Research Association of Nurses, which I all gratefully acknowledge.

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APPENDICES

Appendix 1. Characteristics of studies in the update of the systematic review

The update of the characteristics and outcomes of the studies included in the review and the functional role of knowledge tests. The table continues from I: Table 1.

Author, year, country	**Study design**	**Intervention (change in knowledge)**	**Control (change in knowledge)**	**Participants (n)**	**Functional role of KT †**
54. Batuyong *et al. 2014* Australia	Pre-post-test	Multimedia education ↑	n/a	Patients undergoing bunion surgery (n=55)	S
55 des Bordes et al. 2017	Pre-post-test	Online educational tool ↑	n/a	Cancer survivors (n=20)	S
56. Chiou &Chung 2012, Taiwan	QE	A multimedia interactive DVD ↑↑	Standard care ↑	Patients with end-stage renal disease (n=60)	S
57. Cho *et al.* 2013, USA	RCT	Combined preoperative patient education ↑	Standard care →	Mastectomy patients (n=145)	S
58. Clark *et al.* 2015, USA	RCT	education-support intervention ↑	Standard care ↑	Heart failure patients (n=50)	S
59. Cleeren *et al.* 2014	RCT	3D animation ↑↑	Sketch animation ↑	Perodonitis patients (n=68)	
60. Crawford *et al.* 2012, USA	RCT	2 Session Nurse Instruction Plus DVD for Teaching Ostomy Care ↑	Standard care ↑	Ostomy patients (n=88)	S
61. Ellet *et al.* 2014, Australia	RCT	Multimedia module ↑↑	Standard care ↑	Patients undergoing gynecologic laparoscopy (n=41)	S
62. Emery *et al.* 2015, USA	RCT	educational voiceover interactive PowerPoint plus standard care ↑	Standard care ↑	Patients who were scheduled for hospital discharge on home parenteral nutrition (n=51)	S
63. Feicke *et al.* 2014, Germany	QE	Self-management training program →	Standard care →	New multiple sclerosis patients (n=64)	S
64. Goossens *et al.* 2015, Belgium	Pre-post-test	Single educational session ↑	n/a	young people with congenital heart disease (n=2019	S
65. Heinrich *et al.* 2012, Netherlands	RCT	Diabetes Interactive Education Programme ↑↑	Standard Care ↑	Patients with type 2 diabetes (n=99)	S

66. Hägglund *et al*. 2015, Sweden	RCT	Home intervention system connected to patient's scale ↑	Standard Care ↑	Patients with heart failure (n=82)	S
67. Jeroen *et al.* 2013, Netherlands	RCT	Nurse-led care guidelines-based, software supported care ↑↑	Standard care ↑	Patients with atrial fibrillation (n=712)	S
68. Kommuri *et al.* 2012, USA	RCT	a 1-h, one-on-one teaching session ↑↑	Standard care ↑	Heart failure patients (n=227)	S
69. Koonce *et al.* 2015, USA	RCT	Individualized information prescription model ↑	Standard care →	Patients with type 2 diabetes (n=160)	S
70. Larsen *et al.* 2014, Norway	RCT	Motivational Interview Intervention ↑↑	Standard care ↑	Psoriasis patients (n =169)	S
71. Melamed et al. 2014, Germany	RCT	disease-specific education and treatment program ↑↑	Standard care ↑	Patients with heart failure (n=395)	S
72. O'Brien *et al.*2014, Ireland	RCT	Individualized educational intervention ↑	Standard education →	Patients with acute coronary syndrome (n=1847)	S
73. Siekkinen *et al.* 2015, Finland	RCT	electronic feedback knowledge of radiotherapy intervention ↑↑	Standard care ↑	Breast cancer patients (n=128)	P,S
74. Stafford *et al.* 2012, Australia	QE	Home-based warfarin education ↑↑	Standard education ↑	Patient with newly initiated warfarin (n =134)	S
75. Urstad *et al.* 2012, Norway	RCT	Renal transplantation educational program ↑↑	Standard care ↑	Renal recipients (n=159)	S
76. Verret *et al. 2012,* Canada	RCT	warfarin patient self-management program ↑	Standard management ↑	Patient with warfarin therapy (n=114)	S

ABBREVIATIONS: RCT, randomized controlled trial; ↑ significantly increased knowledge level; → no significant change in knowledge level; ↑↑ Knowledge increased more than in comparison group; KT, knowledge test; QE, quasi-experimental;

† functional roles of knowledge tests in patient education: P = Placement evaluation: to determine learner performance at the beginning of education, F = Formative education: to monitor learning progress during education, D = Diagnostic evaluation: to diagnose learning difficulties during education, and S = Summative evaluation: to evaluate achievement at the end of education

Appendix 2. Update of the analysis of the systematic literature review. The characteristic, quality and content of the knowledge tests included in the review. The table continues from I: Table 3.

Researcher †	Name of knowledge test	Item type (number of items)	Content validity ‡	Construct validity ‡	Internal consist. ‡	Reproducibility ‡	Framework /base of development	Content of the knowledge test §
54. Batuyong *et al. 2014*	n/a	True-false-don't know (20)	n/a	n/a	n/a	n/a	Education intervention objectives	Bf
55. des Borders et al. 2017 (Pande et al. 2000)	Osteoporosis Knowledge Questionnaire	Multiple choice (20)	2	2	2	2	Literature, experts, patients	Bf
56. Chiou & Chung 2012	n/a	True-false-don't know (20)	1	n/a	2	2	n/a	n/a
57. Cho *et al*. 2013	Breast Cancer Knowledge Questionnaire	n/a (10)	n/a	n/a	n/a	n/a	n/a	n/a
58. Clark *et al*. 2015	HF Knowledge Test	Multiple choice (20)	1	n/a	1	n/a	Literature, experts	Bf
59. Cleeren *et al.* 2014	n/a	Multiple choice (10)	n/a	n/a	n/a	n/a	n/a	Bf, Fu
60. Crawford *et al.* 2012	The colostomy test The ileostomy test	Multiple choice (13) Multiple choice (14)	n/a n/a	n/a n/a	n/a n/a	n/a n/a	n/a	Bf, Fu Bf, Fu
61. Ellet *et al.* 2014	n/a	True-false-don't know (14)	n/a	n/a	n/a	n/a	Literature, experts	Bf
62. Emery *et al*. 2015	n/a	Multiple choice (6)	1	n/a	n/a	n/a	Literature, experts	Bf, Fu
63. Feicke *et al*. 2014	n/a	True-false-don't know (14)	n/a	n/a	1	n/a	The content of the training programme	n/a
64. Goossens *et al*. 2015 (Moons *et al*. 2001)	Leuven Knowledge Questionnaire CHD	Multiple choice (34)	2	0	0	0	Literature, experts, patients	Bf, Fu
65. Heinrich *et al*. 2012	n/a	Multiple choice (29)	2	2	2	2	Diabetes Interactive Education Programme	Bf, Fu
66. Hägglund *et al*. 2015 (van der Wal *et al*., 2005)	Dutch Heart Failure Knowledge Scale	Multiple choice (15)	2	2	n/a	n/a	Literature	Bf, Fu
67. Jeroen *et al.* 2013 (Hendriks *et al.* 2013)	Atrial Fibrillation knowledge scale	Multiple choice (11)	2	2	0	2	Literature, experts, patients	Bf, Fu
68. Kommuri *et al*. 2012	Heart failure knowledge questionnaire	Multiple choice (30)	n/a	n/a	n/a	n/a	n/a	Bf, Fu

69. Koonce *et al.* 2015 (Fitzgerald *et al*., 1998)	MDRTC Diabetes Knowledge Test	Multiple choice (23)	2	2	1	n/a	National expert group using several methods	Bf, Fu
70. Larsen *et al.* 2014 (Wahl *et al.* 2013)	Psoriasis Knowledge Questionnaire	True-false-don't know (49)	2	n/a	2	n/a	Literature, experts, patients	Bf
71. Melamed et al. 2014	Knowledge Questionnaire	n/a	n/a	n/a	n/a	n/a	Topics of educational programme	n/a
72. O'Brien *et al.*2014 (Riegel *et al*. 2007)	Coronary Syndrome Index (knowledge subscale)	True-false (21)	2	2	2	2	Literature, experts, patients	Bf
73. Siekkinen *et al*. 2015	RT Knowledge	True-false (28)	2	1	0	n/a	Literature, experts	Bf, Fu
74. Stafford *et al.* 2012 (Zeolla *et al*. 2006)	Oral Anticoagulation Knowledge test	Multiple choice (23)	2	n/a	2	n/a	Literature, experts	Bf, Fu
75. Urstad *et al*. 2012 (Urstad *et al.* 2011)	Knowledge Questionnaire for renal recipients	Likert (19)	2	2	n/a	2	Literature, experts, patients	Bf, Fu
76. Varret *et al.* 2012 (Zeolla *et al*. 2006)	Oral Anticoagulation Knowledge test	Multiple choice (23)	2	n/a	2	n/a	Literature, experts	Bf, Fu

† The author in the brackets is the developer of the knowledge test
‡ The rating of psychometric properties: 2 = positive, 1 = intermediate, 0 = negative (Table 2)
§ The content of knowledge tests: The identified dimensions of knowledge of the knowledge tests Bf=biophysical, Fu=functional, So=social, Ex=experiential, Et=ethical, and Fi=financial dimension
n/a = the information not available in the report

Appendix 3. Feedback strategies in patient education

Author(s) Year Country	Participants	Intervention	Type of FB	Timing	Mode	Comparison	Function	Results of FB
1. Cheung et al. 2015, Singapore	People with rheumatoid arthritis	Education on tender and joint count and FB of performance	Performance FB	Immediate	Oral	Goal	Corrective	Intervention improved patients ability to assess joints
2. Toumas-Shehata et al. 2014, Australia	People with asthma	verbal and visual FB with demonstration	Performance FB	Immediate	verbal and demonstration	Goal	Corrective	Verbal and visual FB is more effective
3. Siekkinen et al. 2015, Finland	Breast cancer patients	e-FB after response to the knowledge test	Knowledge FB	Immediate	Electronic	Goal	Corrective	improvement in anxiety and QOL
4. Wu et al. 2014, Australia	Women aged 25–44	Group-based osteoporosis education with bone density FB	Bio-physiological FB	Delayed	Written	Goal	Motivational	n/a
5. Climov et al. 2014, Belgium	Patients with cardiovascular disorder	Rehabilitation programme with BioFB of cardiac coherence	Bio-physiological FB	Immediate	Technological	Goal	Motivational	n/a
6. Gopalan et al. 2014, USA	patients with controlled diabetes	FB of glycaemic control in form of letter grades " ranging from A to F or emotion faces	Bio-physiological FB	Delayed	Written	Goal	Motivational	No difference between the groups
7. Tait et al. 2014, USA	Patients scheduled for diagnostic cardiac catheterization	interactive iPad-based informational program with exercises and corrected FB	Knowledge FB	Delayed	Electronic	Goal	Corrective	n/a
8. Mehring et al. 2013, Germany	Individuals with a BMI ≥ 25	a web-based coaching program	Weekly performance self-FB	Recurrent	Electronic	Progression	Motivational	n/a

9. van Straten et al. 2008, Netherlands	People with different types of mental problems	a Web-based self-help intervention with exercises	Performance FB of exercises	n/a	Electronic	Progression	Motivational	n/a
10. Hay et al. 2007, Australia	people with eating disorders	Information of treatments, self-help, and services). FB on scores on measures of ED symptoms and quality of life	Health behaviour FB	n/a	n/a	Goal	Motivational	n/a
11. Schumann et al. 2008, Germany	current and former smokers	a computer-tailored smoking cessation intervention with FB letters	Health behaviour FB	Scheduled	Electronic	Progression	Motivational	No difference between the groups
12. Lipkus et al. 2006, USA	Smokers	Education based on lung age and respiratory symptoms FB	Bio-physiological FB	Immediate	Oral	Goal	Motivational	No difference between the groups
13. Martens et al 2013, USA	Undergraduate university students	Personalized normative FB or behavioural strategies FB	Health behaviour FB	Immediate	Oral	Process	Motivational	personalized normative FB was more effective than other methods
14. Jouriles et al. 2010, USA	College students with heavy drinking episode(s)	personalized drinking FB 1) sent home, 2) reading the FB, and 3) writing down as FB as much as they remember	Health behaviour FB	Delayed	Written	Goal	Corrective / Motivational	After reading and writing the FB, the students retained more information

15. Trinks et al. 2010, Sweden	ED patients with risk drinking	The short or long FB was tailored on the basis of the individual patient's responses	Health behaviour FB	Immediate	Electronic	Process	Motivational	No statistically significant difference between short and long FB
16. Barnett et al. 2010, USA	Patients in an emergency department	Motivational interview with personalized FB or FB only	Health behaviour FB	Immediate	Oral	Process	Motivational	Motivational interview and FB was slightly more effective than FB only
17. Merchant et al. 2011, USA	Adult emergency department patients	Tailored FB to responses about the reported HIV risk behaviours	Health behaviour FB	Immediate	Electronic	Process	Motivational	No difference between the groups
18. ter Bogt et al. 2009, Netherlands	Overweight patients with hypertension and/or dyslipidaemia,	Training programme and FB on food diary, physical activity	Health behaviour FB	Scheduled	Oral	Process	Motivational	n/a

FB = feedback. All feedbacks were individualised. The provider was in all studies a health care professional.

Appendix 4. KNOWBACK Test

SELKÄLEIKKAUSPOTILAAN TIETOTESTI

Tämän kyselyn tarkoituksena on selvittää tietojanne selkäleikkaukseen liittyvistä asioista. Valitkaa seuraavista **ympyröimällä** mielestänne parhaiten sopiva vaihtoehto

1. Raskasta ruumiillista työtä tekevillä on muita enemmän selkäsairauksia.	oikein	väärin	en tiedä
2. Jalkaan säteilevä kipu on aina merkki selkäsairaudesta.	oikein	väärin	en tiedä
3. Leikkaus on tehokkain selkäkivun hoitomuoto.	oikein	väärin	en tiedä
4. Huomattava ylipaino lisää riskiä haavatulehdukseen.	oikein	väärin	en tiedä
5. Nukutuksen jälkeen saattaa esiintyä kurkkukipua ja äänen käheyttä	oikein	väärin	en tiedä
6. Leikkauksessa laitettava laskuputki (dreeni) ehkäisee haavatulehdusta.	oikein	väärin	en tiedä
7. Leikkauksen jälkeinen pahoinvointi poistaa elimistöstä nukutusaineita	oikein	väärin	en tiedä
8. Leikkauksen jälkeen puetaan tukisukat ehkäisemään jalkojen turvotusta.	oikein	väärin	en tiedä
9. Haava-alueen punoitus on merkki haavan paranemisesta.	oikein	väärin	en tiedä
10. Leikkausta edeltävän ravinnotta olo ehkäisee vatsan sisällön joutumista hengitysteihin nukutuksen yhteydessä.	oikein	väärin	en tiedä
11. Selkäleikkauksen jälkeinen fysioterapia nopeuttaa toipumista.	oikein	väärin	en tiedä
12. Suihkuun saa mennä vasta haavaompeleiden poiston jälkeen.	oikein	väärin	en tiedä
13. Selkäleikkauksen jälkeen vuodelepo edistää toipumista.	oikein	väärin	en tiedä
14. Tupakointi edistää leikkaushaavan paranemista.	oikein	väärin	en tiedä
15. Autolla ajo on kielletty kolme kuukautta leikkauksen jälkeen.	oikein	väärin	en tiedä
16. Suomen selkäliitto on terveydenhuollon ammattihenkilöstön. yhteistyöelin.	oikein	väärin	en tiedä
17. Vierailuaikojen keskittäminen iltapäivään ehkäisee sairaalainfektioiden leviämistä.	oikein	väärin	en tiedä
18. Selkäleikkauksen jälkeen sairausloma on puolesta vuodesta yhteen vuoteen.	oikein	väärin	en tiedä
19. Leikkausta edeltävä pelko on normaali tunne.	oikein	väärin	en tiedä
20. Potilaan myönteinen asenne selkäleikkausta kohtaan edesauttaa leikkauksesta toipumista.	oikein	väärin	en tiedä

21. Leikkauksen jälkeinen kivun kokemus on erilainen eri ihmisillä.	oikein	väärin	en tiedä
22. Lääkäri päättää potilaan hoitovaihtoehdon.	oikein	väärin	en tiedä
23. Hoitoonsa tyytymätön potilas voi pyytää potilasasiamiestä tekemään valituksen.	oikein	väärin	en tiedä
24. Potilaan lähisukulaisilla on oikeus halutessaan tutustua potilasasiakirjoihin.	oikein	väärin	en tiedä
25. Sairauspäiväraha korvaa työkyvyttömyyden aiheuttamaa ansion menetystä korkeintaan kymmenen päivää.	oikein	väärin	en tiedä
26. Julkisen terveydenhuollon vuodeosastohoidosta potilas itse maksaa 150 € vuorokaudessa.	oikein	väärin	en tiedä
27. Kela maksaa korvausta pääsääntöisesti leikkaukseen liittyvistä matkoista.	oikein	väärin	en tiedä

Appendix 5. The verbal and visual description of surgical procedure

Kuvailkaa mahdollisimman tarkasti, mitä teille tehtiin leikkauksessanne _____

_____

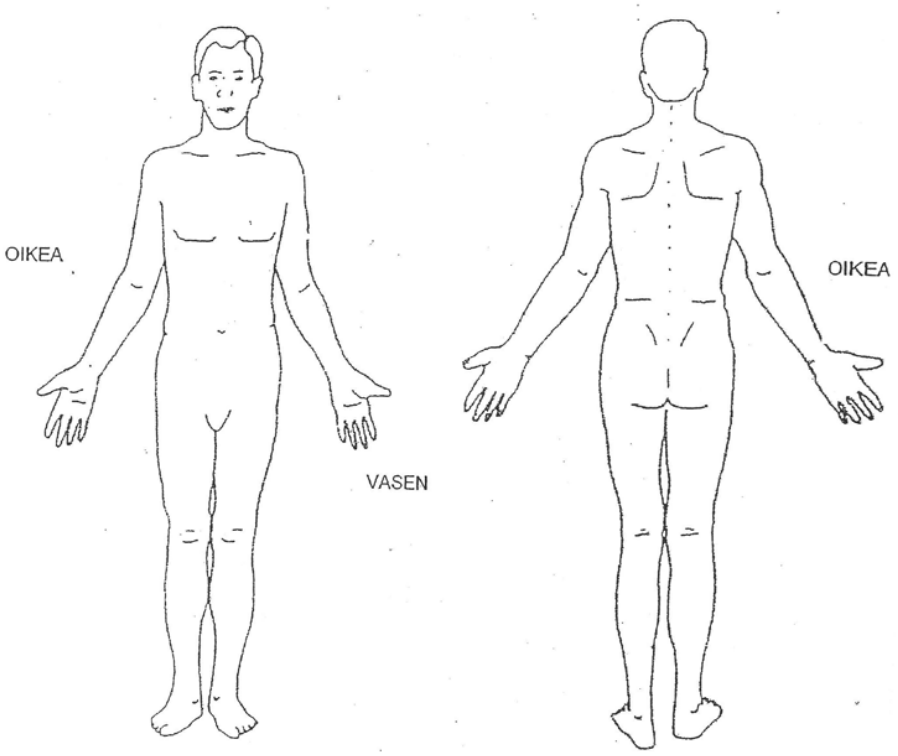
_____

_____

_____

_____

Piirtäkää oheiseen kuvaan leikkauspaikka ja haavan koko mahdollisimman tarkasti



Appendix 6. Sample items of the State-Trait Anxiety Inventory (Y1 Scale)

ITSEARVIOINTILOMAKE

(Finnish version of the STATE-TRAIT ANXIETY INVENTORY©) (STAI - Y1 SCALE))

Ohjeet: Alla on joukko väittämiä, joita ihmiset ovat käyttäneet kuvaillessaan tuntemuksiaan. Lue kukin väittämä ja merkitse sitten rasti siihen väittämän oikealla puolella olevaan ruutuun, joka parhaiten kuvaa omia tuntemuksiasi **juuri** nyt, eli **tällä hetkellä.** Väittämiin ei ole olemassa oikeita tai vääriä vastauksia. Älä käytä liikaa aikaa pohdiskeluun, vaan merkitse rastilla se vastausvaihtoehto, joka tuntuu parhaiten kuvaavan tämänhetkisiä tuntemuksiasi.		En lainkaan	Jossain määrin	Kohtalaisen paljon	Hyvin paljon
1	Tunnen oloni tyyneksi.	❑1	❑2	❑3	❑4
2	Tunnen oloni turvalliseksi.	❑1	❑2	❑3	❑4
3	Olen kireä.	❑1	❑2	❑3	❑4
4	Tunnen oloni stressaantuneeksi.	❑1	❑2	❑3	❑4
5	Tunnen oloni mukavaksi.	❑1	❑2	❑3	❑4

Appendix 7. RAND-36

TERVEYTEEN LIITTYVÄ ELÄMÄNLAATU

A. Onko terveytesi yleisesti ottaen

[1] Erinomainen
[2] Varsin hyvä
[3] Hyvä
[4] Tyydyttävä
[5] Huono

B. Jos vertaat nykyistä terveydentilaasi vuoden takaiseen, onko terveytesi yleisesti ottaen

[1] Tällä hetkellä paljon parempi kuin vuosi sitten
[2] Tällä hetkellä jonkin verran parempi kuin vuosi sitten
[3] Suunnilleen samanlainen
[4] Tällä hetkellä jonkin verran huonompi kuin vuosi sitten
[5] Tällä hetkellä paljon huonompi kuin vuosi sitten

C. Seuraavassa luetellaan erilaisia päivittäisiä toimintoja. Rajoittaako terveydentilasi nykyisin suoriutumistasi seuraavista päivittäisistä toiminnoista? (Merkitse yksi numero joka riviltä)

	Kyllä, rajoittaa paljon	Kyllä, rajoittaa hiukan	Ei rajoita lainkaan
a) Huomattavia ponnistuksia vaativat toiminnat (esimerkiksi juokseminen, raskaiden tavaroiden nostelu, rasittava urheilu)	[1]	[2]	[3]
b) Kohtuullisia ponnistuksia vaativat toiminnat, kuten pöydän siirtäminen, imurointi, keilailu	[1]	[2]	[3]
c) Ruokakassien nostaminen tai	[1]	[2]	[3]
d) Nouseminen portaita useita kerroksia	[1]	[2]	[3]
e) Nouseminen portaita yhden kerroksen	[1]	[2]	[3]
f) Vartalon taivuttaminen, polvistuminen,	[1]	[2]	[3]

g)	Noin kahden kilometrin matkan kävely	1	2	3
h)	Noin puolen kilometrin matkan kävely	1	2	3
i)	Noin 100 metrin kävely	1	2	3
j)	Kylpeminen tai pukeutuminen	1	2	3

D. Onko Sinulla viimeisen 4 viikon aikana ollut ruumiillisen terveydentilasi takia alla mainittuja ongelmia työssäsi tai muissa tavanomaisissa päivittäisissä tehtävissä?

		Kyllä	Ei
a)	Vähensit työhön tai muihin tehtäviin käyttämääsi aikaa		
b)	Sait aikaiseksi vähemmän kuin halusit	1	2
c)	Terveydentilasi asetti sinulle rajoituksia joissakin työ- tai muissa tehtävissä	1	2
d)	Töistäsi tai tehtävistäsi suoriutuminen tuotti vaikeuksia (olet joutunut esim. ponnistelemaan tavallista enemmän)	1	2

E. Onko Sinulla viimeisen 4 viikon aikana ollut tunne-elämään liittyvien vaikeuksien
(esim. masentuneisuus tai ahdistuneisuus) takia alla mainittuja ongelmia työssäsi tai muissa tavanomaisissa päivittäisissä tehtävissäsi?

		Kyllä	Ei
a)	Vähensit työhön tai muihin tehtäviin käyttämääsi aikaa	1	2
b)	Sait aikaiseksi vähemmän kuin halusit	1	2
c)	Et suorittanut töitäsi tai muita tehtäviäsi yhtä huolellisesti kuin tavallisesti	1	2

F. Missä määrin ruumiillisen terveydentilasi tai tunne-elämän vaikeudet ovat viimeisen 4 viikon aikana häirinneet tavanomaista (sosiaalista) toimintaasi perheen, ystävien, naapureiden tai muiden ihmisten parissa?

1 Ei lainkaan
2 Hieman
3 Kohtalaisesti
4 Melko paljon
5 Erittäin paljon

G. Kuinka voimakkaita ruumiillisia kipuja Sinulla on ollut viimeisen 4 viikon aikana?

1 Ei lainkaan
2 Hyvin lieviä

[3] Lieviä
[4] Kohtalaisia
[5] Voimakkaita
[6] Erittäin voimakkaita

H. Kuinka paljon kipu on häirinnyt tavanomaista työtäsi (kotona tai kodin ulkopuolella) viimeisen 4 viikon aikana?

[1] Ei lainkaan
[2] Hieman
[3] Kohtalaisesti
[4] Melko paljon
[5] Erittäin paljon

I. Seuraavat kysymykset koskevat sitä, miltä Sinusta on tuntunut viimeisen 4 viikon aikana. Merkitse kunkin kysymyksen kohdalla se numero, joka parhaiten kuvaa tuntemuksiasi.

	Koko ajan	Suurimman osan aikaa	Huomattavan osan aikaa	Jonkin aikaa	vähän aikaa	En lainkaan
a) Tuntenut olevasi täynnä elinvoimaa	[1]	[2]	[3]	[4]	[5]	[6]
b) Ollut hyvin hermostunut	[1]	[2]	[3]	[4]	[5]	[6]
c) Tuntenut mielialasi niin matalaksi, ettei	[1]	[2]	[3]	[4]	[5]	[6]
d) Tuntenut itsesi tyyneksi ja rauhalliseksi	[1]	[2]	[3]	[4]	[5]	[6]
e) Ollut täynnä tarmoa	[1]	[2]	[3]	[4]	[5]	[6]
f) Tuntenut itsesi alakuloiseksi	[1]	[2]	[3]	[4]	[5]	[6]
g) Tuntenut itsesi loppuun kuluneeksi	[1]	[2]	[3]	[4]	[5]	[6]
h) Ollut onnellinen	[1]	[2]	[3]	[4]	[5]	[6]
i) Tuntenut itsesi väsyneeksi	[1]	[2]	[3]	[4]	[5]	[6]

J. Kuinka suuren osan ajasta ruumiillinen terveydentilasi tai tunne-elämän vaikeudet ovat viimeisen 4 viikon aikana häirinneet tavanomaista sosiaalista toimintaasi (ystävien, sukulaisten, muiden ihmisten tapaaminen)?

[1] Koko ajan
[2] Suurimman osan aikaa
[3] Jonkin aikaa
[4] Vähän aikaa
[5] Ei lainkaan

K. Kuinka usein seuraavat väittämät pitävät paikkansa Sinun kohdallasi? (Merkitse yksi numero joka riviltä)	pitää ehdottomasti paikkansa	pitää	en osaa sanoa	enimmäkseen ei pidä paikkaansa	ehdottomasti ei pidä paikkaansa
a) Minusta tuntuu, että sairastun jonkin verran	1	2	3	4	5
b) Olen vähintään yhtä terve kuin kaikki muutkin	1	2	3	4	5
c) Uskon, että terveyteni tulee heikkenemään	1	2	3	4	5
d) Terveyteni on erinomainen	1	2	3	4	5

Appendix 8. Oswestry Disability Index (ODI)

OIRE- JA HAITTAKYSELY (Oswestryn indeksi ja kipujana)
Päiväys

Tämän kyselykaavakkeen tarkoituksena on antaa lääkärillenne tietoa siitä, kuinka kipunne on vaikuttanut kykyynne suoriutua jokapäiväisen elämän toiminnoistanne viimeksi kuluneiden 7 vuorokauden aikana. Yrittäkää vastata jokaiseen kohtaan. Merkitkää jokaiseen kohtaan vain se ruutu, joka sopii oireistoonne. On ilmeistä, että jokaisessa kohdassa on ehkä kaksi väittämää. jotka sopivat oireistoonne. Yrittäkää rastittaa vain se ruutu, joka tarkimmin kuvaa ongelmaanne.

1. Kivun voimakkuus

☐ Voin sietää kipuni käyttämättä särkylääkkeitä
☐ Kipuni on kovaa, mutta selviydyn ilman särkylääkkeitä
☐ Särkylääkkeet vievät kipuni täysin
☐ Särkylääkkeet helpottavat kipuani huomattavasti
☐ Särkylääkkeistä ei ole paljoakaan apua kipuun
☐ Särkylääkkeistä ei ole mitään apua kipuun enkä käytä niitä

2. Omatoimisuus (pukeutuminen, peseytyminen jne.)

☐ Selviydyn näistä toiminnoista normaalisti ilman, että niistä aiheutuu lisää kipua
☐ Selviydyn näistä toiminnoista normaalisti, mutta siitä aiheutuu ylimääräistä kipua
☐ Näistä toiminnoista selviytyminen aiheuttaa melkoisesti kipua ja vaatii aikaa ja varovaisuutta
☐ Tarvitsen apua, mutta selviydyn useimmista toiminnoista itsenäisesti
☐ Tarvitsen apua joka päivä useimmissa omatoimisuuteen liittyvissä toiminnoissa
☐ En yleensä pukeudu tai peseydy lainkaan itse, pysyttelen sängyssä

3. Nostaminen

☐ Voin nostaa raskaita taakkoja jotakuinkin kivuttomasti
☐ Voin nostaa raskaita taakkoja, mutta se aiheuttaa jonkin verran kipua
☐ Kipu estää minua nostamasta raskaita taakkoja lattialta, mutta voin nostaa niitä, jos ne ovat sijoitettu sopivasti, esim. pöydälle
☐ Kipu estää minua nostamasta raskaita taakkoja, mutta voin nostaa kevyitä taakkoja, jos ne ovat sijoitettu sopivasti
☐ Voin nostaa ainoastaan hyvin kevyitä taakkoja
☐ En voi nostaa tai kantaa mitään

4. Kävely

☐ Kipu *ei* estä kävelyäni missään määrin
☐ Kipu estää minua kävelemästä kahta kilometriä enempää
☐ Kipu estää minua kävelemästä yhtä kilometriä enempää
☐ Kipu estää minua kävelemästä puolta kilometriä enempää
☐ Voin kävellä vain käyttäen keppiä *tai* kyynärsauvoja
☐ Olen enimmäkseen vuoteessa ja minun on ryömittävä WC:hen

5 Istuminen

☐ Voin istua millaisessa tuolissa tahansa niin pitkään kuin haluan
☐ Vain määrätynlaisessa tuolissa voin istua miten pitkään tahansa
☐ Kipu estää minua istumasta tuntia pidempään
☐ Kipu estää minua istumasta puolta tuntia pidempään
☐ Kivun takia en voi istua kymmentä minuuttia pidempään
☐ Kivun takia en voi istua ollenkaan

Käännä

6. Seisominen

☐ Voin seistä miten pitkään tahansa ilman, että se aiheuttaa kipua
☐ Voin seistä niin pitkään kuin haluan, mutta se on kivuliasta
☐ Kivun takia en voi seistä tuntia pidempään
☐ Kivun takia en voi seistä puolta tuntia pidempään
☐ Kivun takia en voi seistä 10 minuuttia pidempään
☐ Kivun takia en voi seistä ollenkaan

7. Nukkuminen

☐ Kipu ei vaikuta yöuneeni lainkaan
☐ Kivun takia uneni on katkonaista, mutta en käytä lääkkeitä
☐ Vaikka käytän lääkkeitä, nukun alle kuusi tuntia
☐ Vaikka käytän lääkkeitä, nukun alle neljä tuntia
☐ Vaikka käytän lääkkeitä, nukun alle kaksi tuntia
☐ Kivun takia en saa ollenkaan nukutuksi

8. Sukupuolielämä

☐ Sukupuolielämäni on normaalia eikä siitä aiheudu kipua
☐ Sukupuolielämäni on normaalia, mutta se aiheuttaa jonkin verran kipua
☐ Sukupuolielämäni on lähes normaalia, mutta hyvin kivulloista
☐ Kipu rajoittaa huomattavasti sukupuolielämääni
☐ Kivun takia sukupuolielämäni on lähes olematonta
☐ Kipu estää minulta kaiken sukupuolielämän

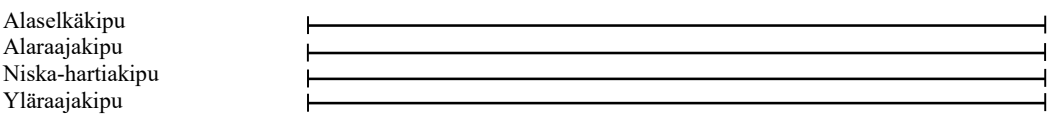
9. Sosiaalinen elämä

☐ Sosiaalinen elämäni on normaalia, eikä siitä aiheudu minulle merkittävää kipua
☐ Sosiaalinen elämäni on normaalia, mutta se lisää kipuani
☐ Kivulla ei ole merkittävää vaikutusta sosiaaliseen elämääni lukuun ottamatta liikunnallisia harrastuksia kuten hölkkääminen, tanssiminen jne.
☐ Kipu on rajoittanut sosiaalista elämääni, harrastukseni ovat vähentyneet aiemmasta
☐ Kivun takia sosiaalinen elämäni on rajoittunut kotipiiriin
☐ Kivun takia minulla ei ole mitään sosiaalista elämää

10. Matkustaminen

☐ Voin tehdä miten pitkiä matkoja tahansa ilman merkittävää kipua
☐ Voin tehdä miten pitkiä matkoja tahansa, mutta siitä aiheutuu kipua
☐ Selviydyn yli kahden tunnin matkoista, mutta niistä aiheutuva kipu on ikävä
☐ Kivun takia minun on rajoitettava matkani alle tunnin kestäviksi
☐ Kivun takia voin tehdä vain alle puoli tuntia kestäviä välttämättömiä matkoja
☐ Kivun takia en voi matkustaa minnekään muualle kuin lääkärin vastaanotolle tai sairaalaan

Kivun voimakkuus
Merkitkää alla olevalle janalle poikkiviiva siihen kohtaan, mikä parhaiten kuvaa kipunne voimakkuutta viimeksi kuluneiden 7 vuorokauden aikana.



ORIGINAL PUBLICATIONS I-IV